SEARPharm Forum

South East Asian FIP-WHO Forum of Pharmaceutical Associations

AN UPDATE

A Database of the incidences of Counterfeit Medicines in the SEA Region
for
2014

Compiled by:

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An Update
DATABASE ON THE INCIDENTS OF COUNTERFEIT MEDICINES IN THE WHO-SEA REGION

Background

Spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines

SFFC medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SFFC medicine is unknown and its content unreliable. SFFC medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.

Defining the extent of counterfeiting is difficult for a number of reasons.
The variety of information sources makes compiling statistics a difficult task. Sources of information include reports from national medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies on specific geographical areas or therapeutic groups. The different methods used to produce reports and studies also make compiling and comparing statistics difficult.

Studies can only give snapshots of the immediate situation. Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day, so when the results of a study are released, they may already be outdated. Finally, information about a case under legal investigation is sometimes only made public after the investigation has been concluded.

Not only is there a huge variation between geographic regions in terms of incidence of SFFC medicines, variation can also be significant within countries: for example, between urban and rural areas, and between cities.

One of the SEARPharm Forum's objectives is to encourage and support a dialogue and collaboration among national and regional pharmaceutical associations in the South-East Asia Region of WHO by supporting WHO-policies and goals and combating the production and distribution of counterfeit medicine and sale of medicine by people who are not qualified. The print and electronic media has been widely reporting the problem. The open source media reports continue to provide coverage on the various permutations that encompass the act of pharmaceutical counterfeiting and substandard drugs like identical copies, look-alikes, rejected and relabeled.

Identical copies: These are made with the same ingredients, formulation and packaging as the originals. As high priced prescription medications, they are irresistible to counterfeiters.

Look-alike: the packaging and appearance are high quality, but there may be little or no active ingredient. Some look-alikes may even contain harmful substances such as chalk, boric acid, glass or fungus etc.

Rejects and relabeled: Drugs that have been rejected by the manufacturer for quality reasons are illegally obtained by counterfeiters or authentic drugs that have expired are relabeled with the longer shelflife and sold.

However, the shortcoming of the open source media reporting is that the same data at times get published by different agencies compound the information and show the problem in a much larger magnitude.

Nevertheless, in the absence of any authentic data, we depend upon news items being published in credible leading newspapers and journals. These reports mainly deal with situation in India, Nepal, Bangladesh, Thailand, Sri Lanka and Indonesia.

The Secretariat has been regularly updating such data since 2001. It is now submitting the updates on the incidents of counterfeit medicines for the year 2014. This list does not reference every media report published, nor does it contain any confidential information.

Pradeep Mishra
Professional Secretary
SEARPharm Forum Secretariat

20th January 2015
New Delhi

METHODOLOGY:

This reports is prepared from published materials collected over internet from published material on web portals, leading national & local newspapers in the SEA region.

Google web search was conducted using seven keywords viz. 'spurious drug, spurious medicine, counterfeit drug, counterfeit medicine, fake drug, fake medicine, fake cosmetic' in combination with specific country name. Upto 50 pages were search under 'web' and 'news' section of Google for each keyword for each SEARPharm member country separately.

Over 300 local and national newspapers from 11 member countries were searched separately using same keywords.

The reports found were documented under specific members' country (in alphabetic order) in this report. The Micellenous section contains any other report (in chronological order) apart from actual incidence that has been published on the concerned topic of counterfeit medicines.

SUMMARY:

Couterfeit medicine is a major problem of concern in the SEA region. Since 2007, each year SEARPharm Forum collects news reports of the incidences of counterfeit medicines reported in published media in member countries to have an idea of the problem in the region.

In this year report, maximum numbers of cases are reported from India (43), as compared to (39) in last year report. There is huge surge in number of counterfeit reports published in Bangladesh, as 41 reports of such incidences were published as compared to 15 last year.

There are six reports from Indonesia, similar to number of reports published last year. The major focus being the counterfeit medicines sold over the online pharmacies.

Six reports were published from Sri Lanka, while three reports were reported from Thailand.

No incidences were reported from Bhutan, Timor Leste, DPR Korea, Maldives, Myanmar and Nepal.

REPORTED INCIDENCES

BANGLADESH

❖ Nine held for making counterfeit cosmetics

The Daily Star, February 18, 2014

A mobile court assisted by Rapid Action Battalion (Rab) inspects the substandard raw materials used for making counterfeit toiletries and cosmetics under the names of foreign brands in a factory at the capital's Lalbagh yesterday. Photo: Banglar Chokh

Nine people were arrested yesterday for manufacturing and selling fake foreign branded cosmetics and toiletries, worth Tk 10 lakh, in three factories in the capital's Lalbagh area.

A mobile court assisted by Rapid Action Battalion members also sealed off the factories and sentenced two of the arrestees, Abdus Salam, proprietor of Akash Cosmetics, and Yasin Sheikh, whose factory had no name, to six-month imprisonment each while the nine were fined Tk 3.7 lakh, said the court officials.

They have been selling the products, including shampoo, cream, hair gel, nail polish and face wash, in the containers similar to the ones of renowned brands like Pantene, Head and Shoulders and Lakme. They were marketing those goods across the country including malls in Dhaka. Three cases were filed against the arrestees.

❖ Fake saline factory busted in capital

The Daily Star, March 21, 2014

Executive Magistrate AHM Anwar Pasha, right, holds some of the packets, produced by ICDDR, B to provide a rice-based oral saline free of cost but which unscrupulous traders got a hold of and were filling up with unhygienic rice powder and harmful ingredients for sale. The factory was unearthed in the capital's Babubazar yesterday and sealed off. Photo: Banglar Chokh

The two packets of saline powder look identical, but one cures diarrhoea and the other causes damage to the kidney and liver; one is distributed free in a hospital and the other sells on the market illegally.
A mobile court yesterday unearthed a place in Old Dhaka where the fake saline powder is put into the packets of rice-based oral saline originally manufactured and distributed internally by ICDDR,B. The original saline

powder contains 40gm of rice powder, and required amounts of sodium chloride, potassium chloride, and trisodium chloride. But a group of unscrupulous people collected the packets, filled them with unhygienic rice powder and harmful ingredients, and sold those on the market.

At the first glance, it would be impossible for anyone to distinguish between the fake and original saline packets. There is only one difference--ICDDR,B does not sell its saline.

In its drive at Babubazar, the mobile court sealed off the factory, and sentenced Obaidur Rahman Palash, 36, one of the four owners, to one year imprisonment and fined him Tk 1 lakh, in default to serve three more months in jail, and fined Himel Fakir, 16, a worker, Tk 10,000, in default to spend one month in jail.

"We conducted the drive on information that some unscrupulous persons are producing fake saline and distributing those across the country through Mitford medicine market," said Executive Magistrate AHM Anwar Pasha, who led the drive.

The factory had been producing the fake saline for three years, and the court seized around 36,000 ICDDR, B packets, mostly empty. Housed on the sixth-floor of a seven-storey building, it produced 3,000 packets a day, said Obaidur, the factory owner.

Shaikat Kumar Kar, superintendent, Directorate General of Drug Administration, said, "If any child drinks the saline, his kidney and liver may get damaged." Dr Azharul Islam Khan, chief physician of ICDDR,B hospital, said they would take action if anyone of the organisation was found involved in providing the packets to the unscrupulous people.

❖ RAB busts hospital

New Age, April 13, 2014

A hospital was busted in the capital's Mohammadpur area where fake doctors had been allegedly using drill machines and substandard anesthetic medicines to carry out surgeries.

During a drive carried out early Saturday, a team of Rapid Action Battalion detained seven people for their alleged involvement in such dangerous and unsafe surgery, at Mohammadpur's Babar Road, said a RAB official. A mobile court of RAB awarded different jail terms and fined the detained.

RAB-2 operation officer Raihan Uddin said that they had received information about alleged fraudulent activity being carried out at a hospital near the National Institute of Traumatology & Orthopaedic Rehabilitation (NITOR). They had been diverting patients from NITOR through brokers.

The owner of the hospital, Paike Babu, had recently received approval for 50-bed hospital from the directorate general of health services. The mobile court executive magistrate AHM Anwar Pasha said he had jailed Babu and his brother-in-law Ratan Krishna for one year each, and also fined them Tk 1,05,000 each.

Pasha said both had no medical background or training. They usually targeted patients from outside Dhaka who had come to NITOR. After 'managing' them through brokers, the patients were kept in unhygienic condition. The hospital had no nurse and only a surgeon. The surgeon was called for critical surgeries, and in other cases, Babu and Ratan usually carried out the operations. Babu injected anesthetics before surgery, while Ratan conducted the surgery using drill machines.

❖ Illegal herbal medicine factory sealed off

The Independent, April 17, 2014

An unauthorised pharmaceutical drug factory was sealed off in Malgram Chapor Para in the town and a large quantity of substandard herbal medicine was seized by a mobile court on Tuesday.

The court announced a six-month simple imprisonment to the company's manager Suren Chandra Dash, 32, after his offence was proved. The court also ordered to destroy the seized medicines. Police said, the court, led by Executive Magistrate Nasrin Akhter, raided Shobuj Harbal and Beverage Laboratories in the area and found different kinds of syrups being produced in an unhygienic condition without any chemist.

Officer in-charge of Bogra Sadar police station AHM Faizur Rahman said acting on a tip-off the police raided the fake company with the magistrate. The owner of the factory could not show certificates of the Directorate General of Drug Administration and Bangladesh Standard Testing Institute (BSTI) for production of drugs. Bogra district drug super Sukorna Ahmed and Sanitary Inspector Shah Ali of the Municipality among other officials were present during the raid. Police said, the fake company owner and others fled the place sensing the court arrival.

❖ Two fake medicine factories shut

The Daily Star, April 23, 2014

A mobile court in separate drives here on Monday sealed off two unlicensed Ayurvedic medicine factories and seized a large number of different types of chemical, bottles and mixing machineries from there.

The factories include NA Pharma Laboratories in Sastthitola area of the town. The court also sentenced Md Obaidullah, owner of the laboratories, to six

months' imprisonment and fined him Tk 50,000 for not producing valid documents against his factory. Executive Magistrate Md Mobarak Hossain led the court, said police.

❖ Fake drug factory unearthed in city, 14 arrested

www.Thereport24.com, March 24, 2014

The Rapid Action Battalion (RAB) unearthed a fake medicine manufacturing factory at Rampura in the city on Monday and arrested 14 people from the factory.

At about 2:00 pm, the RAB conducted the drive at the Green Life Herbal Industry at the House No. 58/1 on the WAPDA Road in West Rampura and found the factory manufacturing fake medicines.

The arrested were the building's owner SM Kabir, employees Selina, Josna Khatun, Al Amin, Mukta Khatun, Ramjan Ali, Shikha, Swapan Mia and others.
The arrested were fined Tk 5,000 each and in default on the fine they will have to serve a jail term of one month.

On the other hand, the manager of the factory, Osman Ali, was fined Tk 2 lakh and in default on the fine, he will have to serve a jail term of three months. But the owner of the factory, Mizanur Rahman, could not be arrested. The RAB said a case would be filed against him.

The RAB-3 conducted the drive aided by magistrate Sharif Mohammad Farhad Hossain. The magistrate said the medicines for sexual diseases on sale at Gulistan, Farmgate and in different other areas of the city were manufactured at the factory.

❖ Illegal homeopathic drug factory sealed

The Daily Star, April 03, 2014

A mobile court of Rapid Action Battalion yesterday sentenced five persons to different jail terms and fined them, along with six others, Tk 8.80 lakh for illegally producing homeopathic medicines in the capital's Uttar Badda. Rab said they sealed off the factory, Model Homeo Complex, which has a licence for six types of medicines but was producing 31 types.

The factory owner Babar Ali was given one-year jail term and fined Tk 2 lakh. Four other accused -- Rafiqul Islam, Fazlul Haq, Abu Mohammad Ruiyam and Nazimuddin -- were sentenced to six months in jail and fined Tk 1 lakh each. Six factory employees were fined between Tk 20 and Tk 80,000.
The factory authority used to forge signature of the director general of Drug Administration for creating fake certificates to produce 25 types of medicines,

Rab said adding, they had been doing it since 1994.
The factory's hygiene situation was also bellow-standard, they added.

❖ Fake medicine factory sealed off

The Financial Express, May 29, 2014

A mobile court in Savar on Thursday sealed off a fake medicine factory and sentenced its nine employees to different terms of jail. The mobile court, led by UNO and executive magistrate Quamrul Hasan Mollah, raided the factory 'SF Laboratory' at Genda adjacent to Savar Upazila Parishad. During the drive, the mobile court found covers and levels of various famed pharmaceutical factories. Later, it sealed off the fake medicine factory and arrested its nine employees. The mobile court sentenced the factory in-charge to one year's imprisonment and eight other employees to six months each. However, factory owner Abdul Jabbar managed to flee the scene, according to a news agency.

❖ Fake medicine factory sealed off in Savar

The Independent, May 30, 2014

A mobile court here yesterday sealed off a fake medicine factory and sentenced its nine employees to different terms of jail, reports UNB. The mobile court, led by UNO and executive magistrate Quamrul Hasan Mollah, raided the factory 'SF Laboratory' at Genda adjacent to Savar Upazila Parishad. During the drive, the mobile court found covers and levels of various famed pharmaceutical factories. Later, it sealed off the fake medicine factory and arrested its nine employees. The mobile court sentenced the factory in-charge to one year's imprisonment and eight other employees to six months each. However, factory owner Abdul Jabbar managed to flee the scene.

❖ Fake pharmaceutical factory sealed off

The Independent, June 09, 2014

Authorities in a drive on Sunday at a residential area of the city sealed off G Sons Laboratories, an unlicensed pharmaceutical factory, for producing fake medicines and jailed its owner. Shafiqur Rahman, superintendent of Directorate General of Drug Administration (DGDA) Barisal office, administrative magistrate Qamruzzaman and Bhaskar Saha, assistant commissioner of Barisal Metropolitan Police (detective branch) led the drive. The drive was operated on basis of a complaint by Sabbir Ahmed, director Indo-Bangla Pharmaceuticals of the city who alleged that the afore-mentioned factory was producing fake drugs. During the drive, it was found that ABM

Monirul Islam under the banner of G Sons Laboratories (AY) had been operating an illegal pharmaceutical factory in a house at Fakirbari Road area in the city center. The factory was sealed off as the owner failed to produce any valid license against medicine production.

The drugs produced in the factory were found to be expired with fungus and prepared with ingredients harmful to public health. Also, production facility of the factory was very unhealthy and substandard machines and equipments were being used there. After collecting samples of the drugs produced in the factory along with the ingredients, and packing materials, the mobile court sealed off the factory and jailed its owner to 2-year imprisonment, said magistrate of the court. Jailed owner of the factory confessing his crimes said that he started producing Ayuverdic (herbal) drugs about five years ago after obtaining a license from the concerned authorities, but did not renew his license after 2009.

❖ Legal actions taken against 28 herbal houses: Nasim tells JS

New Age, June 19, 2014

The health minister, Mohammad Nasim, told parliament on Wednesday that legal actions were taken against 28 medicine centres in Dhaka for cheating people providing them with substandard herbal treatment.

Besides, 85 such institutions have been sealed off, 171 people have been punished and Tk 4.60 crore has been fined during the last one year and a half, he said. Replying to a question from Md Sohrab Uddin [Kishoreganj-2], the minister, in his scripted answer, said that the government, through the Directorate of Drug Administration, was taking legal actions against the fake herbal medicine houses. He said that mobile courts have taken legal actions against the 28 institutions.

❖ RAB seals fake cosmetics factories

www.bdnews24.com, Jul 08, 2014

A mobile court of the Rapid Action Battalion (RAB) has sealed 17 fake cosmetics-manufacturing factories in the capital's Bangshal area. The owners of two factories have also been sentenced to two years in jail.

RAB magistrate AHM Anwar Pasha led the five-hour long drive that commenced on Monday morning. He said RAB also destroyed 10-truckloads of fake cosmetic goods following the raid. Two persons -- 'Anwar' and 'Sanwar' -- were detained.
Magistrate Anwar told bdnews24.com, "We conducted a sudden drive at Moina Haji's premises near Matitola Mosque and Chitra Cinema. We found

that fake cosmetics goods worth hundreds of thousands of taka were being manufactured there. “Later, we decided to seal 17 manufacturing units and their store houses.” bdnews24.com’s staff correspondent Kamal Talukder reported from the scene that fake cosmetic goods of local and foreign brands were stocked in two factories. The first floor was used as manufacturing unit. Detained Anwar said they used to buy empty deodorant bottles from the streets and fill them with fake deodorants before selling them.

Worker Mashiur, who joined one of the factories a few months ago, told bdnews24.com, “Here my job is to paste the labels on deodorant bottles." RAB’s Keraniganj camp officer Major Shamim Ahmed, Lalbagh camp officer Md Kowser and other officers took part in the drive.

❖ Fake drugs haul seized in capital

www.thereport24.com, July 09, 2014

A mobile court has seized a haul of adulterated and fake drugs after raiding a warehouse on Topkhana road in the capital city on Wednesday morning.

Executive Magistrate of the court Anwar Pasha said the raid was conducted at Navana Healthcare Limited, a depository, around 11:00am. “Counterfeit and adulterated drugs were seized from the warehouse,” he said. Owner of the warehouse Aminul Ehsan was also held during the raid, added the executive magistrate.

❖ 10-truck counterfeit goods seized

The Daily Star, July 08, 2014

A mobile court led by the Rapid Action Battalion yesterday seized 10 truckloads of counterfeit goods used in producing toiletries and cosmetics in 18 factories in the capital's Malitola.

The court of magistrate Anwar Pasha also jailed each of the two arrested factory owners--Mohammad Howlader, 42, and Sanowar Howlader, 38,--for two years and fined them Tk 2 lakh.

The factory workers were let go after questioning. One employee, Mashiur, said, “Colouring and aromatic agents are mixed with liquid soap used in garment factories for washing clothes for producing shampoo...Body spray is manufactured through the process of mixing colourings with substandard spirit.”

During the raid, one of the owners, Mohammad Howlader, told Rab officials that he had been involved in purchasing waste papers and empty containers as a hawker visiting from door to door since 1991. He was a wholesaler of

empty containers. His confession led to the unearthing of the 18 factories and the huge seizure that included fake holograms, labels, and chemicals. The used empty containers of renowned brands like Pantene, Dove, Head & Shoulders, Sunsilk, Clear, Brute and Havoc. “The seized fake toiletries will be destroyed tonight. These products had been supplied across the country for a long time,” said the magistrate. “These cosmetics harm skin badly and causes hairfall,” he added. In a press release, Rab urged people to destroy empty containers after use.

❖ Illegal medicine factory unearthed

The Independent, July 10, 2014

The elite force Rapid Action Battalion (RAB) yesterday unearthed an illegal medicine factory at Topkhana road in the capital. They also seized huge amount of fake medicines of different well known brands.

RAB’s executive magistrate Anwar Pasha, who led the drive, said on secrete information, they raided at house no 27/7 of Topakhana road and unearthed the fake drug factory. The also arrested the owner of the fake drug factory with huge fake medicine.

The arrested was identified as Md Aminul Ehshan, 40, son of late Amirul Islam, hailing from Topkhana area in the capital. He admitted that they supplied the medicine at different pharmacies at Topkhana road and Midford area in the city. Later, the mobile court sentenced him two years imprisonment.

❖ Fake medicine factory busted

The Daily Star, July 10, 2014

A mobile court backed up by Rab recovers a huge quantity of fake drugs at a home in Segunbagicha in the capital yesterday and arrested one person in this connection.

A mobile court backed by Rab members yesterday busted a medicine factory in the capital's Topkhana for producing spurious antibiotics, including those for children, and jailed its owner for two years.

Owner Aminul Ehsan, 40, had been running the unauthorised business on the ground floor of his four-storey building over the last three years. The mobile court led by Executive Magistrate of the Rapid Action Battalion Anwar Pasha also fined the owner Tk 2 lakh. If he fails to pay the fine, he will have to serve a sentence of three more months.
“Aminul used his experience as an employee of a pharmaceutical company and had been running the heinous business for 10 years,” the magistrate said.

The court began the drive around 10:30am and seized seven types of fake antibiotics worth around Tk 20 lakh and a significant amount of ingredients and labels.

Among them, there were fake medicines with labels of well-known drugs like Duracef, Navacef, Fixcef and Cefox of Navana Healthcare. Navacef is a popular antibiotic for children, Anwar said.

The factory had been supplying medicines worth around Tk 1 lakh to the Mitford wholesale market every week. Aminul used to buy low quality powder as ingredients and get labels printed from local printing press.

"For an antibiotic that would cost around Tk 200, he spent only Tk 20 to 30 [to manufacture per piece of the drug]," Anwar quoted the factory owner as saying. Didarul Alam, deputy director of the Rab-2, and Mohammad Azizullah, coordinator at the Directorate of Drugs Administration, were present during the drive.

❖ 2 fake vermicelli (and Cosmetics) factories sealed

The Independent, July 13, 2014

A mobile court of the Rapid Action Battalion (RAB) yesterday sealed three 'unauthorised' factories for manufacturing adulterated and low quality vermicelli and fake cosmetics in old Dhaka of the capital.

Two owners of the factories were awarded one year jail sentences and fined Tk one lakh each while the owner of the other factory was fined Tk 50,000. Executive magistrate of RAB AHM Anwar Pasha led the five-hour drive at Champatuli Lane, Swarighat, and Chotokatra area in the capital. "We conducted a sudden raid and found that the owner of a vermicelli factory was packaging fake vermicelli in an unhygienic environment using renowned trade brands like 'Kolson and Alauddin'. We also found that he has been continuing with this illegal trade for the last 4 years," Pasha said.

"The owner, Kazi Sumon, admitted that he buys low quality vermicelli at a price of Tk 35 per kilogram and packages those using the wrappers of different brands containing the BSTI logo. Though the packets show the net weight of the vermicelli is 200gm, in reality no packets weigh more than 150gm," he added.

"As the owner was packaging vermicelli in an unhygienic environment in a small room, he has been sentenced to one year in jail with a fine of Tk one lakh. He was also fined last year for committing the same offence," the magistrate added.

The magistrate also said that they fined the manager of another vermicelli factory, Abdul Hye, with Tk 50,000 for packaging low quality vermicelli. The mobile court also seized 100 maunds of low quality vermicelli.

The mobile court also sealed a cosmetic factory for manufacturing low quality hair oil and cream using paraffin in soybean, green colour, and essence. The owner, Md Hossain, said that he and his father have been running the business for the past 15 years but they admitted that they never took the products for the use of their family members.

❖ Death of 76 Kids from Adulterated Drugs: 3 Adflame officials jailed for 10yrs

The Daily Star, July 22, 2014
www.Thereport24.com, July 22, 2104
The Independent, July 22, 2014
New Age, July 23, 2014

Three officials of Adflame Pharmaceuticals have been awarded 10-year rigorous imprisonment for manufacturing adulterated drug that killed 76 children in the 1990s.

Judge Abdur Rashid of Dhaka Drug Court also fined the three convicts Tk 2 lakh each. The convicts are Adflame director Helena Pasha, manager Mizanur Rahman and production officer Nigendra Nath Bala.

The court, however, acquitted two other accused – Noman and Afsar Pasha – saying that the plaintiff did not mention their designations in the case. While delivering the verdict, the judge said the convicts had committed crimes against humanity. So, it is better to award them 10 years' imprisonment, the maximum punishment under Drug (control) Ordinance, 1982, he added.

Later, the court sent Helena, 75, and Mizanur, 68, to jail as they were present at the courtroom during the judgement. The other convict, Nigendra Nath, remains absconding since the case was filed in 1992.

The punishment of Nigendra Nath will be effective from the day of his arrest or surrender, the court said. Terming the verdict "expected", Public Prosecutor Shaheen Ahmed Khan said, "We are happy as the court awarded the three officials the highest punishment".

Law enforcers take Adflame Pharmaceuticals director Helena Pasha to jail after a court on Tuesday awarded her along with two others to a 10-year rigorous imprisonment for manufacturing adulterated drug that killed 76 children in the 1990s.

He came up with the reaction while talking to reporters at the court premises.
Until 1991, complaints were filed with the government relating to the death of as many as 76 children from acute renal failure after taking "Flammodol", paracetamol syrup produced by Adflame. The medicine was tested positive for deadly industrial chemical diethylene glycol.

The then drug superintendent, Abul Khayer Chowdhury, filed the case against the five on December 19, 1992. The case had been stalled since 1994 following an order of the High Court. The trial resumed after November 11, 2009 following an investigation by The Daily Star and it took more than four and a half years for the case to reach the climax.

The case against manufacturing company Adflame was one of the four that sued separate pharmaceuticals. Three other manufacturers accused of producing the same adulterated paracetamol syrup were Polychem Laboratories Ltd, BCI (Bangladesh) Ltd, and Rex Pharmaceuticals.

The fifth pharmaceutical -- City Chemical and Pharmaceutical Works Ltd -- was not prosecuted apparently for having a close connection with the then ruling BNP.

❖ Fake and substandard medicines

The Independent, July 24, 2014

A court verdict on Tuesday sentenced three persons of a pharmaceutical company to 10-year imprisonment for their role in the death of 76 children who died after taking adulterated paracetamol syrup produced and marketed by that company. But that was 22 years ago and the verdict after such a long time can be described more as justice delayed for too long a time than justice delivered at last. Meanwhile, real concerns remain about the potency, quality and genuineness of some of the medicines marketed in the country. The users of such improper medicines suffer in several ways. First of all, instead of curing their sicknesses they may become more ill from taking fake medicines. Cases have been noted of persons who died after taking fake pills or after bogus injections were pushed on them. Secondly, there are nondescript producers who hardly employ quality control or take other steps to ensure the potency or effectiveness of their medicines. After the drug policy of 1983 many local pharmaceutical companies appeared in the scene. While some of them have attained world class standards and some of their medicines have acquired a sound reputation even in foreign markets, the little known local companies present an opposite picture.

Medicines such as antibiotics made by these nondescript companies are found in some cases to be lacking in potency. Therefore, the users of such sub-standard drugs relapse back into infections after feeling improvements in their medical conditions for a while. These companies use insufficient quantities of antibiotic powders and other ingredients to make antibiotics and other products. This is done to maximise their profits by declaring that an amount of medicinal substance is in a capsule or tablet whereas actually a lesser amount is given. Besides, these practices, large quantities of foreign drugs are entering the country as smuggled goods and many of them are fake products.

All cases of locally made fake medicines, substandard medicines and smuggled and fake medicines, are to be monitored by the Public Health and Drug Testing Laboratory (PHDTL). But it suffers from serious handicaps of not having enough manpower, resources and testing facilities to keep watch over the medicine market. But it could also do better work within its existing limitations if it did not suffer from corrupt employees within its fold.

Therefore, steps need to taken to strengthen the PHDTL by recruiting more people to run its services ; the number of its testing facilities must increase adequately in number. But the greatest need seems to be deep cleansing it of corruption.

The elite force Rapid Action Battalion (RAB) yesterday unearthed an illegal medicine factory at Topkhana road in the capital. They also seized huge amount of fake medicines of different well known brands.

RAB's executive magistrate Anwar Pasha, who led the drive, said on secrete information, they raided at house no 27/7 of Topakhana road and unearthed the fake drug factory. The also arrested the owner of the fake drug factory with huge fake medicine.

The arrested was identified as Md Aminul Ehshan, 40, son of late Amirul Islam, hailing from Topkhana area in the capital. He admitted that they supplied the medicine at different pharmacies at Topkhana road and Midford area in the city. Later, the mobile court sentenced him two years imprisonment.

❖ Fake cosmetics factory sealed in Keraniganj

New Age, July 26, 2014
The Financial Express, Jul 26, 2014

A mobile court of Rapid Action Battalion sealed off a fake cosmetics factory at Brahmankitta Natun Bazar in Keraniganj on Thursday.

The mobile court also fined the factory manager Kabir bin Jakir Tk 50,000.
The cosmetics factory 'Ayurbatic Himtaj Product Ltd' had been producing different fake cosmetics using brand names of India, Pakistan and South Korea for a longtime.

Members of Rab-10, led by RAB headquarters executive magistrate AHM Anwar Pasha, conducted the drive in the cosmetics factory from 3:00pm and continued till evening. The factory was producing the fake products without any chemist or laboratory. Later, the magistrate of the mobile court sealed off the factory and fined its manager. The mobile court also ordered the authority concerned to take legal step against the factory owner.

❖ Drug admin official jailed for ignoring court

The Independent, Aug 28, 2014

The Dhaka Drug Court yesterday sent a director of the Directorate General of Drug Administration (DGDA) to jail for non-compliance of its order on 18 occasions to testify as complainant in two cases of spurious paracetamol against BCI Pharmaceuticals Ltd, reports UNB. Passing the punitive order, Dhaka Drug Court Judge M Abdur Rashid said that the complainant Abul Khair Chowdhury will remain in jail until prosecutor Syed Rezaur Rahman cross-examines him on Sunday (August 10).

The court said that complainant Khair Chowdhury has been avoiding the court for 26 months from May 31, 2012, despite issuing summons time and again and warrant for his arrest, which resulted in helping the accused. According to the case records, many children died in 1992 after taking the toxic paracetamol.

The same Drug Court on July 22 delivered a judgment sentencing three pharmaceutical owner-officials of Adflame Pharmaceuticals to jail for 10 years and fined Tk 2 lakh each under the Drug (Control) Ordinance, 1982 over the children's death from toxic syrup more than two decades ago.

❖ Fake medicine factory unearthed; 2 held

The Independent, Aug 09, 2014

Police unearthed a fake medicine factory and seized huge spurious drugs in Bharalipara area under Shahmukhdum police station in the city on Thursday, reports BSS. The police team also arrested two persons in connection with the malpractice. They are Kamal Hossain, 30, and Jewel Rana, 19. Sayeedur Rahman Bhuiyan, officer-in-charge of Shahmukhdum police station, said being informed a police team conducted a raid at a house at around 3.30 pm and seized 354 bottles of spurious medicines and huge medicine manufacturing instruments and ingredients from the factory. A case was recorded with Shahmukhdum Police Station in this connection, he said.

❖ Medicines sold without prescriptions in Khulna

The Independent, Aug 30, 2014

In Khulna city and district, there has been an alarming rise in the number of patients buying medicines, especially antibiotics, without prescriptions of registered physicians, posing a major health threat to the general public. Besides, the owners of these medicine shops have been selling low quality, banned, contraband Indian and date-expired medicines under the nose of the

law enforcing agencies, endangering the life of the people. As a result, the innocent patients, especially the poor, are becoming victims of the adverse effects of these medicines.

Being completely ignorant of health risks, many patients visit medicine or drug shops, describe their ailments and purchase medicines as per the advice of pharmacists or even salesmen. Even the shop owners are cashing in on the ignorance to boost their sales without prescriptions of the registered doctors. Some pharmacies even offer free counseling for patients and reduction in the prices of medicines.

It is alleged that the Drug Control Department, Khulna has taken no action against the dishonest traders. Sources said that the owners of medicine shops have been making windfall profits by selling life saving medicines, especially steroid, capsules, enzyme, and vitamin of America, China and India. After taking the medicines, the conditions of many patients deteriorate instead of getting cured. The patients rather develop many disorders because of the side effects of the medicines.

A critically ill Bijoy Sarkar Rony is now counting his days due to damage to his two kidneys after taking painkillers from a local medicine shop for long without proper medical supervision.

Abdus Sobhan alias Sidam (58), a construction worker, who come to buy medicine without prescription for his chronic asthma from a shop in the city told he usually do not manage three times meal to his six-members family, so he has no ability to consult a registered doctor.

Civil Surgeon of Khulna district Dr Md Yasin Ali Sarder said selling medicines without a physician's prescription is very common in the country. It has become a tradition to take medications on the salesmen's advice.

Many shop owners discourage people to visit doctors, apprehending a decrease in the sales if they do not come back, Civil Surgeon added. He further said no mobile court is being conducted against the sellers of spurious medicines.

Assistant Director of Drug Administration, Khulna Md Iqbal Hossain said the practice by some drug store owners, selling of medicines without registered physician's prescription is a complete violation of Bangladesh Medical and Dental Council Act, but there is no monitoring system by the authorities concerned to cancel their drug licences.

He also said that the owners of medicine shops are likely to advise medications without thinking of side effects. It poses a serious threat to public health and it is also an immoral practice. World Health Organisation (WHO) has drawn up guidelines not to sell medicines without physicians' prescriptions, but it is a recurring event in the country. Many people suffer and fall critically ill after such improper medications. Local people urged the authority concerned to be vigilant against the dishonest medicine traders for

public interest.

❖ Unani medicine factory sealed for irregularities

The Daily Star, Aug 31, 2014

A mobile court, conducted by Rab, yesterday sealed off a Unani medicine factory at Ashrafabad in the capital's Kamrangir Char for producing and marketing unauthorised medicines.

The law enforcers also sentenced three employees to one year in jail each and destroyed the fake medicines and equipment.

The convicted are factory manager Abul Hossain, chemist Nazrul Islam and unani medicine practitioner Jinnat Rehana Parveen. The factory is licensed to producing 17 types of drugs but it has been manufacturing medicines outside the authorised ones, said the law enforcers.

❖ Two fake medicine factories unearthed in capital

www.thereport24.com, Sept 10, 2014

Rapid Action Battalion (RAB) in separate raids on Wednesday unearthed factories of spurious medicine in the city's Mitford and Keraniganj areas.

A mobile team of RAB-10 headed by executive magistrate Anwar Pasha unearthed four factories of spurious medicine at Kushiarabagh, Keraniganj and at wholesale medicine markets at Mitford and arrested one Rusel, 30, in this regard, a RAB official said.

They seized with a huge quantity of spurious medicine including antibiotic of ACI, Beximco, Square and SKF and raw material of producing those. RAB earlier on December 29 in 2012 arrested and sentenced Rusel for doing business of spurious medicine, he said, adding that he (Rusel) started the business again immediate after releasing from the jail. A case was lodged the owner under Special Powers Act.

❖ Unlicensed drug stores mushroom in Khulna

The Independent, Aug 18, 2014

Hundreds of drug stores, popularly known as pharmacies, have been running their business, in almost every corner of Khulna city and district without license, flouting regulations of the drug administration. Besides, the owners of these medicine shops have been selling low quality, banned, contraband and date-expired medicines under the nose of the law enforcing agencies,

endangering the life of the people. It is alleged that the Drug Control Department, Khulna has taken no action against the 'dishonest' traders. Sources said that the owners of unlicensed drug stores have been making windfall profits by selling sub-standard medicines, especially vitamins, enzymes and life saving drugs of the non-marketable companies. According to existing regulations, a drug store must secure a license from the drug administration in order to run a business and employ a pharmacist with least a category "C" listing. Bangladesh Chemist and Druggist Samity (BCDS), on approval from the Bangladesh Pharmacy Council (BPC), offers a three-month basic course for Category "C" pharmacists where they are taught the basics of drug science. The aspirants must at least have a secondary education degree and the course fee is Tk 2,760.

Preferring to be unnamed, the owners of a number of drug stores in the city told The Independent that they could not legally do business with proper documents even if they wanted getting a license from the Director General of Drug Administration (DGDA), Dhaka was really hard. They alleged that some of the DGDA officials demand healthy bribes for issuing the licenses. A drug store owner in the city's Custom Ghat area told that despite having successfully completed the training and submitting all the necessary documents for becoming a category C pharmacist two years ago, he was yet to get his hands on the certificate.

Deputy Commissioner of Khulna Md Anis Mahmud said that the regional drug office is responsible to look after the matter. But for public interest he will look after the matter. Assistant director of Drug Administration, Khulna Md Iqbal Hossain said, "We cannot launch random mobile court drives against these unlicensed drug stores due to lack of necessary magistrates in the administration concerned. The magistrates are often tied up with routine duties which make them unavailable for mobile court." He, however, said despite the shortage, they are trying their best to regularly conduct drives against illegal drug trading in the division and save people from their grip."
Chairperson of Nagorik Forum, Khulna Sheikh Abdul Qaiyum alleged that many medicine companies have been marketing sub-standard medicines without obtaining certificates and they have been doing it with roaring publicity.

A section of physicians are also patronising the manufactures of these products by prescribing the same medicines to the patients in exchange for lucrative gifts and financial benefits. As a result, the innocent village patients, especially the poor, are becoming victims of the adverse effects of these medicines. President of Conscious Citizen Committee (CCC), Khulna unit Begum Ferdousi Ali said that most of the owners of the unlicensed drug stores are allegedly paying some officials on monthly basis to carry on their business. Date-expired medicines are being sold after changing or covering up the original expiry dates on the packets.

The sub-standard medicines have no therapeutic value. After consumption of these medicines, many patients fall sick. The side effects of these medicines can be extremely harmful, physicians said.

❖ Huge spurious unani medicines seized in capital

Observer, Aug 30, 2014

Rapid Action Battalion personnel seized huge spurious unani medicines and medicine making materials from Rasulpur under Keraniganj thana in the capital on Saturday.

RAB-2 ASP Iqbal Shafi said acting on secret information, a mobile court raided Happy Pharmaceuticals at about 2:30pm and seized huge spurious medicine and medicine manufacturing materials.

During the raid, three officials of the company were also arrested. They are manager Abul Hossain, chemist Nazrul Islam and hakim Jannat. Later, the mobile court sentenced the three to one year imprisonment each.
The factory was also sealed off.

❖ Factories making spurious branded drugs busted

Protom Alo, Sep 10, 2014
The Financial Express, Sep 10, 2014
The Independent, Sep 10, 2014
The Daily Star, Sep 11, 2014
New Age, Sep 11, 2014

A Rapid Action Battalion (RAB) mobile court on Tuesday seized 12 types of fake medicines of different branded companies, including ACI, Beximco, Square and SKF, from the two factories and warehouses factories in old Dhaka and Keraniganj on the outskirts of the city.

During the drive, the mobile court also seized huge quantities of fake medicines, medicine-making ingredients and instruments, and arrested owner of the two fake medicine factories Rasel.

Sources at the Rab headquarters said the mobile court, led by magistrate AHM Anwar Pasha and assisted by Rab-10, conducted drives at Amir Market at Islampur Road, Babu Bazar Medicine Market and later at Baro Kushiarbagh of Keraniganj.

Rasel was arrested from his Keraniganj factory. During interrogation, Rasel revealed that he had been producing fake medicines for the last 10 years and he used to sell those in wholesale in a lower price than that of the original one.

Earlier, Rasel was arrested on 29 December 2012 on the same charge. He, however, started producing fake medicines again after securing bail.

As Rasel was arrested for the second time on the same charge, the mobile court asked the authorities concerned to file a case against him under the Special Powers Act. He was later handed over to Keraniganj Model Police Station.

❖ 1,700 bottles of Phensidyl seized

The Independent, Sept 15, 2014

At least 1,700 bottles of Phensidyl concealed under sacs were recovered from Char Khidirpur frontier area early yesterday. BGB-37 Battalion sources said a petrol team of Talaimari BOP camp recovered the Phensidyl. Anwar Ul Alam, commander of BGB-37 Battalion, said acting on a tip-off, they came to know that some drug peddlers smuggled huge Phensidyl from India and storage those at Char Khidirpur area to sell all over the country. After getting the news, BGB members rushed to the spot and recovered the Phensidyl. But BGB members could not arrest any drug peddlers from the spot. A case has been filed in this connection.

Another report adds: Police arrested a salesman with huge fake cosmetics from Shaheb Bazaar of the city yesterday morning. The arrestee has been identified as Sadikul of Rajapari Hat area under Godagari upazila in Rajshahi. Police said Sadikul works as a cosmetics distributor at Shaheb Bazaar of the city for long time. But he sells fake cosmetics using brand cosmetics logo, like Fair & Lovely, Modern Cosmetic and GM Chemicals to his customers. After getting this information, a team of Boalia Model police station led by Inspector Khairul Islam raided Khairul's house at Haragram area of the city and arrested him with huge fake cosmetics. Brojo Gopal Karmaker, Sub-Inspector of Boalia model police station filed a case against Khairul in this connection.

❖ One held with fake cosmetics in Rajshahi

Observer, Sept 16, 2014

A team of police arrested an alleged person with adulterated cosmetics from Saheb Bazaar area of the city on Sunday evening.

The arrestee was identified as Sadiqul Islam of Rajabarihat area under Godagari Upazila of Rajshahi.

Khairul Islam, Inspector (investigation) of Boalia Model Police Station, told this correspondent that Sadiqul was making different popular adulterated cosmetics for long time.

❖ Huge quantity of smuggled drugs seized at Mitford

The Daily Star, Sept 24, 2014

The Directorate General of Drug Administration yesterday raided five drug stores and seized "smuggled" drugs worth around Tk 65 lakh at Metro Medicine Market in the capital's Mitford.

The shops include Amin Drug House, Sahara Medical Hall, Tumpa Medical and Selim Medical.

The seized drugs are of about 250 generic names which had been smuggled into Bangladesh from India, Thailand, Egypt, Kuwait and Saudi Arabia, said DGDA Director Abul Khair Chowdhury, who led the drive.

DGDA officials suspect that majority of the seized drugs were smuggled into Bangladesh as similar local drugs are costlier. The director said they suspect that the shopkeepers might be involved in trading counterfeit drugs as well.
The officials also found that majority of the drugs that need to be stored within a consistent cold chain were kept in open air causing the drugs to lose their potency.

A mobile court of Rapid Action Battalion on September 10 seized a large quantity of spurious drugs at two factories and three warehouses in the Mitford area.

❖ A mobile court conducted raids at Babubazar of Old Dhaka and seized huge quantity of fake medicines

The Daily Observer, Spet 24, 2014

A mobile court conducted raids at Babubazar of Old Dhaka and seized huge quantity of fake medicines on Tuesday.

❖ 2 medicine factories sealed off

New Age, Sept 26, 2014
The Daily Observer, Sept 25, 2014

A mobile court in Chittagong on Thursday sealed off two drug factories in the city's Khulshi area for cheating on people with the life-saving medicines.
The court also sentenced a factory manager to two years' imprisonment and fined the owner of the two factories Tk 2 lakh.

The convict was identified as Sadhan Bishwas, manager of Formic Laboratory.

Assistant police superintendent SM Mobassher Hossain of Rapid Action

Battalion-7 said they had secret information that 'Formic Laboratory' and 'Brothers', owned by a single person, had long been producing illegal medicines and selling date-expired medicines produced in a unhygienic environment.

Following the information, a RAB team along with the district administration, led by executive magistrate Rakib Hasan, launched a raid on the factories on three floors of a five-storey building in the morning.

During the drive, it was found that the two factories had no valid documents except for Drug Administration registration for producing drugs, said the executive magistrate.
It was also seen that the bottles were being used after those being washed in dirty water.

❖ Fake medicine factory busted

The Daily Star, October 01, 2014

A mobile court yesterday busted a fake medicine factory and jailed its three staff for six months for producing counterfeit drugs in an unhygienic environment in the capital's Mirpur-7.

The employees are Nazib Uddin, general manager of Innova Pharmaceuticals, its accountant Mozammel Haque, and distribution manager Tofazzal Hossain.

The court led by Metropolitan and Executive Magistrate Sarwar Alam also fined the trio Tk 2 lakh each and sealed the factory off and seized a huge quantities of drugs and medicine-making ingredients from it.
Magistrate Sarwar told The Daily Star that the factory had been producing drugs since 2004 without obtaining required licence.

The factory had been producing various types of counterfeit antibiotics and food supplements of its own brand and selling those at about 70 percent cheaper rate than the usual price of the similar drugs in the market, he said.

❖ Fake cosmetics, toiletries galore

The Financial Express, November 09, 2014

The recent seizure of ten truckloads of spurious ingredients used for manufacturing cosmetics and toiletries by the law enforcers in the city has surprised many. This reflects to what extent fakery has gone deep into the society exposing public health to serious hazards.

The large scale manufacturing of counterfeit cosmetics and toiletries came to

light when a team of Rapid Action Battalion (RAB) raided as many as 18 factories in the city's Malitola.

A mobile court which led the drive arrested two factory owners and sentenced them to suffer two years in jail and fined Taka 2,00000 each.

The mobile court interrogated factory workers and allowed them to go. A factory employee told the law enforcers that liquid soap used for washing clothes in garment factories is turned into shampoo by mixing chemical dyes and aromatic substances. Both the agents are not meant for use in human body.

On the other hand, the factory worker disclosed that low quality indigenous wine treated with a variety of colours is developed into body spray. The spray presents a look and fragrance of a genuine product.

One of the factory owners, reported by the media, told RAB officials that for more than two decades his main job is to collect empty containers of cosmetics and perfumes from house to house. The man is now a wholesaler of empty containers.

In course of raid, the RAB team seized large quantities of counterfeit labels, chemicals, holograms and other materials. The empty containers seized from the factories are rich collection of world famous brands that include Head and Shoulder, Clear, Sunsilk, Pantene, Dove, Brute and Havoc.

Such spurious products are being sent to markets all over the country for quite a long time, according to factory owner. To what extent these fake cosmetics and toiletries will harm the users is a subject of medical profession. But it is sure that the skin health of a user will be badly affected and the application of shampoo may result in quick hair fall.

After the seizure of fake materials of cosmetics and toiletries, the RAB in a statement called upon the people to destroy their empty containers so that these cannot be sold and refilled with spurious materials.

In another raid conducted recently, the RAB unearthed a factory producing fake herbal cosmetics in city's Lalbagh area.A photograph of the factory published in a local daily showed how a young boy was engaged in preparing paste in large containers by mixing different dyes for selling those as face cream of famous Indian brand, Ayur.

A mobile court which led the drive fined the factory owner Taka 0.1 million for producing counterfeit foreign herbal cosmetics. It was revealed that the factory was making spurious hair gel and cream for skin care for the last two months.

As we told earlier in this column that counterfeit cosmetics and toiletries are on sale in large quantities in Dhaka city and elsewhere in the country. Some traders, according to press reports, have admitted that the packaging of these

fake cosmetics and toiletries are so faultless that they themselves find it difficult to differentiate between the genuine and the adulterated products.

They claimed that though a number of manufacturers are not in the trade the products are on sale in the market under their previous brands.

An employee of a cosmetic shop at the city's Moulvibazar said that the popular brand of cosmetics they sell are not original. He was also reported to have stated that they have to sell adulterated products because of their high demand in the market. The trader disclosed that the spurious cosmetics are produced mainly in Lalbagh, Hazaribagh and Kamrangir Char areas and also in some villages at Keraniganj across the river Buriganga.

The police are aware of such trade and crack down on the manufacturers from time to time. At times mobile court realises fine from them. There are allegations that the manufacturers of fake products run their business with the help of a section of law enforcers. Otherwise, how the supply of spurious items, one may assume, can be maintained when the sources of production are fully known to the authorities.

The Bangladesh Standards and Testing Institute (BSTI) is assigned to check cosmetics, food items, beverages, etc., either produced locally or imported and certify whether those are fit for human consumption.

Use of spurious cosmetics may cause various skin diseases. It is advisable that the BSTI should look into the matter seriously and take measures to stop manufacture of those counterfeit products with the help of law enforcers.

❖ Fake medicine factory unearthed in city; 3 jailed

UNB, November 13, 2014
The Financial Express, November 13, 2014

A mobile court unearthed a fake medicine factory and sentenced its owner and two managers to different jail terms in the city's Matuail area on Thursday.

A team of Detective Branch (DB) of Dhaka Metropolitan Police (DMP) conducted a drive at the fake drugs factory around 4pm and arrested its owner Saidur Rahman, 50, and managers Jasimuddin, 25, and Mainuddin, 25, from inside the factory. They also seized 5,900 bottles of fake medicines from the factory.

Contacted, assistant commissioner of DB Mahmuda Afroz Lucky told UNB that medicines, including 'Korean Ginseng' brand drink, were being illegally produced at the factory. Later, Executive Magistrate M Abdul Quddus sentenced Saidur Rahman to two years' imprisonment while Jasimuddin and Mainuddin to three and six months' terms respectively.The factory was also sealed off during the raid.

❖ Fake medicine factory sealed off in capital; owner punished

The Independent, December 09, 2014

A Rapid Action Battalion (RAB) mobile court unearthed a fake medicine factory in the capital yesterday and sealed it off and punished its owner, reports UNB. The mobile court, led by RAB Headquarters Executive Magistrate AHM Anwar Pasha, along with Rab-10 personnel conducted a drive at a house at Khilghar road in Kosaituli under Bangshal police station around 5pm. During the drive, it was found that medicines of several famous brands were being manufactured at the factory using their levels. At that time, the elite force arrested factory owner Akbar Hossain Bhasani. Later, Executive Magistrate Pasha sealed off the fake medicine factory, sentenced Bhasani to two years' simple imprisonment and fined him Tk 2 lakh, in default, to suffer three months more in jail. The arrestee confessed to the mobile court that he had been producing fake medicines under the cover of famous brands for the last two years. Those medicines were used to be sold at Mitford Wholesale Medicine Market. Assistant police super Sazzad of Rab-10 and Directorate General of Drug Administration representative Mahbub Hossain were present during the drive.

❖ Mobile court unearths fake drug factory in Dhaka

New Age, December 09, 2014
The Financial Express, December 09, 2014

A mobile court of Rapid Action Battalion unearthed a fake drug factory at Khilghar Road in the city's Bangshal area and jailed its owner for two years on Monday.

The factory owner was identified as Akbor Hossain Bhashani, 40. The court also fined him Tk 1 lakh default, in default, three more months in prison.

RAB executive magistrate AHM Anwar Pasha led the court and handed down the verdict. The executive magistrate said the convict had been running the factory for two years.

He used to manufacture six types of fake medicines including antibiotics, drugs for heart diseases and tetanus injections, the official said.

❖ Smuggled drugs seized in Dhaka

www.bdnews24.com, December 21, 2014

The Directorate General of Drug Administration has seized a large consignment of foreign-made drugs from a store within a kilometre of its office in Dhaka.

SK Enterprise at Purana Paltan had illegally imported those drugs, mostly anti-cancer and food supplements, from the US, Argentina, Spain, and India.
"They are worth Tk 7.5 million," Director General of drug administration Major General Dr Md Jahangir Hossain Mollik at a press briefing on Sunday.

He said his team seized those drugs in a lightning raid on Thursday soon after getting information that the drugs were being couriered illegally. No case, however, has been filed as yet. The director general said they would file the case "shortly" in the drug court.

Punishment for illegal drug import can be a maximum 10 years in prison or Tk 200,000 fine or both. But usually, it takes many years to settle a case in the drug court. Deaths linked to consumption of spurious Paracetamol took 23 years to settle in the drug court.

Bangladesh's burgeoning drug industry meets almost the entire national demand with more than 1,200 generic and 27,000 brand registered items produced in the country. Besides, 5,000 different types of brands are being imported to Bangladesh officially -- only 3 percent of the local need. But illegal foreign drugs, particularly 'food supplements', are widespread in Bangladesh.

Doctors also prescribe them, allegedly for commissions. Even the big private hospitals sell those drugs to patients. The drug administration filed 41 cases this year after seizing such drugs. They conduct drives to seize such illegal or counterfeit drugs, either on their own and with the help of mobile court.

The DG said he cannot prevent doctors from prescribing those illegal drugs.
"I have requested Bangladesh Medical Association, BMDC and relevant authorities to stop doctors from prescribing those drugs," he said, replying a question. He said the illegal importers dodge customs duty to market such drugs in Bangladesh.

❖ Two truckloads of counterfeit cosmetics destroyed in city

The Independent, December 22, 2014
The Financial Express, December 22, 2014

A mobile court yesterday destroyed two truckloads of adulterated cosmetics after their seizure from a market at Chalkbazar in old part of Dhaka city. The court also punished seven people in this connection. A team of Rapid Action Battalion (RAB) led by its executive magistrate AHM Anwar Pasha conducted a drive at Khan Market of Chalk Mughaltuli in Chalkbazar, the largest

wholesale cosmetics market in the city. The court seized two truckloads of adulterated cosmetics of renowned brands like Pantene, Head and Shoulder, Rejoice, Sunsilk, Clear, Dove, Garnier and Vasline. Among the cosmetics, worth Tk20 lakh, there were shampoo, body spray, body lotion and soap. Anwar Pasha said, "Haji Mafiz, president of the Cosmetics Factory Owners' Association, owns a factory on the third floor of the market. There were three godowns to store adulterated cosmetics on the floor. The factory makes Johnson brand soap which cost Tk85 with Meril soap worth Tk20." Din Islam, owner of a factory, told the mobile court that they collected empty containers of the brand shampoo and body spry of Do IT, FOGG, EX, Cool, Maxi etc. They also make face wash, lotion, powder, skin cream and other cosmetics, added Shamim, owner of another factory. Those cosmetics are highly injurious for human health as they are made with low quality raw materials, he added. Major Md Sohel Hassan said, "We destroyed 20,000 adulterated cosmetic items worth Tk 20 lakh. We conducted such drive third time and handed down them different terms of jail."

The court sentenced Md Din Islam,57, Md Delwar Hossain,48, Md Shamim,42, Md Hemayet Khan,20, and Md Sayeed Hossain,32, to two years' jail and fined them Tk1.5 lakh or three months more jail, in default, and Md Samad,42, manager of a factory, one and a half years' jail and fined him Tk1.5 lakh. Monir Hossain, a representative of Bangladesh Standard Testing Institute (BSTI), was also present during the drive.

❖ **Workers producing soaps with fake name**
The Daily Observer, December 22, 2014

Workers producing soaps with fake name in a factory, which RAB sealed with huge amount of fake cosmetics and caught the adulterators red handed in the city on Sunday. Later, the law enforcers destroyed the cosmetics and arrested 7.

BHUTAN

❖ No Reported Incidences.

DPR KOREA

- No Reported Incidences.

INDIA

- **Four held for selling spurious medicines**
  WebIndia123, January 14, 2014

Federation of Regional Indigenous Society (FREINDS) and Ayurvedic Doctor Association of Manipur today rounded up four persons for allegedly selling banned medicines as Ayurvedic medicines.

The four identified as Kamal Singh, Ram Rali Singh, Rajkumar Singh , Chhotu Singh all from Atta Jhalon District of Uttar Pradesh.

Sapamcha Jadumani, President of FREINDS said reports were coming of selling of banned medicines as Ayurvedic medicines by some persons. Various organisations were alerted and four persons were finally caught selling expired and banned medicines as Ayurvedic medicines. They were allegedly selling medicines in the name of Amar Jeevan Ayurvedic and Company.

FRIENDS said many people specially from other parts of the country sell spurious goods and run away after some time. People were warned to be cautious while purchasing medicines.

- **Tripura assembly uproars on spurious drug issue**
  WebIndia123, Feburary 20, 2014

Tripura assembly witnessed uproar today over spurious drug distribution in government hospitals and inaction of the left front government against the erring officials allegedly involved in the scam. The opposition Congress legislators demanded impartial inquiry into the scam against Chief Secretary K V Satyanarayana, former health secretary J K Sinha who is now on

deputation in Delhi, Director of health service and six other officials expelling health minister Tapan Chakraborty from the cabinet. Meantime, Leader of the opposition Sudip Roy Barman said that the party had already registered case against all the accused including the minister in Supreme Court seeking CBI probe over spurious drug issue and alleged inaction of police over the complaint lodged by PCC Spokes person Ashok Sinha. Health minister Tapan Chakraborty became embarrass when entire opposition sought his reply why the department procured substandard life saving drugs for past few years though license of the pharmaceutical companies were expired in 2009. They also demanded reply from the Chief Minister Manik Sarkar over police inaction in investigation of the spurious drug procurement and distribution by the health department and why did not government take action against the officials. According to Mr Roy Barman, in the beginning of the year the department had ordered several important medicines worth of about rupees one crore to the company through restricted tender and on Mach 22 last year the department first noticed the discrepancy in the consignment of the medicines sent to central medical store. In the month of April last, the laboratory testing report had confirmed a few medicines were spurious, Roy Barman said adding despite knowing the fact of sub-standard medicines and illegal functioning of the company and administration did not take any action. Since April to till date about 87 hospital deaths were reported in various government hospitals which are not allegedly due to negligence in treatment but the death cases were not only occurred due to negligence in medication also consumption of such spurious drugs. Without taking action against the irregularities health minister Tapan Chakraborty attempted to protect the erring officials by issuing a statement through Deputy Drug Controller Partha Sarathi Das that spurious drug did not affect on body, Roy Barman alleged. "We feel that state government is callous. Only the Supreme Court and CBI probe can find out all the irregularities for purchasing spurious medicines and its supply in government run hospitals before the mandatory drug testing report", he added. Surprisingly, when the minister could not reply the opposition, Speaker Ramendra Chandra Debnath suddenly adjourned the proceeding and left the chair.

❖ CB probe indicts top officials in drug scam

Greater Kashmir, March 22, 2014

The Crime Branch (CB) investigation in the spurious drug scam has revealed that top government functionaries including former Director Health, Jammu, Dr Madhu Khullar, approved the purchase of medicines from Lifeline Pharmaco Surgicals (LPS), even as it didn't possess the three year good manufacturing practice (GMP) certificate and had submitted fake authority letter and false affidavit to bag the purchase order.

Khullar, who has been charge-sheeted in the case, has been accused of clearing documents of LPS and abusing her official position as Chairperson of Purchase Committee-II (PC-II) of Government Medical College (GMC) Jammu. The PC-II had approved the rate contract of LPS for procurement of

the drug Maximizin-625 following which different health institutions placed orders for supply of 2,65,000 tablets of the drug. The drug later failed in laboratory test and was found to be lacking in the content of amoxicillin.

The CB has however acquitted Lotika Khajuria, Deputy Drug Controller, Jammu, who was member of Purchase Committee-II, after her statement to the investigating agency that she had not taken part in any of the meetings of the PC-II held on 20 April 2012 and 7 May 2012 due to her pre-occupation in some other jobs.

The investigation agency has held that the official was neither a party to the checking, evaluation of technical bid papers of the firms nor had conducted any scrutiny of the documents.

However counsel for the petitioner, Advocate Bhat Fayaz, appearing in the spurious drug case titled Dr Nisar-ul-Hasan Vs State of Jammu and Kashmir, has held that a 'key player' in the drug scam has been left out.

Documents available with Greater Kashmir show that Khajuria attended the PC-II meeting on 15 May 2012. As per the minutes of the PC-II meeting, Khajuria represented Controller Drug and Food

Control Organisation in the meeting which was called to open financial bids of the qualifying firms against the tender notice no. 4 of 2012. In the meeting, financial bids for 57 participants were opened and marked as signed by the committee members.

However, Inspector General of Police, Crime, Javed Mujtaba Gilani stuck to the findings of the investigation that there was no credible evidence of involvement of Lotika in the drug scam.

The CB has found that LPS bagged the contract for supply of drugs even as the other bidder, Ascho Drug Traders (ADT) Srinagar, should have been preferred. In violation of the conditions of the bid, a minimum of three years of GMP of the principal manufacturer was to be produced for the quoted drugs, but LPS had produced the photo copy of GMP certificate of one year of Medley Pharmaceuticals. The ADT had GMP certificate of two years.

Even as the tender had clearly specified that that there should be an original turnover certificate to bag the order, the turnover certificate attached by the LPS was not original and in violation of the requirements of tender the balance sheet and the income tax return certificate was not produced by it to get the contract. The CB has noted that ADT had produced annual turnover certificate of 9 years and fulfilled the criteria of balance sheet and income tax returns.

The LPS had attached the authority letter of M/S Medley Pharmaceuticals without any number, date and name of authorized signatory and the office from which it was issued. The logo of Medley and its full name didn't match with the authority letter. The LPS had produced the drug manufacturing

license of M/S Medley Pharmaceuticals, issued by Drug Licensing Authority, Director Medical and Health Services, UT of Daman and Diu, which was only valid up to 31 December 2011.

The LPS had annexed fake authority letter and a false affidavit that all documents submitted by it to get the contract were original. Furthermore, the CB investigation has found that LPS was given registration by PC-II on 24 January 2012, more than three weeks after the bids were issued.

The CB investigation has found that officials in PC-II, while checking, evaluating and scrutinizing the documents of the firms, misused their position with intention to accept the tender documents of LPS in contravention of norms.

Besides Khullar, the CB has charge sheeted Reva Gupta, former administrator of associated hospitals Jammu, and Joginder Kumar, former accounts officer, GMC Jammu and other officials in the case.

❖ Drugs in JK's government hospitals substandard, says CDSCO report

Greater Kashmir, March 27, 2014

A report by the Central Drugs Standard Control Organization (CDSCO) has revealed that a large number of drug samples lifted from government hospitals in the State in the past one year were "not of standard quality."

The CDSCO report has noted that many of the drugs lifted by its inspectors from government hospitals—following an outrage over the supply of spurious drugs in the State—were found to be substandard.

The substandard drugs include both injections and tablets tested by the government analysts of Central Drugs Laboratory, Kolkata, and Regional Drugs Testing Laboratory Chandigarh.

As per the CDSO report the drugs failed in tests of particulate matter as well as the claims of ingredients. The drugs have also been found to be not disintegrating properly thereby making them less effective.

The drugs that have been found to be substandard include those lifted from the Sher-i-Kashmir Institute of Medical Sciences (SKIMS) Srinagar, and different District and Sub District hospitals in Kashmir.

The report shows that drugs supplied in the government hospitals have not only failed in the "disintegration tests, but in uniformity of content and tests for particulate matter and description.''

The amoxicillin and potassium clavulenate injection manufactured by Karnataka Antibiotics and Pharmaceuticals Ltd, Bangalore, lifted from SKIMS

Srinagar, failed in the tests of particulate matter and clarity of solution. Also the drug sample Zepoxin injection, manufactured by M/S Neon Laboratories Mumbai, was found not to be of standard quality' at SKIMS, Srinagar.

The report reveals that the drugs supplied at District Hospital Pulwama, Sub District Hospital Pampore, Shri Maharja Gulab Singh Hospital Jammu, Sub District Hospital Sopore, Medical Store government hospital Udhampur, Mother and Child Care Hospital, Sopore, District Hospital Baramulla, District Hospital Doda, Sub District Hospital Bhaderwah, and Psychiatric Disease hospital Srinagar, were found to be "not of standard quality."

State Drug Controller, Satish Gupta, admitted that the samples lifted from the government hospitals failed in the tests. "We are regularly lifting the samples from the market as well as government hospitals and many of the samples from government hospitals have failed in the tests," he told Greater Kashmir.
The CDSCO report notes that some 156 samples of different categories of drugs were lifted from the market and government institutions recently, out of which samples of 13 government hospitals in the State have failed in the drug tests.

❖ Kashmiris have consumed large stocks of fake medicines: DFCO

Greater Kashmir, April 04, 2014

What may have caused major health complications among people in Kashmir, large stocks of substandard medicines have been consumed in the Valley, a report by Drug and Food Controller Organization (DFCO) has revealed.

The report, prepared after the spurious drug scam came to fore in the State last year, notes that the DFCO couldn't completely seize some spurious drugs from market as they had been already consumed by people.

The report reveals that 27 drugs were found substandard in laboratory tests recently. "A total of Rs 21.35 lakh worth unconsumed stocks of 14 drugs were seized and in rest of the 13 no seizure could be made as the stocks were already consumed by people," notes the DFCO report.

Admitting that people have consumed large stocks of substandard drugs, State's Drug Controller, Satish Gupta, said the organization has however issued drug alerts from time to time asking people not to consume the drugs, which failed in tests at their laboratories.

Government records reveal that earlier after sample of Maximizin-625 was found spurious on 6 February 2013 by the Drug Testing Laboratory Srinagar, the drug had been found mostly utilized at government hospitals. Over 2.3 lakh tablets of the substandard drug were consumed in different health

institutions in the State with maximum number of tablets consumed in hospitals under Director Health Services, Kashmir.

President, Doctors Association Kashmir (DAK), Dr Nisar-ul-Hassan, said government can't escape the responsibility for the large stocks of substandard drugs being given to people here. "Not only does it take long time for the drugs to get tested at laboratories, but fresh disclosures of substandard drugs being consumed by people are shocking," he said.

“Earlier in case of Maximizin also large stocks were consumed by people. The consumption of fake Maximizin could have only severed the infections in people. There is a possibility that hundreds of people would have died due to the use of substandard drugs at tertiary care hospitals after the diseases remained untreated in them," he said.

The government records further reveal that increasing number of samples have been found to be substandard. Officials said while in 2008-09, 10 samples were found to be substandard by the Drug Testing Laboratory, Srinagar, the number was 15 in 2009-10, 6 in 2010-11, 68 in 2011-12, 43 in 2012-13 and 61 in 2013.

❖ 76 more drug samples found substandard

Greater Kashmir, April 06, 2014

The J&K Government has come across fresh cases of substandard drugs, forcing the Drug and Food Control Organization (DFCO) to cancel licenses of some manufacturers.

A report prepared by the Deputy Secretary to Health and Medical Education department, dated 27 March, notes that 76 new drug samples have been found to be substandard. The drugs include the largely-consumed drugs including Paracetamol and Diazepam. The report has been prepared after the involvement of officials in the spurious drug scam came to fore earlier in the Public Interest Litigation (PIL) filed by President of the Doctors Association Kashmir (DAK), Dr Nisar-ul-Hasan, through advocate Bhat Fayaz.

The report reveals that Paracetamol manufactured by Pharose Remedies Limited, Bari Brahmana, Jammu, has failed in the dissolution test. Government documents reveal that after the drug failed in the test, the license of the firm was suspended by the Controller Drugs Jammu and Kashmir vide order no DFO/D-T/OSS/2013-14/18/2370-77 dated 5 February 2014. Also the drug Marycal-500 (calcium carbonate tablets) with batch no MMT-657-May/2014, manufactured by A K Biotech Private Ltd, Export Promotion Industrial Park Jammu, failed in the disintegration test following which the product permission of the firm was withdrawn vide order no DFO/D-T/OSS/2013-14.07/5361-68 dated 5 August 2013.
As per the report, Diazepam tablets with batch no T809 manufactured by Biotech Pharma, 64, Phase III, Gangyal Jammu, has been found to be not of

standard quality. "Most of the tablets in each strip were found to be in broken condition and few tablets were found to be not sufficiently hard to withstand handling with crumbling," the report notes. A show-cause notice has been issued to the manufacturer on 22 March 2014.

Moreover the drug Cardpin-5 with batch no BT-2352 manufactured by Biosearch Organics, DIC Industrial Estate, Govindsar Kathua, has also been found to be substandard. The documents reveal that show-cause notice has been issued vide letter no DFO/D-T/OSS/2013-14/21/14186-93 dated 22 March 2014 in the case.

The report has further mentioned that some injections have also failed in the particulate matter test. Officials said there is a possibility that the injections may contain "dust particles" and might have also caused deaths. State's Drug Controller, Satish Gupta, said the drugs are being lifted continuously from the market to ensure that the people don't consume substandard medicine. "We are ensuing that the test reports of the drugs are prepared by the laboratories at the earliest and the samples are lifted regularly from the market," he told Greater Kashmir.

❖ 66 drug samples found sub-standard

The Hindu-Business Line, April 15, 2014

Next time you buy a pill or an over-the-counter antibiotic from a drugstore be sure to look at the quality code.

The country's drug-quality regulator, Central Drugs Standard Control Organisation (CDSO), has found a range of basic medicines, such as ranitidine (used to treat ulcers and acidity), levocetirizine (used to treat cold), paracetemol and amoxicillin (an antibiotic), to be sub-standard.

The regulator's zonal offices across the country sampled and tested a range of medicines, such as aspirins, painkillers, antibiotics, and other drugs. According to CDSO sources, the sub-standard samples include those made by Rallis Heathcare, Elder Pharmaceuticals, Hecatomb Laboratory, Scott-Edil Pharmacia Ltd, and Laborate Pharmaceuticals.

The CDSO study found at least 66 substandard drug samples between January and March 2014. While some of the medicines failed tests for dissolution and disintegration, others were found to be misbranded or carrying labels with incorrect information, the sources said.

According to official data, last year, 706 drug samples were taken from nine States. Of these, 306 were tested and 35 declared as samples of sub-standard quality. Senior CDSO officials said action could be taken against the manufacturers under the Drugs and Cosmetics (Amendment) Act, 2008.

As there is no restriction on who can produce these generic medicines, many companies have gotten into the business, and quality standards have been hit, said the CDSO sources.

According to official guidelines, manufacture of spurious or adulterated drugs face imprisonment of more than 10 years and a fine of ₹10 lakh or three times the value of the drug confiscated, whichever is more.

❖ FDA busts online trade of Viagra

The Times of India, April 15, 2014

The Food and Drugs Administration (FDA) has seized Rs 2 crore worth of sildenafil citrate, popularly known as Viagra, from 27 online firms located in Mumbai, Thane and Pune for selling it illegally to African and European coutries. The firms did not have the requisite licence from FDA to sell the drug online or were selling them against fake prescriptions.

"We received a tip off on several irregularities in online sale of medicines run by internet pharmacy firms in Maharashtra. We formed teams and conducted raids on these firms, which are mainly concentrated in Mumbai followed by Thane and Pune, and seized huge quantity of sildenafil citrate worth over Rs 2 crore. A few more raids are in the offing," said state FDA commissioner Mahesh Zagade.

Two online pharmacy firms from Pune located in Kharadi and Salisbury Park were trapped in the FDA raids.

"Like the firms in Mumbai, we found the firms in Pune too were primarily selling sildenafil citrate tablets to people living abroad. The firm based in Kharadi was operating the online sale without a licence. We seized stock worth Rs 3.25 lakh from the firm. The firm at Salisbury Park had obtained the licence but was found dispensing sildenafil citrate against invalid prescriptions hence we cancelled its licence forthright. Further investigation is on," said B R Masal, joint commissioner (drugs), FDA, Pune.

Elaborating, S K Patil, FDA's joint commissioner (drugs) for Greater Mumbai said, "We found the firms were selling large quantities of sildenafil citrate to people living in the US, African and European countries and that they had no buyers in the domestic market. The firms were dispensing the tablets via air courier without obtaining the drug licence from FDA and export licence from the assistant drug controller's office. A few other firms had licences and also the export licence, but were found to be involved in dispensing drugs against invalid and fake prescriptions. Further investigation is on."

Patil said the demand for sildenafil citrate from Indian firms is more, as it is cheaper compared to the price of the same tablets manufactured and sold in US, African and European countries. "Hence there is a lot of illegal sale of

these tablets," Patil said.

Precautions for buying drugs online

- Make sure the site requires a prescription and has a pharmacist available for questions.
- Buy only from licensed pharmacies with drug licence from FDA
- Don't provide personal information such as credit card numbers unless you are sure the site will protect them

Why illegal sale of viagra ?

Compared with India, the drug is costlier in US, African and European countries. There is lot of demand for this drugs in international market. Irregularities about online drug sales found in Maharashtra. Online pharmacy firms do not have mandatory licence from FDA. Some have licence but dispense drugs against fake scanned prescription copies

Break up of online pharmacy firms found at fault by FDA
Mumbai: 19
Thane: 6
Pune: 2

❖ Licences of 134 drug shops suspended, fake drug seized in Kashmir

WebIndia123, April 27, 2014

Licences of 123 medical shops had been suspended for violation of Drug Control Act in the Kashmir valley, where drugs worth more than Rs 95,000 has been seized during the past one week.

An official spokesman said that during the week-long special drive conducted by the department of Drug & Food Control Organization, Kashmir Division, 624 medical shops were inspected by various teams throughout Kashmir Division.

Licence of 123 Medical Shops was suspended for violating various provisions of D&C Act 1940. Besides, 26 medical shops were put on the show cause notices.

The chemists were asked to maintain sale and purchase records of various drugs properly including day book and to store the drugs as per their requirement and to supply drugs only on production of prescription and to issue Cash Memo's strictly. They were asked to retain photo copies of Schedule H1 & Psychotropic Drugs with them for inspection of enforcement staff.
During the drive, two Medical Shops in Bemina and Batmaloo locality were found running without a valid drug sale licence. The drugs worth Rs 95,913

were seized from these shops.

Moreover, the department lifted 334 samples from Government, private establishments, wholesalers and retailers for analysis in order to ascertain their quality. The drive was launched to ensure that quality drugs are available to the ailing at right prices.

The public is asked to lodge their complaint against any Drug or Medical Shop on the department's helpline no:-0194-2495191.

❖ 83 more drugs found substandard

Greater Kashmir, May 03, 2014

A latest report on drug sample analysis submitted by the state government in the Jammu and Kashmir High Court has attested 83 fresh samples, out of 3130, as substandard.

A total of 3423 samples were lifted for analysis by drug inspectors of the State, the report said. Besides, it said, 27 samples out of 156 lifted by the Central Drug Control Organization (CDCO) were declared substandard after lab analysis.

Observing that a mere administrative action would not suffice, a division bench of Justice Hasnain Massodi and Justice Ali Muhammad Magrey said the Drugs and Cosmetics Act prescribes punishment of 10 years extendable up to life imprisonment against those culpable of manufacturing and marketing substandard drugs.

The court directed the respondents to file report indicating the action taken against the pharmaceutical companies found to have marketed the substandard drugs as also fate of 293 samples that were not tested or whose reports are awaited.

The court said report filed by the concerned authorities should also indicate progress for setting up Additional Drug Analysis Laboratories and augmenting the existing structure.

Moreover, the Central Drug Control Organization (CDCO) lifted 156 samples out of which 27 were declared substandard. However, prosecution against none of the manufactures, chemists or retail outlets has been launched till date.

“The CDCO has felt satisfied with taking some administrative steps like cancelling of drug manufacturing licence and issuance of show cause notice,” the court observed. “But the action taken does not satisfy the requirement of Drugs and Cosmetics Act because in terms of Section 27 of the Act, prosecution is to be launched against the Pharmaceutical companies if the allegations of manufacturing, marketing or transporting spurious and

substandard drugs are proved."

While Assistant Solicitor General S A Makroo appearing for the Government of India submitted that while samples are being lifted by the CDCO, the prosecution is to be launched by the state government. The State Advocate General MI Qadri insisted that the prosecution is to be carried out by the CDCO. He argued that the state government is bound to launch prosecution only when the samples are lifted by its drug inspectors and found substandard.

The court however sought a fresh status report in this regard after Makroo proposed and solicited time to file it. In its status report, the state government has however confirmed action taken against five pharmaceutical companies for manufacturing and marketing substandard drugs, after their products were found substandard by the CDL Kolkata.

Meanwhile, in a separate direction, the court asked the state government to file action taken report on the inquiry against the erring officials in the drug scam submitted by an officer to the General Administration Department.

In yet another direction, the court asked the government to file report on the steps taken to fill up 12 vacant posts of drug inspectors after it observed that 84 posts of drug inspectors have not been filled so far.

❖ Spurious Drugs Sold Outside GB Pant

Rising Kashmir, May 02, 2014

Suspecting that fake drugs were being sold to patients by chemists around GB Pant Pediatric hospital, Kashmir High Court has directed Drug Inspector Srinagar to have surprise inspection of the said chemists.

The directions came after senior counsel Bashir Ahmad Bashir highlighted that chemists located in and around the hospital have again resorted to storing sub-standard and spurious drugs and alleged that doctors posted in the hospital are prescribing such drugs.

A division bench of the court also directed Drug Inspector Srinagar to take custody of photo copies of prescriptions which shall be available at the time of surprise inspection at the shop and samples shall be sent for analysis. The division bench also passed the directions on a Public Interest litigation seeking amends for the existing healthcare in the hospitals.

❖ SKIMS gets sub-standard supply

Rising Kashmir, May 5, 2014

A special court has issued arrest warrants against four persons for manufacturing and supplying sub- standard bandage to S-K Institute of Medical Sciences (SKIMS).

According to local newsgathering, KNS, Advocate Musavir Joo, the standing counsel of Food and Drug Control Organization, said that the special TADA court issued the arrest warrants against Sanjay Ahuja, Syed Ahmad, Saghir Bhaksh and Muhammad Amin who are proprietors, manufacturers and suppliers of Aroma surgical house and standard surgical dressing company based in Prthviraj Gunj Cant. The court has fixed the next date of hearing on May 31.

Local newsgathering KNS quoted Advocate Joo, saying, three samples of bandages lifted from SKIMS were sent to laboratory for analysis and the report has declared them 'sub standard'. Pertinently, the drug control officials had lifted samples of many dressing items in SKIMS for analytical procedures. The drug department had also directed the SKIMS officials not to use the material till the analytical reports come, official sources had revealed to KNS. But, instead implementing the directive the hospital authorities had distributed all sub standard material among the hapless patients.

Earlier a report by the Central Drugs Standard Control Organization (CDSCO) revealed that a huge number of drug samples lifted from government hospitals across the State in the past one year were "not of standard quality." The CDSCO report has noted that many of the drugs lifted by its inspectors from government hospitals—following an outrage over the supply of spurious drugs in the State—were found to be substandard.

The substandard drugs include both injections and tablets tested by the government analysts of Central Drugs Laboratory, Kolkata, and Regional Drugs Testing Laboratory Chandigarh.

❖ Business as usual after raid at Bhagirath Palace

Deccan Herrald, May 08, 2014

Business was as usual at Jai Saraswati Medicines in Bhagirath Palace on Thursday. A day before, the shop was raided by a team of 18 drug inspectors for allegedly flouting norms.

"Raids are regular at the medicine stores here. But this really doesn't affect business. The pharmacies are a little careful for two weeks, following which, things are back to square one," said Deepak Jain, a store owner, pointing to the rush of customers in neighbouring Jai Saraswati medicine store.

During inspection, it was found that the store stocked a considerable amount of medicines without any purchase bills.

"You can hardly blame a trader for this. It is almost impossible to have supporting documents for every crate of medicine coming from West Bengal, Bihar or any other state," said Jain.

Bhagirath Palace in Chandni Chowk is one of the biggest wholesale medicine markets in the country. However, it has also earned the reputation of being a supplier of spurious drugs with these medicines entering the market from various states.

During Wednesday's raid, insulin injections — which need to be refrigerated — were found lying outside a shop. The inspecting team seized stocks worth Rs 6 lakh.

"I think the government should conduct raids more often. Traders have reduced the sale of medicines to a joke. A life-saving drug which should be stored at six degree Celsius is lying outside at 40 degree Celsius. They have a readymade excuse of not having space due to overstocking of injections," said an owner of a medicine store, on condition of anonymity.

On Thursday, no crate of injections were seen lying outside stores. Rajeev Khattar, who deals in surgical disposables, said only raids can help upgrade the market. "But there are hardly any repercussions on the wholesale dealers' business."

For a few other traders, conducting raids is 'sheer drama'. "Traders will learn a lesson only if licences are cancelled. This drama of conducting raids, which does not change the existing situation, should end," said a store owner, who has been dealing with general medicines for 20 years now.

Most checks and balances are required in medicine stores as these store the most sensitive drugs.

Among the eight shops that the team had raided, anti-biotics were seized from a store and sent for quality testing. The stores, which were found flouting norms under the Drugs & Cosmetics Act and Rules, were also issued spot notices. The store owners have been asked to respond by May 12.

Santosh Agarwal, whose shop also came under the scanner, said this was the first time in four years that his shop was raided. "I am not scared as I didn't flout any rules. They must have got a wrong tip-off. Also, the sale of medicines is intact. The raid cannot affect my business."

❖ Govt orders drugs from 'dubious' companies

Greater Kashmir, May 21, 2014

In a shocking revelation, the state government has made repeated purchase of medicines from the pharma companies which had supplied substandard drugs to the government hospitals resulting in an uproar in the entire State.

The purchase orders were placed with the companies despite alerts issued by Drug and Food Control Organization (DFCO) asking people to desist from consuming the drugs, officials said.

The documents, available with Greater Kashmir, show that government placed repeated purchase orders to the companies and the practice has continued for the last more than a year despite the furore over sale of substandard drugs here.

In the spurious drug scam report, prepared by the State's Health and Medical Education department last month, while it has been noted that the product permissions of some of the companies have been withdrawn, the details of the drugs found substandard reveal that government placed repeat orders for the medicines.

The drugs, for which repeat orders were made, include Curecef-1000 tablet, manufactured by M/S R.H. Laboratories, Gondpur Industrial Area, Paonta Sahib (HP); Vidin Ointment (Povidone Iodine Ointment), manufactured by Zee Laboratories, 47,Industrial Area Poanta Sahib; Cefotaxime Injection, manufactured by Vivek Pharmachem (India) Limited, EPIP, Bari Brahmana and Ampicillin injection manufactured by Vivek Pharmachem (India).

The documents reveal that government also purchased Delin injection from Ind Swift Ltd even as earlier the drug Phena injection manufactured by the company and supplied to the government hospitals, was found sub-standard. The purchase of drugs continued from the companies even as the laboratory tests carried out by DFCO found that its drugs failed in different tests.

The records reveal that the repeat orders came even within the same month the drugs were found substandard. The DFCO test reports have revealed that both the Cefotaxime and Ampicillin injection manufactured by M/s Vivek Pharmachem (India) were found substandard in July last year.

As per the government report, the substandard drugs which were supplied to the hospitals, include Pantoprazole injection manufactured by M/S SGS Pharmaceuticals Pvt. Ltd., 162/1, Pohana Iqbalpur Road, Nanhera Rorkee, and drug Marycal 500 by M/S A.K. Biotech Pvt. Ltd., Export Promotional Industrial Park, Kartholi, Jammu.

State's Health Minister, Taj Mohi-ud-Din, said that the repeat orders "shouldn't have been placed to purchase the drugs after they were found substandard earlier." "I will look into the matter," he said.

❖ Spurious Drugs: 25 Govt officials face action

Greater Kashmir June 01, 2014

The state government is contemplating disciplinary action against 25 officials of different government departments involved in the spurious drug scam. The officials have been accused of facilitating purchase of substandard medicines as members of the Purchase Committees.

General Administration Department (GAD) has asked Financial Commissioner Industries and Commerce, Principal Secretary Finance and Commissioner Secretary Health & Medical Education Department to initiate action against the accused officials in light of the recommendations made in the inquiry report by the then Commissioner Secretary, Rural Development Department, Farooq Ahmed Peer.

"The undersigned is directed to forward herewith a copy of the inquiry report submitted by Farooq Ahmed Peer, Commissioner Secretary Government, Department of Rural Development &Panchyati Raj, vide no S/CS/RD&PR/Inquiry/H&ME/87/2013 dated 25/11/2013 to the Financial Commissioner Industries and Commerce department, Principal Secretary to Finance Department and Commissioner Secretary H&ME and requests them to take necessary action in the matter under the J&K CCA, Rules 1956 under intimation to the GAD," reads the communication sent by Special Secretary GAD.

As per official records, Peer had submitted his report to the government on 25 November 2013 recommending action against 25 officials for administrative lapses after the inquiry found that as members of the Purchase Committees they approved the rate contract of the drug Maximizin-625 mg in favor of a firm which had failed to comply with the terms and conditions of the contract.

The Purchase committee had Accounts Officers of GMC Jammu, Medical Superintendent of SMGS hospital, Functional Manager in the Industries and Commerce department as well as the officials in Health and Medical Education department and Drug and Food Control Organization (DFCO) as its members.

Investigations in the infamous spurious drug scam that rocked the state last year found that the members of the verification boards of the hospitals including some senior faculty members of GMC Srinagar, "were found to have approved the drug Maximizin without proper verification of its specifications, label claim and other features."

Sources said the government is contemplating disciplinary action against the accused officials which may even include dismissal from service.
Director Health Services Kashmir, DrSaleem-ur-Rehman, said the role of the members of the verification board is under investigation. "We need to look into the findings of inquiry report submitted to the government before initiating action against the accused officials," he said.

❖ Fake Drugs over Rs. 25 lakh Seized, Four Arrested

Patna Daily, June 07, 2014

Authorities in Patna on Friday, following a series of raids in Sri Krishna Puri and other areas, arrested four persons and seized fake medicines of various national brands to the tune of Rs. 25 lakh.

While the medicines appeared to have been manufactured in Maharashtra, Andhra Pradesh, and Uttarakhand, the labels and cartons were probably manufactured and printed in Patna, Senior Superintendent of Police (SSP) Manu Maharaj said.

The arrested men were identified as Manish Kumar, Surendra Kumar, Dhananjay Kumar, and Raj Kumar, all of Patna.

The SSP said that the samples of the seized medicines, mostly meant for children or women, would be sent to labs to identify their ingredients.
Attempts will be made to identify the manufacturers of the fake drugs, he said.

❖ Fake drugs worth Rs 25 lakh seized, four arrested

The Times of India, June 8, 2014

Patna police on Friday seized suspected fake medicines worth Rs 25 lakh and arrested four persons in this connection.

Several raids were conducted by investigating teams comprising Patna police and drug inspectors at the godowns of medicine suppliers at S K Puri and adjoining areas. A large number of medicines cartons were found stored at the godowns. The medicines were dumped in different cartons while their labels were stored in separate boxes.

A police official said, "The labels were probably locally printed, and we are looking for the manufacturing companies of such medicines. The capsule and tablet strips were printed and manufactured in different states like Uttarakhand, Maharashtra, Andhra Pradesh and other states."

The types of medicines seized included calcium, vitamins and hormones. Most of them were for infants and pregnant women. The raiding teams also arrested four persons who used to sell the medicines to other districts.

Patna SSP Manu Maharaaj said, "The arrested persons were identified as Raj Kumar, Dhananjay Kumar alias Trilok, Manish Kumar and Surendra Kumar alias Monu. All of them are natives of Patna district. They have revealed to police that they used to bring the medicines from Delhi via trains and couriers." The raids will continue, he said.

"The medicines found during the two-day-long raids would be sent to forensic laboratory to check their authenticity. But, on the face of it, it seemed that the seized medicines were fake," said an investigating officer preferring

anonymity. Further raids would be conducted in districts like Sitamarhi, Gopalganj, Gaya, Darbhanga and other places.

❖ 23 chemists prosecuted, 4 convicted

The Times of India, June 13, 2014

Food and Drugs Administration (FDA) officials have filed criminal cases against 23 chemists in Pune division between April 2013 and March 2014 for violations ranging from dispensing medicines without licence to selling substandard medicines. Four more chemists and drug manufacturers were also convicted during the same period.

Of the 23 chemists against whom the officials filed criminal cases in the court, 14 chemists faced prosecution in Pune district. Among them, seven are from Pune city, four from Pimpri Chinchwad and three from rural parts of Pune.

The Pune administrative division of the FDA also includes Satara, Sangli, Kolhapur and Solapur districts in its jurisdiction, from where nine chemists faced prosecution. Of them four are from Solapur, three from Satara and one chemist each from Sangli and Kolhapur.

"We file criminal cases against erring chemists after drugs samples drawn from their establishments draw negative results. The 23 chemists against whom we have filed cases in the court between in 2013-14 were either found to be selling substandard or spurious drugs or they were caught operating chemists shop without a valid licence. Some were also prosecuted for overcharging. The cases against all of them are yet to be decided," said Vinita Thomas, assistant commissioner (drugs), FDA, Pune.

The year 2013-14 also saw four convictions in Pune divisions. The criminal cases against them were lodged in the past.

"A chemist from Shirur was fined Rs 5,000 and imprisoned for a day when an offence of overcharging against him was proved with adequate evidences. In another case, a drug wholesaler from Kolhapur was found operating without a valid licence and was fined Rs 50,000," Thomas said.

In another case, a drug manufacturer from Nashik, whose drug samples were drawn in Pune and found to be substandard, was punished. "Two persons involved in the case were fined Rs 10,000 each, with one day imprisonment. Another drug manufacturer from Vasai was fined Rs 40,000 after the manufacturer published and circulated objectionable advertisement regarding his product - a capsule meant for enhancing sexual vigour," Thomas said.

The FDA officials also filed 11 first information reports (FIR) against chemists for various offences during 2013-14. "As many as 14 people were arrested against the 11 FIRs filed during this period," Thomas said

In one case, the FDA official had busted the sale of banned painkiller dextropropoxyphehne (DXP) in Pune and elsewhere in the state. The officials, in a two-week operation, had nabbed a drug consignee agent and a pharma company's depot manager in Pune. Together, they had sold capsules containing the drug worth over Rs 60 lakh in Pune, the rest of Maharashtra and Goa.

"We also filed three separate FIRs with police in Baramati, Yavat and Pimpri Chinchwad for illegal sale of pregnancy retaining drug which was sourced in a large quantity from the supplier in Mumbai, who did not possess valid licence," Thomas said.

Criminal cases filed against chemists in Pune division
Pune 14
Sangli 1
Satara 3
Kolhapur 1
Solapur 4

(Source: Food and Drugs Administration, Pune division)

❖ Keep an eye out for spurious medicines

Deccan Herrald, July 1, 2014

Next time when you go to avail a medical treatment and use drugs dispensed by government hospitals in the city, there are chances that you might get to consume sub-standards drugs. At least a random drug sampling has indicated so!

This matter came into light when activist Rajhans Bansal filed a Right To Information (RTI) query. According to the Delhi Drug Control Department, which noted that during the period April 2008 to March 2013, seven samples of drugs were taken from a government hospital in Delhi were declared 'not of standard quality' and the matter was referred to the concerned State Drugs Controller from where the manufacturer belonged.

The hospitals from where drug samples were taken include medical stores at All-India Institute of Medical Sciences, GTB Hospital, Sri Dad Devmatri Avam Shishu Chikitsalya (Dabri), Sanjay Gandhi Memorial Hospital (Mangolpuri), Medical Store Sanjay Gandhi Memorial Hospital, MCD Allopathic Dispensary (Chandhi Chowk) and Central Medical Store MCD Building (Civil Lines).

Commonly used anti-hypertensive drugs – Atenolol and Ramipril – were found to be below standard at the AIIMS medical store, GTB Hospital and the allopathic dispensary run by the municipal corporation in Chandni Chowk, as per the information submitted by the Delhi Drug Control Department to the National Human Rights Commission (NHRC).

Dr Ratan Kumar Vaish, senior consultant, department of medicine, Rockland Group of Hospital, said, “It is very difficult to differentiate between standard and substandard medicines, until and unless we test them. Although hospitals do maintain the standard, such cases happen in suburban areas.”

“Two things can occur if someone consumes sub-standard medicines on a regular basis. Firstly, the disease will not get cured and secondly, the bacteria present in the body will get immune to the sub-standard medicines and develop resistance. Hence, it will only hamper the patient in the long run, especially children and elderly people because their immune systems are not strong enough. And such goof-ups happen from the supplier side only,” added Dr Vaish.

Talking about how such sub-standard medicines can hamper the reputation of doctors, Dr R K Singal, principal consultant and HOD Internal Medicine, BLK Super Speciality Hospital, said, “If a patient is given sub-standard medicines and he or she is not getting cured, it will automatically create a bad name for the doctor. Also, the impurities present in the drugs can have side-effects, which can be quite harmful.” So the next time you take a medicine and feel it hasn’t worked at all, it could have been a sub-standard drug!

❖ Police get lead in fake vaccine case

The Times of India, July 08, 2014

A joint squad of Directorate of Drug Control Administration (DDCA) and commisisonerate of police on Monday raided premises of a vaccine stockist at Bidanasi in Cuttack in connection with the fake vaccine racket in the state.

Drugs inspector S K Sinha said the raiding team seized certain documents, which may offer vital clue into the transit route of the bogus pentavalent vaccine. "We found many purchase bills of the pentavalent vaccine from the stockist. A comparison of their batch numbers with that of stock of the manufacturer at its Odisha depot did not match," Sinha said.

The drugs inspector said the stockist is unable to give a satisfactory reply regarding the source from which he purchased the vaccine. "It would be a crucial link to establish how the counterfeit vaccine reached Odisha," he said.
DDCA sources said the stockist is not an authorized dealer of pentavalent vaccine. He was, however, trading by purchasing these on subsidy from authorized distributors. Though such practice is legal since the stockist possess drugs licence, he has to substantiate with documents the legal route of procurement and supply to doctors.

A government source said the joint team of police and DDCA will interrogate a Balsore-based doctor, who had given statement to DDCA that he procured the fake vaccine from the particular stockist. Sinha said DDCA intelligence wing is alert to track possible use of the vaccine earlier and rule out its future use.

The fake vaccine was being sold as popular pentavalent (combination of five), vaccine of a France-based manufacturer, effective against diphtheria, tetanus, pertussis, polio and certain invasive infections. Each vial, both original and its look-alike, cost around Rs 2,500 and is given to infants after six weeks. Odisha consumed around 2,000 vials per month till it was in supply. It is out of stock now.

❖ Drug purchase scam rocks council

The Times of India, July 16, 2014

BJP members rocked the legislative council during zero hour on Tuesday over the huge financial irregularities to the tune of Rs 1 crore in drug purchase for Nalanada Medical College hospital (NMCH).

Raising the issue, BJP member Sanjeev Shyam Singh said the government had set up a five-member committee to probe the irregularities in drug purchase in 2008-09 and 2009-2010. The committee submitted its report to the state health department on June 20 this year, Singh said.

Singh said the government purchased a multivitamin tablet at the rate of Rs 40 in 2008-09 while it was available in the market at Rs 13. Similarly, ampicilin capsule was purchased at the rate of Rs 1.49 against the market price of 59 paise. Several other drugs for blood pressure were also purchased at inflated rate, he said. According to Singh, the drugs were purchased at the higher than market rates only to favour particular pharmaceutical agencies.

Earlier, another BJP member, Baidyanath Prasad, moved an adjournment motion on drug purchase scam in PMCH demanding special debate on this issue. The Chairman rejected the motion. Intervening amid noisy scenes, leader of opposition in the council, Sushil Kumar Modi sought the government reply on this issue. He reminded the treasury benches that CM Jitan Ram Manjhi had announced in the house a fortnight ago to set up a committee to probe into the matter related to the purchase of essential drugs and scarcity of essential drugs in the PMCH.

BJP member Mangal Pandey also sought to know from the government about the probe committee. "If the government had set up a committee, where is the probe report," he asked. Health minister Ram Dhani Singh, who was present in the house, said he would communicate this matter to the CM.
Later, talking to reporters, Modi said the BJP has demanded CBI inquiry into the purchase and supply of fake (substandard) drugs in Bihar hospitals. He also said 60 percent of the purchase has been made from only three 'blacklisted' pharmaceutical companies at higher rates.

Modi also questioned the credential of the probe committee when joint secretary, health, Sanjay Kumar is the chairman of the technical evaluation committee. Kumar, according to Modi, has served as a PA to former CM

Nitish Kumar. Similarly, he said, the MD of Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) an Indian Revenue Service officer. As per the BMSICL bylaws, the MD should be an IAS officer, he said, adding that the government was trying to evade the issue to save its 'men'.

Modi vs Chaudhary

There was a piquant situation in the council when water resources development minister Vijay K Chaudhary had a verbal duel with leader of opposition in the house Sushil K Modi during question hour. Modi was asking supplementary question over the deaths of more than 150 children due to acute encephalitis syndrome (AES) in Bihar. Chaudhary wanted to reply on the government behalf. Interrupting Chaudhary, Modi said since health minister was sitting in the house, nobody could reply on his behalf.

❖ 14 drugs made in Himachal Pradesh fail tests

The Times of India, July 22, 2014

The quality of drugs manufactured in Himachal Pradesh has come under scanner once again with samples of 14 drugs failing the test conducted by Central Drugs Standards Control Organization (CDSCO) in June last. While CDSCO has issued an alert about the failed drugs, state authorities on their part have issued show cause notices to concerned companies and have asked them to withdraw the batches from the market.

Among the list of 41 drugs which failed the test, 14 were manufactured at Nalagarh, Baddi, Paonta Sahib, Kala Amb, Jharmajri and Sansarpur Terrace in Kangra. Himachal Pradesh caters to around 40% demand of domestic market. With around 650 manufacturing units, pharmaceutical industry of the state is pegged at around Rs 25,000 crore. The state also exports drugs worth Rs 9,000 crore each year, sources said.

After finding the drugs failing the test, CDSCO has issued safety alert about drugs manufactured in Himachal Pradesh which includes Tapentadol and Paracetamol tablets, Ofloxacin tablets, Amoxicillin and Dicloxacillin capsules, Misoprostol tablets, Amoxycillin and Potassium Clavulanate tablets, Salbutamol Sulphate tablets, Cefuroxime Axetil tablets, Megarab 20 tablets, Albendazole tablets, Cefixime dispersible tablets, Trypsin Chymotrypsin tablets, Ceftricor 1g, Ceftriaxone and Sulbactam for injection and Gencin 80mg/2ml injection.

According to sources, this is not the first time when drugs manufactured in Himachal Pradesh have failed the tests in other states. Sources said that in the past too, such instances were brought to the notice of state drugs authority, but despite this, samples were failing the quality tests outside.

Himachal Pradesh drug controller Navneet Marwaha said that companies whose samples have failed the tests conducted by CDSCO were issued show

cause notices. "We have asked them to withdraw their batches. As samples have failed outside Himachal Pradesh, we could only take administrative action against the companies," he said.

He accused the board, which was named as the first respondent, of turning a blind eye to its complaints. "The board has failed to take any action to halt the illegal importation of the affected drugs and has failed to respond to the complaints by the petitioner," the court heard. Cipla's EA Regional Manager James Bradford says Lords Ltd was selling 12 products that bear its trademark but had not been sourced from them.

❖ Illegal, Fake Drug Racket Rocks Bihar Assembly

The Outlook, July 25, 2014

An illegal drug racket busted recently in the state capital rocked the Assembly today with opposition BJP demanding CBI probe into it alleging involvement of health department officials.

Raising the issue during Question Hour, BJP MLA Vikram Kunwar asked how license was reissued to Hanuman Drug Agency in April when expired medicines were seized from it during a raid in September 2010.

Kunwar said a raid in July 9 this year at the same agency had yielded a huge cache of expired medicines meant for use in state government hospitals, and demanded a CBI enquiry.

Rejecting the demand for a CBI probe, Bihar Health Minister Ramdhani Singh said the matter was under the jurisdiction of the state government and it would be investigated by his department's officials.

Supporting the demand for CBI enquiry, Leader of the Opposition Nand Kishore Yadav said, "This is a very serious issue as it concerns lives of poor people. The expired medicines recovered in raids are for government hospitals where poor people go for treatment."

Dates on these expired medicines were changed and then sent to places like New Delhi, Uttar Pradesh and even Nepal, Yadav said adding health department probe would not work as roles of health department officials were questionable.

Congress Legislature Party leader Sadanand Singh also joined the issue asking who was the health minister when drug license of the agency concerned was renewed.

Treasury bench officials led by Finance Minister Bijendra Prasad Yadav said the crackdown on fake and illegal medicines was continuing with raids almost on a daily basis and "we should wait for the full report to come".

At this, opposition members stood up shouting anti-government slogans and Speaker Uday Narayan Chaudhary ordered that the discussion on the issue would be taken up on a later date will all its supplementary questions.

The drug control administration has conducted a series of raids since July 9 busting a major drug racket in Patna and seizing around 3,000 types of medicines worth over Rs 10 crore, officials sources said.

A majority of these medicines had their expiry dates tampered with and were meant for supply in government hospitals. Price stickers were put on medicines bearing 'Government use only' stamp.

A large quantity of physician samples that are not for sale, fake bills and other documents regarding diversion of medicines supposed to be used at government institutions, fake stickers and wrappers were also recovered during the raids, they said. The drug control officials have lodged an FIR against 85 people so far. They hinted at the involvement of international mafia as the drugs were also supplied to neighbouring countries.

❖ Drug racket had links with Meerut, Nepal

The Times of India, July 25, 2014

The racket of drugs busted by the drug control administration earlier this week has had links with Meerut and Nepal.

According to drug control authorities, Sri Hanuman Agency used to procure physicians' samples from SP agency of Meerut. It has also been made an accused in the FIR. Altogether 85 persons have been booked following raids on godowns of Sri Hanuman Agency, which is accused of stocking physicians' samples and drugs meant for government supply as well as tampering with expiry dates of drugs.

Sri Hanuman Agency is allegedly a habitual offender. Despite two FIRs lodged against it in 2005 and 2010, the drug control authorities issued a fresh licence to it in April this year. According to one of the team members that included Subhash Chandra, Sachichidanand Prasad and R N Singh of drug control administration, Dheeraj and Neeraj of Hanuman Agency procured physicians' samples from a Meerut-based agency on May 30, 2013. The ‘not for sale' note was erased with blades and MRP sticker pasted on them.

The authorities found the agency once inadvertently sent back a consignment of drugs to a manufacturing firm, M Cure, saying it was not used and asking for refund. However, the firm replied they were physicians' samples not to be sold in the market.

Sri Hanuman Agency procured drugs worth Rs 10 crore from 40-odd Delhi agencies against fake bills. "There is no record. The drugs might be spurious or counterfeit," said one of the team members.

The authorities have also found that the consignments meant for 27 agencies of Bihar, including those in Begusarai, Hajipur and Darbhanga, used to reach the godowns of Sri Hanuman Agency at Govind Mitra Road. The drugs meant for government supply in nine districts too reached Govind Mitra road. The FIR has also named the eight courier companies through which Sri Hanuman Agency used to procure the drugs. "They have been booked because they would change the destinations of the consignment on the request of Sri Hanuman Agency. Blank bills of various agencies of Sasaram, Rohtas, Begusarai, Purnia, Asansol and Basti (UP) were also recovered," a source said.

The seized drugs include insulin, antibiotics, injections, life-saving drugs, antivenoms and even Pentajocin, a drug that is controlled under the Narcotics Act. "Labelling is considered a part of drug manufacturing. Sri Hanuman Agency used to relabel the drugs while it is not licensed to do the same," the source said.

A debit card of one Mahesh Prasad of Nepal has also been recovered. The authorities believe Sri Hanuman Agency used to supply drugs to him. One private hospital based on the Patna bypass road has also been supplied drugs by this agency.

❖ FDA intercept car, seize 20 cartons of spurious cosmetics soap

WebIndia123, Aug 01, 2014

A team of Food & Drug Administration (FDA) intercepted an SUV outside super mart-1, DLF-IV, Gurgaon carrying 20 cartons of spurious Cosmetics soap.

These were meant for supply to a chemist shop in a high end market. The details placed on the labels showed that these were manufactured by Kailash Khadi Gram Udyog, 503/13, Khasara No 909, Sadhrana, Gurgaon.

In FDA records, there was no such licensed factory for manufacturing Cosmetic product. FDA has sent the samples of toilet soap for testing to ascertain the quantity and quality.

Vehicle used for illegal supply has also been taken into custody by team of FDA, Gurgaon. The approximate cost of the products is total Rs 52,000. The case has been registered under Drugs and Cosmetics Act, 1940. It is an offence punishable under Drugs and Cosmetics Act, 1940 and accused may be liable for 5 year rigorous imprisonment with a fine of Rs 1 lakh.

❖ Madhya Pradesh: 147 medicine samples in hospitals of

inferior quality, Congress seeks CBI probe

DNA India, August 13, 2014

A total of 147 medicine samples collected from various government hospitals across Madhya Pradesh in last two years were found to be of sub-standard quality, prompting the opposition Congress to demand a CBI probe into their distribution.

"A total of 3255 samples were collected from July 1, 2012 to May 31, 2014 (from various hospitals), and their quality was examined by a state-level laboratory. Out of them, 147 samples were found sub-standard," state Health and Parliamentary Affairs Minister Narottam Mishra said in a release yesterday.

Mishra also said that samples of only two types of medicine were given under the state government's Free Medicine Distribution Scheme, "which is just 0.5 per cent and is quite less than the national average of 3-5 per cent." Meanwhile, the Leader of Opposition in Madhya Pradesh Assembly, Satyadev Katare today sought a CBI probe into the distribution of "sub-standard" medicines.

"A total of 147 sub-standard medicines were being distributed in hospitals across the state and the same should be banned immediately," he told reporters here. Katare said that a probe by the central agency would reveal who were responsible for distribution of the samples and why such drugs were supplied to hospitals. "Those behind it should be punished," he added.

❖ J&K ministers involved in selling substandard drug in Kashmir

WebIndia123, August 13, 2014

Terming selling of substandard and fake drugs in Kashmir valley as a matter of concern, hardliner Hurriyat Conference chairman Syed Ali Shah Geelani alleged that the state government is equally responsible for the crime as some of its ministers are involved in the scam.

Geelani also expressed concern and anguish over selling of fake and substandard pesticides for orchards which instead of benefitting cause severe harm to the fruit production.

A Hurriyat spokesperson here today said a high level delegation of All Kashmir Chemists and Distribution Federation (AKCDF) met Geelani at his residence and revealed some alarming facts about the supply and trade of spurious and substandard medicine in Kashmir.

He said the delegation informed Geelani that all the activities related to the supply of medicine were shifted from Srinagar to Jammu in 90's and now the

winter capital was used as launching pad for making and supplying spurious and substandard medicines to the Valley.

'According to the delegation, many ministers were involved in this scam and due to their patronage the criminals, who are playing with the lives of the people in Kashmir, are roaming free,' he alleged.

Meanwhile, Geelani assured the delegation that Hurriyat Conference will observe the possibilities to act against people involved in this scam. Geelani, however, said some greedy doctors are also involved in this scam. 'These people are not only defaming this noble profession, but are acting as killers,' Geelani said. Meanwhile, Geelani said some known and famous companies of the state are manufacturing and selling substandard pesticides for personal gains.

❖ Court asks Govt to seize all identified drugs from market

Rising Kashmir, August 26, 2014

High Court has directed the state to seize stock of all identified spurious drugs from the market.

A division bench of Chief Justice M M Kumar and Justice Hasnain Masoodi directed the State and Central Drug Standard Control Organization (CDSCO) to seize the drugs supplied to chemists, government hospitals and dispensaries which have been found spurious/substandard.

Court said keeping in view the seriousness of the issue and interest of general public the state government and CDSCO is directed to take immediate steps so that people are saved from using these drugs which have been found spurious.

In a status report filed by Controller Drugs and Food Control Organisation, 99 identified drugs have been found spurious.

Court is passing direction while hearing a Public Interest Litigation filed after spurious drug scam came to fore in the state. During the hearing, the division bench observed that only action taken by the state is the permission to prosecute the companies. State was not able to give satisfactory reply after court raised query saying what will happen to these companies during period of trial.

Court said there is concern whether these companies will continue to supply spurious drugs to the state or their agreements to supply drugs have been cancelled by blacklisting such companies.

❖ Woman dies after taking 'weight-loss' pills in Madhya Pradesh

The Times of India, September 13, 2014

Overdose of 'slimming pills' apparently led to death of a 30-year-old woman in Chhindwara district of Madhya Pradesh.

Deceased Sita Nagwanshi, resident of Nolakhapa village, was admitted at district hospital by her family members on Wednesday morning where she died after a few hours. Doctors said she suffered a cardiac arrest.

Sita's family said they were still clueless on the circumstances that led to her death and requested a probe. Matter then was informed to police and autopsy was done.

However a doctor was informed by her husband that Sita was reeling under depression because of obesity and was consuming some unknown fat-burning pills for the last two weeks.

"Going by what her family told me, I am personally of the opinion that overdose of the unknown wright-loss drug killed her," said a health officer wishing anonymity.

Dr Nerendra Hanote who conducted postmortem said detailed analysis was required to ascertain circumstances that led to her death. "I am not in a position of give any definite opinion now. Samples would be sent for forensic analysis," Dr Hanote told TOI.

There are several medical shops in Chhindwara and adjoining Nagpur in Maharashtra where such pills are being sold over the counter.

According to Indore based bariatric surgeon Dr Mohit Bhandari, "There have been several reports of death due to the so-called fat burning pills in the state. Drugs like Sibutramine suppress appetite and block the reuptake of neurotransmitters to trick the brain into thinking the stomach was full. They were extremely dangerous".

He said placebos and steroids are being sold in the name of weight-loss drugs across the state.

In 2010, Drug Controller General of India (DCGI) had issued notices to all state drug controllers directing them to suspend licenses granted to manufacturers for sales, manufacturing and distribution of sibutramine, R-sibutramine and their formulations with immediate effect. The decision to stop manufacturing of the drug was taken in the wake of the studies suggesting higher risk of heart diseases from the use of this drug.

❖ Counterfeit medicines seized from three shops

Tribune, September 27,2014

In a major breakthrough, the Health Department has detected counterfeit medicines of a multinational brand from three shops in the city. The department while confiscating the stocks of the medicines has sent the samples for testing.

The investigations regarding the origin of counterfeit medicines has seemingly reached a dead-end for now as the medicine provider having his shop on Tarn Taran road has gone into hiding. However, the department has sealed his shop and filed a police complaint.

The sale of counterfeit medicines came to light after the officials of the MNC approached local health department with a complaint yesterday. The sources in the department said as the company officials had information about sale of counterfeit medicines they purchased medicine from 40 different shops in city. Later, it was found that medicines purchased from four shops were counterfeit.

Starting the investigations immediately, a drug wing team raided Bagga Medical Store outside Guru Nanak Dev Hospital. The team seized three strips of counterfeit medicine from the shop.

On investigation, the team found that a person named Prince was supplying the medicines. As Prince was called to the shop on the pretext of a fresh order by the shopkeeper, the team caught hold of him and enquired about the source.

Later, the team raided Dyal Pratap Pharma and V Brothers Pharma in Katra Sher Singh area, who allegedly revealed the name of Raman Kumar, a medicine retailer operating from Tarn Taran road. The department collected a total of 51 strips of the medicine out of which few have been sent for testing.

However when the team reached the place, they found the shop locked. Drug inspector Sukhdeep Singh said, “The team went to his home but no one came out after repeated calls.” The department has sealed the shop owned by Raman Kumar and informed the police about the matter.

❖ Fake medicines supplied from Agra

Tribune, September 29, 2014

An investigation into the sale of fake medicines of a multinational brand in the local market by the drug wing of the Health Department has revealed that these were supplied by a firm based in Agra.

The drug wing had earlier sealed the shop of a retailer operating from the Tarn Taran road for supplying these fake medicines to at least three shops in the city.

On a request by a retailer to inspect the shop premises, the team found more than a dozen strips of the medicine. The department has sent the samples of the seized medicines for testing.

Sources in the department revealed that though the medicines were seized from the shop, the shop owners had refused to sign the statement given to the team officials.

Further investigation will require an inspection of PP Pharma, an Agra-based firm whose name was revealed by owner of the shop on the Tarn Taran road, Raman Kumar.

The shop owners have also supplied the bank account number of an Agra-based bank and the telephone numbers on which they used to get the medicine.

Officials of the Health Department here stated that as the matter concerned another state, they had sent a report to the state officials for action.

Earlier a multinational medicine manufacturing company had approached the local Health Department on September 26, stating that the counterfeit of a medicine manufactured by them was being sold in the city.

Later, a health team had recovered the counterfeit medicines from three shops in city. The medicines seized from all these shops were sent for testing. It was revealed that fake medicines weresupplied by a firm based in Agra.

❖ Spurious drug scandal: ASO charge sheeted

State Times, October 01, 2014

Over a year after the registration of case, the Crime Branch wing of the Jammu and Kashmir on Tuesday charge-sheeted Assistant Scientific Officer of J&K Forensic Science Laboratory (FSL) for preparing a false and fabricated opinion on chemical analysis of Maximizine-625-a drug which was found to be spurious, during a random test of hospital supply.

FIR 21/2013 under section 420,193,218 RPC was registered against the accused Abdul Gani Bhat (Assistant Scientific Officer FSL, Srinagar), resident of Brane Nishata, Srinagar.

The CB has produced the Challan of the case wherein he abused his official position to prepare a fabricated opinion. Brief facts of the case are that in connection with the investigation of FIR 10/13 registered under section 274,420,465,467,468,471, 120-B RPC r/w section 5(2) P.C Act Svt. 2006 and section 27 Drugs and Cosmetics Act-1940 regarding supply of spurious drug Maximizine-625 mg (tablets) to State Health Department by M/s Lifeline Pharmaco Surgicals, sample of seized unused drug Maximizine-625 mg

(tablets), the sample of the same drug was sent to Director FSL, Jammu for chemical analysis, which was tested by Abdul Gani Bhat, Assistant Scientific Officer FSL, Srinagar, camp Jammu, who furnished the report that Amoxicillin Trihydrate and Potassium Clavulanate was found present in the samples, which was contrary to the report furnished by the Drug Testing Laboratory, Dalgate, Srinagar.

In order to have a definite and conclusive opinion, another sample of the said drug was sent to CFSL, New Delhi, wherefrom it was reported that Amoxicillin Trihydrate was not present in the samples.

It transpires from the perusal of the scientific analysis reports that the Assistant Scientific Officer FSL, Srinagar, camp Jammu, Abdul Gani Bhat had intentionally prepared a fabricated opinion with respect to the drug Maximizine-625 mg, knowingly that the same shall be used as false evidence at any stage of judicial proceedings, thereby deceiving the Investigating Agency in order to shield the accused persons from the process of law, in connivance with some other interested persons in the case including the officers/officials of the FSL, J&K, obviously for extraneous considerations thereby abusing his official position.

From the evidence, oral as well as documentary, collected during investigation of the case, the accused person were found to have committed the offences under section 420,193,218RPC and has accordingly been challaned in the Court of law for judicial determination.

M/s Lifeline Pharmaco Surgicals had participated in the tender process flouted by the government for the supply of drugs Amoxicillin Trihydrate IP` equivalent to Amoxicillin 500 mg and `Potassium Clavulanate Diluted IP` equivalent to Clavulanate Acid 125 mg, by quoting the rate for 10X10 tablets @ Rs 428.40 for the drug manufactured by M/s Medley Pharmaceuticals Ltd under the brand name Maximizin-625.

An authorization certificate purportedly issued by M/s Medley Pharmaceuticals Ltd was also produced and the rates quoted by the supplier were found the lowest by the Purchase Committee.

During the probe it was found that the M/s Medley Pharmaceuticals Ltd had not issued any authorization to M/s Lifeline Pharmaco Surgicals and the documents were forged to secure the supply contact. The Purchase Committee-II, without verifying the tender documents and credentials of the suppliers had approved the rate contract by abusing their official position, causing wrongful gain to the suppliers and huge loss to the public exchequer and threatening the lives of the people.

Three persons, identified as Ashok Kumar Raina, Akhil Gadoo and one Amardeep Raina were arrested in this case.

❖ 7 booked for selling false drugs

Hindustan Times, October 06, 2014

The police have booked seven dealers from Khanna, Ferozepur and Ludhiana for selling spurious and sub-standard drugs manufactured by Madhya Pradesh-based Anupam Biotech Company.

PD Bansal, president, Lok Sewa Club, said in the year 2012, one of the members of the club had purchased a medicine called Kenflox-200 from a local drug store for which the chemist charged `20 for a strip of 10 tablets.

Bansal said the print rate of the strip was Rs. 80, which posed doubts about the quality of the medicine. He said they had filed a Right to Information with the State Licensing Authority (SLA) of Himachal Pradesh seeking information whether the medicine was from a registered company or not. However, the SLA disclosed that no drug manufacturing license had been issued to a company called Anupam Biotech Company.

He further said a team of drug inspectors from the health department including Parneet Kaur from Khanna and Dinesh Gupta from Ludhiana conducted raids in the drug stores on Samadhi Road in Khanna and Ferozepur Road in Ludhiana on November 8, 2012 and seized a massive stock of medicines manufactured by the said company. Samples of these medicines were also sent for laboratory tests. All the samples failed the lab tests and were proved to be sub-standard, miss-branded and spurious. Besides, the medicine strips and cartons bore different drug manufacturing license numbers, he added.

He also said during investigation it transpired that local dealers purchased drugs manufactured by the Anupam Biotech Company from various dealers based in Gwalior.

Bansal said the dealers in Gwalior had purchased medicines from M/s National Medical Store in Bhind (MP), which failed to file a reply. He said the health department team led by Dinesh Gupta visited Gwalior for physical verification and found that the dealers there did not exist and the Anupam Biotech Company at Bhind locked.

The police have registered a case under Section 27C of Drugs and Cosmetics Act 1940 and Sections 420 (cheating and dishonestly inducing elivery of property), 465 (forgery), 468 (forgery for purpose of cheating) and 471 (using as genuine a forged document or electronic record) of the Indian Penal Code.

❖ Northeast a dumping ground for inferior drugs

The Times of India, October 29, 2014

The northeast has become a dumping ground for spurious and substandard drugs with dubious manufacturing companies using the region to spread their

business.

The region, as per analysts at the Regional Drug Testing Laboratory, Guwahati, has the highest number of spurious drugs in circulation in the country. Lack of awareness and dearth of qualified pharmacists have contributed to the menace, posing a serious health risk.

Central Drugs Standard Control Organization (CDSCO), in its September list of misbranded drugs, has declared 45 drugs, medical devices and cosmetics as substandard. Close to 20 such items were manufactured in Assam alone while others being produced in Himachal Pradesh, Andhra Pradesh, Jammu, Goa, Punjab and Uttarakhand.

Thirty such samples were collected from Regional Drugs Control Laboratories (RDTL), Guwahati. Samples of suspected misbranded drugs are collected and tested randomly. The list is made every month.

It is not known whether these drugs are sold over the counter in the northeast as lack of awareness on spurious and misbranded drugs is low. Some of the drugs are manufactured in Kokrajhar, Indore, Uttarakhand, West Bengal and Himachal Pradesh. "Substandard drugs are mainly pushed through distribution channels where there are no pharmacists or fake pharmacists are operating. Hence, presence of pharmacists in pharmacy outlets is mandatory in Pharmacy Act, 1948, and Drugs & Cosmetic Act, 1940," added Mazumder.

❖ Chhattisgarh govt bans 4 medicines

The Times of India, November 13, 2014

The Chhattisgarh government on Wednesday banned the sale of four drugs, ibuprofen, Ciprocin, injection Lignocaine, and Xylocaine gel, as well as absorbent cotton - each with their batch numbers and the name of their manufacturers - which were distributed to women who underwent sterilisation at Takhatpur, Pendra and Marwahi health camps leading to 13 deaths.

According to officials, preliminary investigations into the botched sterilisations indicate drugs distributed to patients post-surgery could be a cause of deaths. The sample of all drugs are being sent to central Drug laboratory, Kolkata, for analyses.

❖ Mahawar Pharma medicines banned in Chhattisgarh following sterilisation deaths

Business Standard, November 14, 2014

The Chhattisgarh government, today, banned the use and sale of drugs manufactured by Mahawar Pharma Pvt Limited - a local pharmaceutical

company suspected of supplying fake medicines.

Thirteen women died while over 80 were affected in the state-organised sterilisation camps in Bilaspur district, recently. Of the women undergoing treatment in different hospitals, condition of nine has been critical.

Death of 12 women was reported from Pendari camp while one woman who had undergone sterilisation surgery in Pendra died in the tragedy. The preliminary investigation suggested that the adulterated drugs used after the surgeries could be the possible reason.

Patients were given antibiotic Ciprocin 500 mg that was manufactured by Mahawar Pharma Private Limited, a local company having its facility in Raipur city. Interestingly, the company burnt Ciprocin stock soon after the incident.

The Raipur police, last night, arrested Mahawar Pharma's director Ramesh Mahawar and his son Sumit after framing charges under section 420 for cheating. The complaint against the company was lodged by Food and Drug Administration department that had yesterday sealed the manufacturing unit of the company.

The department also raided a unit of Kavita Pharmaceuticals in Bilaspur that had also supplied medicines to the sterilisation camps in the district, and collected drug samples for testing. Meanwhile, the state government today issued an order banning the drugs manufactured by the Mahawar Pharma. Samples collected from the company units and used during the sterilisation camps have been sent to the Kolkata-based Central Drugs Laboratory for testing. The state government has also appointed a single-member probe commission headed by retired District and Sessions Judge Anita Jha for conducting the judicial probe. The commission will submit its report to the state government within three months.

- **Chhattisgarh sterilization deaths: Another drug company's director arrested**
  The Times of India, November 15, 2014
  The Tribune, November 15, 2014
  South Asian Media, November 15, 2014
  Asian Age, November 15, 2014

Continuing its crackdown on suppliers of the suspected spurious drugs, the Bilapsur Police arrested the Director of Kavita pharmaceuticals in Bilaspur, Rakesh Khare, late Friday night.

Khare is second pharmaceutical manufacturer and supplier to be arrested in connection with the botched sterilizations that have claimed 13 lives and left another 100 odd women ailing. The police has earlier arrested the directors of Mahavar Pharma Pvt Ltd, Ramesh Mahawa and his son, Sumit Mahawar. They all have been booked under Section 420 of the IPC.

Both the companies are suspected to have supplied the antibiotic, Ciprocin 500mg, which were distributed to the women, post sterilization procedure. Traces of rodenticide, Zinc Phosphide, have been found in the medicines and are suspected to be the cause behind the tragedy.

The state health department, which banned the sale of drugs of Mahawar pharma pvt ltd on Tuesday, has so far seized 46 lakh tablets including Ciprocin 500, manufactured by them from raids across the state.

❖ Spurious Drugs May Have Caused Tubectomy Deaths

NDTV, November 14, 2014
Deccan Herald, November 15, 2014
www.Wn.com, November 15, 2014
News Mobile Health Bureau, November 15, 2014

The death of 13 women in Chhattishgarh following sterilisation surgeries in government medical camps in Bilaspur district may have been caused by sub-standard medicines given to those women in the post-operative care, suggests the findings of an expert panel. "Sepsis - the initial diagnosis - may not be the sole cause in all the patients and contamination of the medications used could be a strong possibility," the seven member expert team from All India Institute of Medical Sciences (AIIMS) said in its report, a copy of which is available with Deccan Herald. The AIIMS team, which was rushed to Chhattishgarh on November 12 after news of the women's death hit the headlines, submitted its report to the health minister J P Nadda on Friday. The doctors also met Chhattishgarh Chief Minister Raman Singh and apprise him of their findings. The doctors suggested all sterilisation camps in the state should be stopped till the exact cause of the death is ascertained. As spurious medicine could be the culprit, they advised the chief minister to test the medicines at two different reputed laboratories to find out if there is any contamination. The AIIMS team is headed by Anjan Trikha, professor of anaesthesia and critical care. Other six members in the team are Sanjay Agarwal (nephrology), Arti Kapil (microbiology), M Mahapatra (hematology), Neena Malhotra (obstetrics and gynaecology), Sanjiv Sinha (medicine) and Kapil Dev Soni (intensive and critical care).

❖ Chhattisgarh sterilisation deaths: Govt asked to recall spurious drug from state health centres

Indian Express, November 29, 2014

Acting on a petition by the Chhattisgarh Congress, the Bilaspur High Court on Monday directed the Raman Singh government to withdraw the Ciprofloxacin medicine of Mahawar Pharma Ltd from all health centres in the state.

The state government has said that the forensic test of Ciprofloxacin, the drug

consumed by women during a recent sterilisation camp in Bilaspur, confirmed that it contained "rat poison". Thirteen women had died following the operations, that were conducted in violation of all procedural guidelines. One sterilisation was allegedly conducted every two minutes during the camp.

Noting that the medicine was being distributed to other patients also, the court asked the health department to conduct camps in villages and make people aware about the spurious drug.

The directors of the pharma company are now in judicial custody. The Indian Express had earlier reported that even though Mahawar Pharma Ltd has been facing a court case for selling "duplicate drugs", and that several of its medicines had been banned by the drug controller, the government had still continued to purchase from it.

Meanwhile, the Congress has stepped up its campaign against the government over the incident and demanded the resignation of both CM Raman Singh and Health Minister Amar Agrawal. The party is holding a six-day padyatra from Bilaspur to Raipur. "The government sold poison. Raman Singh must accept his failure and step down," Congress spokesperson S N Trivedi said.

❖ 131 medical shops prosecuted for violating Drugs Act

Deccan Herald, November 29, 2014

In the last two years, the Drugs Controller office has launched prosecution against 131 medical shops for violating the Drugs and Cosmetics Act and Drugs (prices control).

Officials say that with the mushrooming of medical shops in the State – as of now around 29,500 – the number of prosecution was also increasing. A senior official said that in most cases medical shops were found to be selling substandard medicines, spurious medicines and sale without prescriptions. During 2013-14, prosecution was launched against 54 outlets, while it has already crossed 77 till date this year.

Apart from launching prosecution, the department has suspended 733 premises and cancelled 1,257 outlets for violating various norms of the Act and licence conditions.

More than 50 per cent:

State Drugs Controller Dr Raghuram Bhandary said the conviction rate in the cases referred for prosecution had been more than 50 per cent. "The units our officials have to cover have been increasing with every passing year. Last year, till March 2014, there have been 25 convictions. The conviction rate has been improving in these cases because of scientific and document-based evidence. One of the main reasons for the rise in the number of prosecutions

is the sharp increase in medical shops. The violations also include outlets without licence and sale of drugs without the presence of a pharmacist," Dr Bhandary told Deccan Herald.

Apart from the sales premises, officials have to inspect manufacturing units, including cosmetic manufacturing units, blood banks, approved laboratories and blood storage centres across the State.

Staff shortage:

The State has 594 manufacturing units, 184 blood banks and 167 blood storage centres. "We have only 25 drug inspectors as against the sanctioned strength of 112. About 60 assistant drug controllers were sanctioned, whereas we have 53. The inspectors have to inspect, submit report, attend to the court and also depose for recording of evidence," the official said.

- **Indian firm sues local medicine distributor over counterfeits**
  Standard Digital, December 03, 2014

Patients especially those living with HIV and Aids are at risk of ingesting drugs whose source and chemical composition is unknown, the High Court has heard. An Indian drug manufacturer, Cipla Ltd, in a suit filed in court yesterday said the Kenyan public was in great danger due to the importation and sale of unauthorised medicine whose sources are unknown. Cipla Ltd accused Kenyan medicine distributor, Lords Healthcare Ltd, of sourcing for drugs from unknown manufacturers, packaging and selling them using its trademark despite having terminated agency agreement with the company. The court heard that the manufacturer had noted that some of its medicines are in the market despite having no local distributor. Cipla, through lawyer John Syekei, told the court it has not authorised any person to use and exploit its drug registration certificates by importing and selling such medicines on the Kenyan market. The company told the court that the flip side of this is that it does not know where the affected drugs are being manufactured, or even what the chemical composition of the affected products is. Some of the medicines Cipla manufactures, the court heard, are anti-retroviral drugs. Mr Syekei said his client had conducted investigations in Nairobi, Eldoret and Embu and found that about 30 different pharmacies and medicine wholesalers located in these towns were selling the counterfeit medicines. "Cipla has discovered the existence of medicines in the Kenyan Market (the illegal products), which bear the same name as those on drug registration certificates issued by the Pharmacy and Poisons Board," he said. Blind eye In the case filed under a certificate of urgency before High Court Judge Isaac Lenaola, the lawyer said Cipla had lodged a complaint about the drugs to the Pharmacy and Poisons Board but the regulator had not taken any action to halt the sale of the drugs. "There is a clear and present danger to the Kenyan public in the importation and sale of unauthorised medicines whose sources

are unknown. This is even more so where some of the medicines that the petitioner manufactures and holds certificate are anti-retroviral drugs for treatment of HIV and Aids," Syekei told Justice Lenaola. He accused the board, which was named as the first respondent, of turning a blind eye to its complaints. "The board has failed to take any action to halt the illegal importation of the affected drugs and has failed to respond to the complaints by the petitioner," the court heard. Cipla's EA Regional Manager James Bradford says Lords Ltd was selling 12 products that bear its trademark but had not been sourced from them.

- **Six kids develop adverse drug reaction, FDA swoops down on hospital**
  DNA India, December 04, 2014

Six children in a BMC-run hospital in Vikhroli developed severe drug reaction after being injected antibiotics on Tuesday. Children aged between 1.5 and 12 years were being treated in the paediatric ward of Mahatma Phule Hospital.

Food and Drug Administration (FDA) officials on Wednesday visited the hospital and collected samples of eight items, including drugs, syringes and needles.

Dr Vidya Thakur, in-charge of BMC peripheral hospitals in the central suburbs, said, "Two children were vomitting, and the others had chills. They may have developed an adverse reaction to the antibiotics."

One of the six, Vikhroli resident Jayesh Mhaske, 11, was admitted on November 26 after contracting dengue. His father Dhondhiram, who works as a private bus driver, said, "My son was being treated in the hospital for close to a week. On Tuesday around 11.30pm, after certain antibiotic injections were administered to him and others, they start experiencing severe chills and developed high fever."

The youngest child, Dhondhiram said, slipped into convulsions and was critical. "Parents were worried... there was wailing and crying all around. Nurses asked us to put cold press on the children's bodies," he added.

While five children — Saniya Bano, 3, Nagesh Dhongade, 9, Anjali Shinde, 10, Amit Kale, 11, and Jayesh, 11 — were shifted to Sion hospital around 12.30am, the sixth, a one-year-old, was taken to a private hospital in Kanjurmarg by his parents.

FDA officials have collected vials of ondasetron (an anti-vomitting drug), ranitidine (an antacid), amoxicillin clavulinic acid, and a combination of cephaperazone and sulbactam (antibiotic injections) for testing.

BMC hospitals have been instructed to stop use of the batches of these drugs. "The samples will be tested for contamination due to pyrogen, sterility

and active drug content to analyse if they were substandard or spurious," said Praveen Mundada, drug inspector (zone IV), FDA. Dr Avinash Supe, dean, Sion hospital said, "The children are stable and under observation. We will keep them for one more day and observe their health."

Adverse drug reaction, or ADR, refers to illness caused by a drug taken in normal or high doses. This August, Saira Shaikh, 47, was among the 28 affected women who were given third generation cephalosporin antibiotics cefotaxime and ceftriaxone. She died soon after.

Many cases go unreported and unaccounted for in absence of a strong notification or investigation system, as doctors may choose not to report cases voluntarily, say officials. As many as 85 lakh ADR cases were reported by WHO last year, of which one per cent were from India.

❖ MP health dept slaps fine on 3 firms for supplying substandard drugs

Hindustan Times, December 08, 2014

The MP health department has issued notices to three pharmaceutical companies for supplying substandard medicines. The department has also imposed penalties on all the three pharmaceutical companies.

According to orders issued by the health department, three medicines — Salbutamol tablet IP 4mg (batch number WB-14019) of Edrayad Pharmaceuticals Pvt Ltd Nagpur, Multivitamin Tablet (batch number WB-14019) of Wilcure Pvt Ltd Indore and Metronidazole tablet 200 mg (batch number MDT-1305) of La-Chemico Pvt Ltd Kolkata — were found to be of substandard quality during laboratory testing conducted by the food and drugs administration (FDA).

On the basis of the report provided by the FDA laboratory, a penalty amount equivalent to the value of the batch has been imposed over all the three companies.

The amounts levied over the three firms are Rs. 30,66,160 on La Chemico Pvt Ltd, Rs. 5,87,180 on Wilcure Pvt Ltd and Rs. 11,75,000 on Edrayad Pharmaceuticals Pvt Ltd. The firms have been asked to submit the amount within seven days of the issuing order.

INDONESIA

❖ BPOM to curb online drug sales

The Jakarta Post, January 09, 2014

The Food and Drugs Monitoring Agency (BPOM) has said it will step up measures to curb the online drugs trade this year after seeing a spike in illegal drugs sold via the Internet in the past three years.

The BPOM said it would immediately start working with the Financial Transaction Reports and Analysis Centre (PPATK) to map online drug transactions in the country.

"We will discuss how we can strictly monitor drug transactions on websites to help save more people from unsafe drugs that could harm them," BPOM chairman Roy A. Sparringa said on Wednesday.

Roy said that cracking down on online drug sales was a challenge for the agency. "Cracking down [on the sale of] illegal and counterfeit drugs on the Internet is one of the biggest challenges that we are facing nowadays, as the technology keeps on developing rapidly and the merchants always find new ways to sell their products online, even after we shut down their websites," he said.

BPOM data shows that 721 different types of illegal and counterfeit drugs, worth Rp 5.59 billion (US$456,885), were sold via 129 websites last year; a significant increase from the 66 types of drugs sold via 83 online outlets in 2012. The agency also found that Ponstan, one of the most popular painkillers in Indonesia, is the most counterfeited medication in the country. Roy said that besides Ponstan tablets, erectile dysfunction drugs (were the most counterfeited). In 2011, the agency discovered 30 websites selling 57 types of drugs, including those containing harmful chemical substances.

Roy said he was optimistic that the collaboration with the PPATK would restrict illegal drug traders' online activities. "The agency has the capacity to track transactions and by having the data [on the specific drug transactions], we will be able to crack down on illicit drugs sold online," he added. He said the agency would also work with the National Police, Interpol, the Communications and Information Ministry, as well as local governments to further improve drug safety in the country.

The BPOM has also noted that the number of violations against food and drug safety standards across the archipelago increased from 661 cases in 2012 to 690 cases last year.

The cases included traditional drugs and cosmetics that were unlicensed, and counterfeit drugs that are widely sold over the counter such as analgesics,

antibiotics, antihistamines and vitamins.

Despite the rising number of illicit drug cases in the past few years, the agency has seen some improvements in the safety of food and drugs in Indonesia.

For instance, BPOM data shows that the distribution of harmful chemicals in food sold in 62 traditional markets across 16 provinces decreased to 12.4 percent by the end of 2013, down from 15.7 percent in 2012.

The agency also claimed that its School Food National Action Program (PJAS) had been a success. The agency found that 80.79 percent of snacks and food sold in 16,993 public elementary schools were safe for consumption in 2013, up by 4.79 percent compared to the previous year.

❖ Police Raid Fake Medicine Factory

www.Tempo.co, January 24, 2014
The Jakarta Post, January 25 2014
Jakarta Globe, January 25, 2014

The Police recently raided a drugs factory at Babakan Ciparay, Bandung, which was suspected of producing fake medicines.

"We found fake drugs of Calcium Lactate in various brand such as Carnofen, Voltaren, Arminofein, and Somadril Compositum," said West Java Police Chief Inspector General Mochamad Iriawan.

Initial investigation revealed that the factory is capable of producing 200,000 Voltaren pills, 100,000 Carnofen pills, 60,000 Aminorfein pills, and 40,000 Somadril-Compositum pills per day.

"This is a large scale production, and it has been going on for about two years. We suspect that it is in the market in Bandung and its surrounding areas," said Iriawan. "The main suspect, Budi Hartono, charged with violating Article 197 on the Medical Law and may be subject to 10 years of imprisonment."

West Java Police chief Insp. Gen. Mochamad Iriawan said that the police had arrested Budi Hartono, the owner of the factory, and eight employees.
“Budi is charged with Article 197 of the Law on health, it carries a maximum penalty of 10 years in prison,” Iriawan said, adding that the factory had been active since 2004, but it had only begun to produce counterfeit drugs over the past two years. He said the factory could produce 400,000 pills per day.
Bandung Police chief Sr. Comr. Mashudi added that four of the eight employees arrested were under 18-years-old. “The suspect [Budi] will also be charged with the Law on child protection for hiring underage workers,” Mashudi said.
During the raid, the police also confiscated various drugs, including

antirheumatic drugs and pain killers, as well as some machinery and ingredients

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❖ Fake drugs sold online seized in crackdown

The Jakarta Post, May 27, 2014

The Food and Drug Monitoring Agency (BPOM) confiscated 1,385,440 pieces of illegal drugs, traditional medicines, cosmetics and food consisting of 868 items marketed online worth Rp 7.47 billion (US$642,420) in a week-long crackdown, codenamed the Pangea Operation.

During the operation, the seventh of its kind, BPOM investigators identified 302 websites allegedly distributing illegal and fake drugs, food items and cosmetics that led to a crackdown on 58 distribution facilities.

The operation was conducted in 15 cities, including Denpasar, Jakarta, Manado, Medan and Surabaya, from May 13 to 20 as part of a global operation coordinated by the International Criminal Police Organization (Interpol) to combat counterfeit drugs, particularly those marketed online, in 110 countries.

The BPOM recorded a steadily increase in the online-marketed of counterfeit drugs, cosmetics and food during the operation. According to official data, the agency confiscated 721 items during the sixth Pangea Operation in 2013, up from 66 and 57 in the fifth and fourth operations in 2012 and 2011, respectively.

“We have requested the Communications and Information Ministry block 302 websites we identified. Of the total, 287 websites have been suspended,” BPOM head Roy A.Sparingga said in a press release on Tuesday.

On Monday, the agency destroyed 428 illegal food items and drugs worth Rp 2.4 billion that were confiscated in operations from 2012 to 2014.

Also on Monday, the BPOM signed an agreement on money-laundering prevention and eradication with the Financial Transaction Reports and Analysis Centre (PPATK) to help eliminate the online marketing of fake drugs by tracing bank accounts used for such transactions.

According to the World Health Organization, more than 50 percent of the drugs circulating globally are fake and illegal, with the figures continuing to increase as the drugs are distributed by underground sources that are difficult to detect and identify.

❖ Expired, unregistered food products seized

The Jakarta Post, June 28 2014

The Food and Drug Monitoring Agency (BPOM) has seized expired, unregistered food products and cosmetics worth some Rp 14.2 billion (US$ 1,18 million) in Jakarta during a raid conducted ahead of the Islamic holy month of Ramadhan.

The agency confiscated the products — ranging from shampoo, milk, baby foods, chocolate and canned fruit cocktails — from three food warehouses in Muara Angke, West Jakarta, on Wednesday.

BPOM head Roy Sparingga said on Friday said that the products had been relabeled with fake registration numbers and expiration dates in order to deceive food inspectors and customers.

“According to our observation, the products are imports. We are still investigating those responsible for distributing the products. The BPOM, in cooperation with the National Police and prosecutors, will bring them [perpetrators] to court,” Roy said.

Roy said that the crackdown was part of a month-long operation ahead of Ramadhan, the month when overall food consumption soars to the highest level of the year.

In addition to the inspections, the BPOM has instructed all associations of food retailers and businesses to not distribute or sell products with fake registration numbers or expiration dates.

The BPOM has also ordered all of its branch offices at provincial levels to conduct similar inspections at warehouses, grocery stores and restaurants.
“We are aware that during Ramadhan, there are many small businesses selling drinks and food, in particular takjil [light meals to break the fast]. Considering that we only have a limited number of personnel, it is pivotal for us to join forces with local governments to educate and monitor [businesses and their products],” Roy added.

Last year, the BPOM found 297 takjil products containing harmful chemicals such as borax, formaldehyde and rhodamine.

Roy acknowledged that Muslims could face difficulties identifying hazardous chemicals in takjil, as well as in expired and unregistered products that had been relabeled.

“For the relabeled products, customers can identify it [expired products] from packaging that is in bad condition. Customers can also check the validity of the product’s registration number by accessing our website at pom.go.id or by contacting the HALO BPOM call center at [021] 500533,” he said.

Prior to the Ramadhan food inspection, the BPOM had identified illegal and counterfeit food, drug and cosmetics products marketed online that were

worth in excess of Rp 7.47 billion (US$623,055).

In the crackdown code-named Pangea operation in May, the agency confiscated 1,385,440 units of illegal drugs, traditional medicines, cosmetics and food, consisting of 868 types of items.

❖ BPOM confiscates illegal drugs and cosmetics worth Rp 31.66b

The Jakarta Post, September 11, 2014

The Food and Drug Monitoring Agency (BPOM) confiscated thousands of illegal drugs and cosmetics worth Rp 31.66 billion (US$2.6 million) after conducting raids across the archipelago from June to August.

BPOM head Roy Sparingga said that the raids, entitled Operation Storm, found 3,556 illegal items, consisting of 173 drug products (4.7 percent), as well as 1,520 traditional drugs (41.6 percent) and 1,963 cosmetic products (53.7 percent).

“The scope of this raid was larger than previous raids because we involved our 31 branches across Indonesia,” Roy told reporters at a conference in Jakarta on Thursday, as quoted by kompas.com.

The illegal drugs and cosmetics were confiscated from 154 locations, such as a factory producing illegal traditional drugs worth Rp 20 billion in Tangerang, Banten, as well as a distributor of illegal needles and syringes worth Rp 1.25 billion and a factory for illegal traditional herbal remedies worth Rp 1 billion in Jakarta.

In many cases, Roy said, counterfeit drug makers mixed chemical ingredients and herbal products to create new drugs. After that, they attached fake distribution permits to the products.

“In some cases, the drugs do not have any distribution permits,” he said, adding that the government found it difficult to stop the production of illicit drugs and cosmetics because of high demand for the products. (alz/nfo)

❖ Rp 2b Worth of Unregistered ‘Herbal’ Drugs Seized in Bekasi

The Jakarta Globe, October 15, 2014

Confiscated pills presented to reporters at the Food and Drug Monitoring Agency (BPOM) building in Jakarta, in this Sept. 11, 2014. Bandung. The Food and Drug Monitoring Agency (BPOM) confiscated over 200 boxes containing unregistered, hazardous drugs in a raid on a warehouse in Bekasi,

West Java, on Tuesday.

The drugs, purportedly traditional herbal medicine (jamu), contained unknown chemicals and some had been given fake BPOM registration numbers, the agency's head of certification and consumer information, Siti Rulia, said on Wednesday.

"In yesterday's raid, we confiscated 238 boxes of drugs," she said, adding the batch was worth Rp 2 billion ($164,000).

The BPOM said the drugs are marketed to treat a range of afflictions such as obesity, gout, asthma, rheumatism and erectile dysfunction, could cause liver and kidney damage, stroke and heart disease.

Five people present at the warehouse at the time of the raid will be questioned, the agency said.

"From the questioning, we will find suspects, the mastermind and the producers of the drugs," Rulia said. "The owner was not there during the raid."

MALDIVES

- No Reported Incidences

MYANMAR/BURMA

- No Reported Incidences

NEPAL

- No Reported Incidences

SRILANKA

- **Trader nabbed selling expired cosmetics**
  Ceylon Today, January 02, 2014

Officials of the Consumer Affairs Authority (CAA), acting on information received through the Colombo North Special Police Unit, raided a shop in Grandpass that was selling cosmetics that were past their shelf life, yesterday. The officials had found the trader selling repacked, low quality henna dye under the popular brand name 'herbal black henna' on which the date of expiry had lapsed. As many as 100,000 such packets were found in the shop.

In addition to this, 15,000 lipsticks, 1,000 jars of cream and 1,500 jars of body lotion, colognes and perfumes, all of which were past their date of expiry, were seized during the raid. The goods were valued at Rs 13 million. Legal action is to be initiated against the trader concerned, while similar action would be taken against any others found guilty of similar offences, CAA sources said.

Officials warn that the use of cosmetics that have expired, on the body, can cause disastrous health effects in individuals.

- **CAA seizes expired meds worth Rs 60 M**
  Ceylon Today, May 14, 2014
  News First, May 14, 2014
  The Nation, May 14, 2014
  Lanka News Alert, May 14, 2014

The officers attached to the Consumer Affairs Authority (CAA), along with its Chairman Rumy Marzook, confiscated a stock of expired medicine worth Rs 60 million in a warehouse at Grandpass yesterday.
The CAA officers had raided the warehouse following an anonymous tip. They

had discovered drugs that were expired in January 2012, January 2013 and February 2014.

In addition, the drugs were being stored at temperatures above 30 degrees. The specified storage temperature for drugs is between 25-30 degrees Celsius. Investigations have revealed the warehouse, which belongs to an importer, had drugs from India for high blood pressure, diabetes, pain killers, drugs used to clean wounds, syrups for children and surgical equipment. The importer had changed the stickers with the expiry date printed on them for drugs that were close to expiry or had already expired and was preparing to sell these expired drugs to the market.

Out of the expired surgical equipment, there were some found to be generally used for hernia operations and these are estimated to have a market value of Rs 44,000. Certain medicines with the government seal were also found at the warehouse.

The CAA is conducting further investigations into the case and while the warehouse has been sealed, the importer is to be produced before the Maligakanda Magistrate next week.

❖ Expired pharmaceuticals worth Rs 500 M seized

Ceylon Today, May 28, 2014

A stock of expired pharmaceuticals, valued at Rs 500 million, was seized in a raid by the Consumer Affairs Authority (CAA) on a warehouse in Attidiya, Ratmalana yesterday. The stock contained vitamins and fairness creams, which had passed their shelf life three years ago.

CAA officers say the warehouse, which belonged to a highly reputed pharmaceutical importer, had been re-packaging the expired stocks and selling them to pharmacies around the country.

When the officers of the CAA had questioned the owners of the warehouse as to why they were stocking those expired pharmaceuticals, they had said they were waiting for an order from the Cosmetics, Devices and Drug Regulatory Authority (CDDRA) to destroy them. "When we inquired of the CDDRA about such an order, they informed us that no such request had been made of them. However, why were they keeping it for three years? You can surely destroy it by that time. We suspect that they were keeping it so that they could resell it to unsuspecting pharmacies at a cheaper price," said a CAA officer, who was involved in the raid.

The suspects are to be produced before the Mount Lavinia Magistrate's Court once CAA investigations are concluded.

❖ CAA to raid pharmacies owned by errant importer

Ceylon Today, May 29, 2014

Following the raid of a pharmaceutical warehouse owned by a reputed drug importer on Tuesday (27), the Consumer Affairs Authority (CAA) has decided to extend its raids to all the pharmacies owned by the importer.

CAA Chairman, Rumy Marzook, addressing a media briefing yesterday said as the drug importer has a large network of drug stores and warehouses, all of them would be inspected to ensure that none of the drugs are expired.

Investigations carried out by the CAA have thus far revealed that not only was this particular importer stocking up pharmaceuticals that had expired in 2013 and early 2014, but he was also repackaging the drugs with dates of expiry changed to 2015. The repackaged drugs would then be ready for the market.

The company has also been calling up several beauty salons in the country and purchasing their low quality cosmetics wholesale at a lower price. These were then repackaged, expiry dates changed and resold to the market.

Adviser to the CAA, Dr. Mahanama Rajamanthri, said it was the responsibility of the distributor to inform the pharmacy three months in advance, if a drug that he is selling is to expire soon. Dr. Rajamanthri also said the consumption of expired drugs could either dilute its effect or cause dangerous side effects in certain patients.

According to the doctor, there is only one place in Sri Lanka where drugs are collected to be destroyed and that is at the Holcim Cement Factory in Puttlam. Dr. Rajamanthri said no distributor or importer can legally store expired drugs in their warehouses.

When asked how consumers could be more aware of these expired medicines, when purchasing drugs from pharmacies, Dr Rajamanthri said there was no certain way of knowing if the drug is expired or not if the printing on the packaging itself is changed. "The expiry date is not printed on the tablet, so we just will not know but consumers must be vigilant about these drugs," said Dr. Rajamanthri.

The CAA has so far this year raided 15 warehouses stocking expired drugs to be resold to the market.

❖ Blacklist companies selling date-expired drugs

Ceylon Today, June 06, 2014

The Consumer Affairs Authority (CAA), which functions under the Trade Ministry, is to request the Health Ministry to blacklist and prosecute pharmaceutical companies which store and distribute drugs after their dates of expiry, or 'best before date' has passed or by fraudulently changing such

dates.

CAA Chairman, Rumi Marzook, said a recent raid carried out by the Authority had resulted in the discovery of a stock of date-expired drugs worth Rs 90 million. He said the CAA acted expeditiously to sue such stockists whilst publicizing their names via the media.

Several trade unions have also taken up this issue with the Health Ministry, urging it to take stern action against such unscrupulous stockists.

When queried, Health Minister Maithripala Sirisena said he is awaiting a report from the CAA to take appropriate action against the errant traders.

Meanwhile, Additional Health Ministry Secretary Dr. Amal de Silva has been appointed as Chairman, Cosmetics Devices and Drugs Regulatory Authority of Sri Lanka.

❖ Expired drugs and cosmetics found at Gamage's clinic

Daily Mirror, August 14, 2014

Expired drugs and cosmetic products were found today during a joint raid carried out at the clinic owned by cosmetic surgeon Dr. Nimal Gamage, following Tuesday's death of a lady doctor who received an injection during a cosmetic surgery.

Police spokesman Ajith Rohana said that health ministry cosmetic unit, the government analyst's department and the Colombo Crime Division carried out the joint raid at the Visakha Road clinic.

The 47-year-old lady doctor identified as Dr. P.A. Priyangi a specialist attached to the Plastic Surgery Unit of the Lady Ridgeway Hospital died at the clinic. She died within several minutes due to complications after administering the injection.

Dr. Nimal Gamage was arrested and remanded till August 18 by the Colombo Chief Magistrate in connection with the incident.

It was reported that following the incident, Health Services Director General Dr. Palitha Mahipala gave orders to a special investigative team of the National Pharmaceutical Authority to raid the cosmetic surgery clinic. (Supun Dias)

THAILAND

❖ DSI and FDA officers seize B10mn of illegal drugs with fake FDA labels

Phuket Gazette, March 21, 2014

Illegal hormone drugs worth about 10 million baht targeted at the Chinese tourist market were seized by Department of Special Investigation (DSI) and Food and Drug Administration (FDA) officers yesterday.

DSI officers declined to give details of the alleged effects of the traditional Chinese medicines, stating only that they were for "improved sexual performance".

However, at least one drug, Tiao Jing Wan, regulates women's menstrual cycles to help improve fertility; it also claims to ease complications of menopause, prevent hyperplasia of mammary glands (which can cause breast cancer) and cure endometriosis and ovarian cysts.

"We were informed by tourists and locals of fake drugs claiming to contain snake parts and other elements of traditional Chinese medicines being sold in Phuket," said DSI Region 8 Director Udom Phetcharakut. "There were people dressed like pharmacists claiming that the drugs boost sexual performance."

The team raided Discovery Park New Treatment Co Ltd in Wichit and Royal Park Phuket Co Ltd on Chao Fa Road. At Discovery Park New Treatment, which offers a snake show, officers seized more than 30 boxes of the drugs, Mr Udom said.

"There was no Thai language displayed on the drug containers, which is an infraction of FDA regulations. Also, the drugs had counterfeit FDA certifications," Mr Udom said.

The drugs were being sold in small bottles containing 80 pills for 3,100 baht and larger bottles containing 180 pills for 5,800 baht. "The drugs did not contain all the ingredients they claimed to," he noted.

At Royal Park Phuket, officers seized more than 50 large boxes of drugs."These drugs did have Thai language on them. However, their Thai FDA certifications were counterfeit," he said. The company owners were charged for selling traditional medicines without a license and for selling drugs that had not been FDA approved. These infractions can both carry a penalty of up to three months imprisonment, up to a 5,000 baht fine, or both.

❖ Huge quantities of fake weight loss drugs seized in Phitsanuloke

Thai PBS, November 27, 2014

About 50 million baht worth of illegal weight-loss or anti-obesity drugs were seized from two godowns in Muang district of Phitsanuloke in a raid today.
The raid was jointly launched by officials from the Department of Special Investigation, the Phitsanuloke provincial health and revenue offices and troops from the fourth infantry division.

The raiding teams raided a three-storeyshophouse which houses the Oho Slim Plus Company, a nearby townhouse and two godowns. Subsequent searches of the godowns unveiled large quantities of weight loss drugs, diet food and health food which did not have any approval from the Food and Drug Administration.

As complained by the provincial health office, police have issued summonses for two executives of Oho Slim Plus Company, MsSirinthraLengsin and MrVorakornYimyoo to acknowledge the charges of selling fake drugs.

Dr. Boonterm Tonsurat, the Phitsanuloe health official, warned consumers not to consume the Oho Slim Plus weight loss drugs or diet drugs saying that they contain Sibutramine which is a health threat if consumed for a long time.

❖ Bt50m worth of illegal diet pills seized in Phitsanulok

The Nation, November 27, 2014

In a raid yesterday, soldiers and related officials seized Sibutramine-laced diet pills worth Bt50 million in Phitsanulok's Muang district. Consumers have also been urged to drop off any of these pills they may have at the Damrongtham Centre.

The Phitsanulok Health Office also summoned two executives of the manufacturing company to acknowledge the charges against them, while the Revenue Department said it will check to see if the company is up-to-date with its tax payments. It is also checking on the financial transactions of some 3,000 to 4,000 distributors.

Fourth Infantry Division commander Maj-General Nopporn Reunchan said the raid led by 50 soldiers - of the company's office, a townhouse nearby and two warehouses in tambon Aranyik -was prompted by public complaints about these products. The provincial health office later tested the product and found that three samples contained Sibutramine.

Health officials will also warn the public against using this product and ensure all its sales outlets, including those online, are closed, he said.

The Food and Drug Administration has banned Sibutramine since 2010 because it can boost blood pressure and increase the risk of cardiovascular problems.

At a press conference yesterday, Pol Major Woranan Srilam, who is in charge of the Department of Special Investigation (DSI)'s division for special cases, said the DSI had learned that some private firm was posting as many as 3,000 packages every day. So the agency decided to look into the fact, which led to the raid in Phitsanulok yesterday.

Muang Phitsanulok Police Station investigator Pol Colonel Samart Juthes said the provincial health office had pressed five charges against executives Sirinthra Sengsin and Worakorn Yimyoo. The charges are selling fake food, punishable by six months to 10 years in jail and a fine of Bt5,000 to Bt100,000; selling food with inaccurate labels for which the penalty is a Bt30,000 fine; selling impure food, punishable by two years in prison and/or Bt20,000 in fine; unauthorised advertisement of a food product's benefits, punishable by Bt5,000 in fine; and selling cosmetic products with inaccurate label, punishable by three months in jail and/or Bt20,000.

Phitsanulok Revenue official Nitcharee Chinnabutr said initial investigation showed that the company, registered in June last year with a capital of Bt1 million, might have produced diet pills worth a total of Bt500 million, as the products seized yesterday alone were worth Bt50 million. Hence, he said, the Revenue Office will check further to see if the company had paid tax accordingly, and if not it will collect back taxes.

TIMOR-LESTE

- No Reported Incidences

MICELLENOUS REPORTS

❖ Painkiller Ponstan Most Counterfeited Drug in Indonesia: BPOM

The Jakarta Globe, January 08, 2014

Ponstan, one of the most popular painkillers in Indonesia, has been reported as the most counterfeited medication in the country.

"From the 13 items [on the list], Ponstan tablets and erectile dysfunction drugs [were the most counterfeited]," Roy Sparingga, the chairman of the Food and Drug Monitoring Agency (BPOM), said on Wednesday. "[Fakes] are commonly found because of consistently increasing demand.

Last December, police confiscated 1.1 million fake Ponstan tablets worth a total of Rp 4 billion ($328,000) in a warehouse in Pluit, North Jakarta. Additionally, police seized 25,200 fake procaine injections — local anesthetic — that were destined for Indonesian drug stores.

One of the telltale signs of fake Ponstan is that the tablets are usually paler in color.

Besides Ponstan, the BPOM reported that in 2013 it found counterfeited Pethidin HCI and codeine, two painkillers, diazepam, a muscle relaxant, Incidal, a popular antihistamine, Nizoral, an anti-fungal tablet, various erectile dysfunction pills (Viagra, Levitra and Cialis), Neurobion, Cartisone Acetate injections, Amoxsan, an antibiotic and Valirlix, a chicken pox vaccine.
Roy said that his agency would bolster its monitoring of pharmacies and involve other institutions and actors to try and crack down on counterfeit medication.

"People must also stay alert and buy medication from the right places," he said.

❖ Spl drive against counterfeit drugs soon: Nasim

The Financial Express, January 20, 2014

Health Minister of the newly-formed government Mohammad Nasim Sunday expressed his determination of conducting special drive against counterfeit drugs by slapping capital punishment to the producers and distributors for safeguarding public health.

The Minister also said the newly set up drugs testing laboratory of the country

will be inaugurated soon and expressed his hope the laboratory will help. With appropriate nurturing, pharmaceutical industry can be turned into a foreign currency earning sector like readymade garments, he added.

Mr Nasim made the remarks while speaking at a meeting with a representative body of Bangladesh Association of Pharmaceutical Industries (BAPI) when the latter called on him at his secretariat office Sunday.

State Minister for Health Zahid Malek, Secretary MM Neazuddin, directorate of drug administration director general, BAPI president Salman F Rahman, lawmaker Nazmul Hasan, BAPI secretary general Abdul Muktadir and Dr Habib-e-Millat were present during the meeting.

❖ Spurious medicines killing patients at government hospitals, growls HDK

Deccan Chronicle, January 20, 2014

Demanding an overhaul of the health department, opposition leader in the assembly H.D. Kum-ar-aswamy has urged the state government to initiate action against officials responsible for supply and distribution of spurious and inferior medicines in government hospitals.

In a letter to Chief Minister Siddaramaiah, Kumaraswamy claimed that some health department officials were involved in a racket in which medicines meant to be distributed in government hospitals, were being sold elsewhere.

Citing the examples of sub-standard and spurious medicines being supplied in government hospitals, he alleged that a medicine named Polyfol Forte, manufactured by a company called Quest Laboratories Pvt Ltd, had failed 21 times in quality tests.

However, this medicine was being supplied to government hospitals and distributed among pregnant women. Glinbenclamide Tablets IP-5mg, Buserelin Acetate Injection provided by a German company and Papapic-250 manufactured by an Indore based company were among over 20 such medicines being supplied to government hospitals.

“There are many instances where patients administered anesthesia in government hospitals, have died of an overdose. Even spurious drugs could be the reason for such deaths. Many health department officials are involved in this racket, the government should moot a detailed investigation into the problem which is harming the health of poor people,” Kumaraswamy stated.

He charged that medicines, which were meant to be distributed to the poor free of cost were being sold in medical shops. Though insulin was being supplied to government hospitals, it is not available for poor patients who are asked to purchase them from the open market.

Health Department officials are involved in this racket too, Kumaraswamy said. Stating that the Health Department was affected by the large number of vacancies, Kumaraswamy urged the chief minister to initiate steps to fill the vacancies.

❖ GLOBAL HEALTH AND DEVELOPMENT: The drug industry's poison pills

The Daily Star, January 21, 2014

ONE does not need to spend a lifetime in the global health-care sector to appreciate that substandard or counterfeit drugs are a major public-health hazard. These bogus products have infiltrated pharmaceutical supply chains from Azerbaijan to Zambia, wrecking the most promising programs to control, manage, and eradicate deadly diseases. Yet little is being done to stop this criminal activity.

Growing up in Pakistan, I realized how vital it was for my mother, like any educated parent, to know which drugs and pharmacies could be trusted. Little has changed since then. Local pharmacists from Lahore to Lusaka continue to sell a variety of brands of the same drug at different prices; and shopkeepers are called upon to give a candid opinion of their benefits and shortcomings.

Unfortunately, the problem runs a lot deeper than a few bad drugs sold at the corner pharmacy. Around $75 billion of substandard drugs are sold annually, causing an estimated 100,000 deaths worldwide, and making many more people seriously ill. The trade in inferior drugs also undermines fragile public-health systems in poor countries. As well as killing consumers, the effects of bad drugs can be passed from parent to child, and even create new drug-resistant strains of diseases that threaten us all.

Yet the fight against substandard drugs has never been taken as seriously as other global health crises such as malaria, HIV, or maternal and infant mortality. This may be because there is no obvious solution.

But, in seeking answers, we must first acknowledge that the issue is larger than just counterfeit medicines. Many legitimate manufacturers worldwide, whether through complacency or incompetence, lack adequate quality controls. In some cases, deficient storage and refrigeration systems turn safe medicines into dangerous substances.

Unfortunately, those drug makers then take advantage of developing countries' weak or poorly implemented legislation and corrupt officials to pass their products through local supply chains and into shops. Public ignorance or apathy means that those responsible are able to avoid prosecution.

The technical expertise and equipment needed to detect inferior products is

usually beyond the financial reach of many developing countries. But there are low-cost alternatives. One approach, for example, would be to include on packaging a “scratch code” that includes a phone number for consumers to call in order to check that the batch number matches an authentic product. But, while this approach would certainly help to catch counterfeits, it would miss the substandard or degraded products made by legitimate firms, which are tested only by the consumer – and often at great cost in terms of health risks.

It is therefore imperative to develop new detection technologies that will work in poorer countries, and that complement existing systems such as bar codes. Detection technology must be capable of analyzing all forms of a drug – whether powder, pill, capsule, or syrup – and of detecting several different grades of quality, not just the junk. It must be simple, affordable, adaptable, and scalable; and it must work at all stages of distribution, whether at customs, in hospitals, or in remote villages.

But technology alone will not be enough. Regulators, hospitals, and drug-safety authorities must take the lead, rather than placing the burden on often poor and uneducated citizens who are struggling to care for loved ones.

The search for new, sustainable solutions, requires at least three initiatives. First, we must encourage innovation by offering research grants to support small initiatives or large-scale projects (like campaigns to fight HIV, malaria, and maternal mortality). Ideally, an international group would coordinate and develop all of the ideas and products, and take them from the laboratory to the field.

Second, we need to harness the creativity and commitment of young students, so that they understand the devastating impact of bad pharmaceuticals and become motivated to make a difference in people's lives.

Third, we must make use of the media. Just as the world cries foul when an illegal shipment of ivory is uncovered, we must launch campaigns in the press, on television, and online to bring to account any trader, state official, or company caught selling or promoting low-quality drugs.

In this way, we will remind those in the industry of a fundamental premise: their most precious commodity is not a blockbuster drug, but the public's trust. If drug makers and pharmacists cannot protect their customers' health, they cannot protect their business.

❖ If I follow US standards, I will have to shut almost all drug facilities: G N Singh

Business Standard, January 30, 2014

At a time India-made medicines appear to be losing sheen the world over, the

country's top regulator, the Drug Controller General of India (DCGI), is struggling to ensure quality of drugs in the domestic market. Faced with criticism on many fronts, DCGI feels the India market might not be ready to follow global standards and the Indian industry might even collapse with the stringent norms followed elsewhere. Talking specifically on Ranbaxy, Drug Controller General G N Singh tells Sushmi Dey the DCGI can become the toughest watchdog when it comes to quality and even ban the company from the India market if it fails further in compliance. Edited excerpts:

Enforcements are increasing on Indian facilities, especially Ranbaxy. All the domestic facilities of the company are now barred from supplying to the US. However, it is still selling medicines in India. What is the Indian regulator doing to ensure medicines available in the market are safe?

We are taking action. I called Ranbaxy executives (on Tuesday), for the first time because I felt they should be accountable. We have also issued a showcause notice to the company, asking it to respond within seven days. I have given it strict warning that it must follow standards according to law. We will do required inspections and if any further deviation is found, we will become the toughest regulator and not hesitate even in banning the company's products from the Indian market. It is my duty as a regulator. I will take tough measures if required.

Ranbaxy's response?

They will respond to the showcause notice within a week. But its officials have assured me that corrective steps will be taken at the earliest. I have asked them to pick up samples of products that are already in movement; we, too are collecting samples. I have also asked them to give me a detailed list of customers to whom they supply APIs (active pharmaceutical ingredients), besides captive consumption. As a central regulator, I have to be sure all products in the chain, not only Ranbaxy's, are safe.

Are you assured that products available in the market are safe? After US FDA's (Food and Drug Administration's) increasing enforcements, people are now scared of taking medicines, especially those manufactured domestically. What's your view on this?

I understand the sentiment and the fear. But I want to assure all that none of the medicines available in the Indian market is unsafe. You must understand that even US FDA has not ordered recall of Ranbaxy products. That is because there is no problem with the quality or efficacy. The problems are primarily process-related and the company is taking corrective measures.

Observations made by the US FDA inspectors show that there were serious contamination, such as presence of flies. Even during earlier inspections, they found embedded hair in tablets, etc. And, US FDA has barred these facilities from further supply. Why is the Indian regulator allowing such violations?

We have inspected Ranbaxy facilities earlier and our inspectors found only

minor violations. Under the Drugs and Cosmetics Act, those violations were not serious enough for us to ban or lock those facilities. You have to understand that standards and norms are different for each country and each regulator. We follow India's law, not the US'. It is not necessary that we will also ban a facility if it has not qualified under the US FDA norms. It is pertinent because the facility is not only supplying to the US but many other countries and no one else has barred it so far.

Are you saying such contamination by flies is permissible under the Indian law? Or is it that medicines not fit for US citizens can be sold to Indians?

I am not saying that. But our society and our economy are different from those in the US. If I have to follow US standards in inspecting facilities supplying to the Indian market, we will have to shut almost all of those. We are not the US, the infrastructure and resources available there are much different from those in our country. Our priority is to make medicines available and affordable to all.
Having said that, I want to stress that medicines manufactured and sold in India are of good quality and we take all required steps to further improve those. It is a dynamic process. Even for Ranbaxy, I have instructed my inspectors, as well as state drug regulators, to keep a stringent check. We are going to inspect Ranbaxy's Toansa plant, too. If any deviation is found, we will take strict action.

But why is the Indian regulator so late in reacting? Ranbaxy has been under the US FDA scanner since 2008 and Toansa is its fourth plant to be barred from supplying to the US. Why did the Indian regulator take so long to call Ranbaxy executives?

We have been carrying out inspections. My inspectors have been meeting Ranbaxy officials. You cannot equate the Indian regulator with the US one. We are still evolving and it will take us at least 10 years to reach that level. We do not have resources and infrastructure equivalent to those of US FDA. We have a total staff of 650, compared with US FDA's 13,000. Look at the size of our manufacturing industry. The Indian industry is currently supplying generics to over 214 countries.
Also, as a national regulator, the steps that we are taking are voluntary. Manufacturing compliance and quality assurance is a state subject.

What are the steps taken by the government to upgrade the regulatory set-up?

We are strengthening the regulatory mechanism in the country through capacity building. Under the 12th Plan, we have around Rs 3,000 crore for regulatory revamping. Of this, the plan is to spend Rs 1,800 crore for upgrade of the central regulator, while Rs 1,200 crore will be used for supporting the regulatory mechanism is states.

The pharma industry, too, is not very happy with the regulatory mechanism. The industry is complaining that the regulator, following the Supreme Court's

directive on clinical trials, is not clearing files and there is a significant delay in new product approvals. This is hampering business and even forcing some companies to go abroad. What's your take on this?

Let them go if they cannot comply with norms. As a regulator, my job is to ensure compliance with the law. I cannot give approval to a company till it complies with regulations, even if that amounts to delay.

❖ Streamlining drug administration

The Independent, January 31, 2014

It is all too well known that the country's drug administration has been in disarray for a long time. Against the backdrop of absence of an effective drug policy, many dangerous things are taking place in the production, distribution and sale of drugs. Newspapers often make screaming headlines on flooding the marketplace with substandard and counterfeit drugs, most of which are usually sold in the rural areas where buyers of drugs are not that much conscious about the potentially threatening sides of such fake drugs. It is a great public health problem but the relative departments of the government have not taken the matter seriously. Even the selling of antibiotics without the prescription of registered doctors has become a common practice in the drug stores everywhere in the country. People sitting in these stores who often lack adequate knowledge of chemical reactions of drugs inside the human body are selling sensitive drugs without any kind of hindrance. People go to them with physical complaints and they both prescribe and sell medicines uncaringly.

When the government is not taking any measure in this regard, it is welcome news that the High Court, following a writ petition, has issued a rule upon the government to explain why a monitoring cell would not be formed to stop the production and marketing of adulterated medicines. It is unfortunate that in our country a vitally important entity like drug monitoring cell of the government to check production, misuse and abuse of drugs has not yet been established for streamlining the drug sector.

Allegedly, there is also little effective check against the unjustified pricing of drugs and the HC rule also touched upon the necessity of preparing a list of prices of drugs as well as a list of the drugs that cannot be sold without prescriptions of specialist doctors. The making of these lists are important to hedge the consumers and to stop misuse and abuse of drugs.

However, it is expected that the law and health secretaries and the directors general of the Directorate General of Drug Administration and the Directorate General of Health Services who have been made respondents to the HC rule would come up with satisfactory explanation before the HC and take necessary proactive measures to make the country's drug administration an efficient one addressing the problems.

❖ With Fake Medicines Potentially Threatening Every One of Us, It's Important to Be Vigilant

The Jakarta Globe, Feburary 04, 2014

When we are ill and we take some medicine, each of us probably has the same mixed feelings of relief and hope that it will make us feel better. Most of us usually get our medicines from somewhere reliable, someone we trust: a pharmacy, a doctor or a nurse. No matter where we get them, the hope is always the same — that they will work and improve our condition. We rarely think that they might not actually work because the pills are fake.

However, the threat of fake medicines in the supply chain is very much a reality in Indonesia. Fake medicines — whether sold directly over the Internet or having infiltrated the local pharmacy, hospital or store — represent a threat, putting both patients and the general public at risk. Fake medicines are a global problem: they are reported in virtually every region of the world. One percent of medicines available in the developed world are likely to be fake. This figure rises to 10 percent globally, but in some areas of Asia, Africa and Latin America, fake medicines may account for up to 30 percent of medicines in circulation. Asia, for instance, accounts for the biggest share of trade in counterfeit medicines. As many as one medicine in two purchased on Internet sites that hide their physical address is fake.

Fake medicines are first and foremost a crime against patients. People believe they are taking genuine medicines but instead are at risk of further illness, disability or even death. However, these harmful products also have wider implications: beyond personal tragedies, they put the health of whole communities in danger by exposing them to greater drug resistance, which means standard treatments become ineffective. International experts have warned that drug-resistant malaria in Southeast Asia is putting at risk major gains in fighting a disease that continues to kill more than 600,000 people every year.

Regrettably, Indonesia remains a counterfeit medicines hotspot. Studies suggest that counterfeits are widely in circulation: out of 518 tablets of an erectile dysfunction drug bought from 157 outlets by University of Indonesia researchers in 2011, 45 percent was fake.

Fake medicines also undermine the functioning of health care systems. As CEO of the International Council of Nurses, I know how important the trust of patients is to nurses who want to do their best and see their patients recover quickly. If they receive a fake medicine, they may lose faith and confidence in health care professionals who try to help them.

A wide range of pharmaceutical products can be and have been counterfeited: life-saving medicines for malaria, tuberculosis, HIV/AIDS, cancer, heart diseases as well as "lifestyle" medicines, for erectile dysfunction and weight loss.

My goal is not to scare you. My goal is to make us all vigilant, which requires increased public awareness about fake medicines and their serious effects. By “public”, I mean all of us — you, me, health care professionals, regulators, governments and anybody else interested and affected. It also requires acting in coordinated ways, as we’re doing through the Fight the Fakes campaign, which brings together individuals and organizations around the world and at all levels of society to help make people aware.

I believe that if we are all aware of the existence of fake medicines and the dangers they pose, we will be better at supporting our governments, and putting pressure on all those involved in the manufacturing and distribution of medicines, to coordinate actions to tackle this public health threat on a global level.

David Benton is the CEO of the International Council of Nurses, which recently launched — together with a host of other organizations representing health care professionals, research institutes, global health and financing institutions as well as the pharmaceutical industry — the Fight the Fakes campaign.

❖ Affordable drugs don't mean spurious: Azad tells US

Deccan herald, Feburary 10, 2014

Against the backdrop of US actions against Indian pharma exports, Health Minister Ghulam Nabi Azad today did some plainspeak with the head of American drug regulator, asserting that Indian drugs should not be treated as spurious just because they are affordable.

Azad's assertion came when he met US Food and Drug Administration (USFDA) Commissioner Margaret Hamburg who conveyed concerns over the issue of quality control.

She said there is a huge expectation and dependence of public on the regulator to ensure the quality of what they consume through drugs and food. Responding, Azad said, "Being affordable should not mean they are cheap and spurious". Emphasising India's commitment to stringent regulatory mechanism, he said it has taken measures for capacity building, strengthening laboratories and more transparency. He added that punishment up to life imprisonment is prescribed for those involved in making and selling spurious drugs.

The USFDA has taken a series of actions against Indian pharmaceutical firms, restricting their shipments to the US, their largest export market. The US health regulator on January 23 banned the import of products manufactured by Ranbaxy Laboratories at its plant at Toansa. This was the company's fourth plant to face regulatory action from the USFDA, after Mohali, Paonta Sahib and Dewas plants.

During the meeting between Azad and Hamburg, the two countries signed a Statement of Intent on Cooperation in the Field of Medical Products, which seeks sharing of information about lack of compliance with accepted current good manufacturing, clinial and laboratory practices medical or cosmetics company in one another's country.

It also intends informing the respective regulatory authorities before undertaking inspections so that host-country inspectors may join inspections as observers.

❖ Illegal drug manufacturing and sale

The Independent, February 14, 2014

The news of seizure of illegal drugs and drug-making equipment from the city Wednesday by RAB reinforces the fact the country is at risk with illegal drug manufacturing companies and drug stores that are posing a great threat to public health. Because of the presence of these illegal drug manufacturers in the scene, the products of the genuine drug manufacturing companies with goodwill and excellent track records are not reaching the hands of patients who need them most. It is common knowledge that many drug shops across the country are selling spurious and banned medicines. This is due to the fact that the relevant agencies of the government including the Directorate General of Drug Administration (DGDA) have failed to monitor and control the sale of these substandard as well as contraband drugs. On its part the DGDA often mentions that shortage of manpower and lack of adequate infrastructure is mostly responsible for this situation. This account of DGDA is not without some truth; but it is also true that in issuing drug licenses and monitoring drug markets, the authorities are not strictly following the rules.

Anyone by paying Tk 1,500 fees can manage to have a drug license in a municipal area and Tk 750 fees outside the municipal area for opening a drug store. But drug licenses are supposed to be issued to only trained people in the business. According to the Drugs (Control) Ordinance, 1982, it is also mandatory for every drugstore to have a trained pharmacist registered with the Pharmacy Council of Bangladesh (PCB). But this legal binding is also hardly followed when licenses are given. Drug stores in the remote places have either a fake drug license or have no license at all.

The presence of illegal drug manufacturing companies and drug stores shows what a pit of irregularities the drug sector has fallen into . The rigour of the problem lies in the fact that it is a chronic one and exacts a heavy price on human health. This points to the imperative of overhauling the country’s drug administration.

The need for reforms gains further importance and urgency as a number of local pharmaceutical companies are not only producing standard drugs but are also exporting those. If the current trend continues, sooner or later, it will hamper our export growth as well. It is expected this time the relevant

authorities would take the matter very seriously and stop manufacturing, distribution and selling of illegal drugs at the soonest.

❖ Medicines Made in India Set Off Safety Worries

New York Times, February 14, 2014

India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators for safety lapses, falsified drug test results and selling fake medicines.

Dr. Margaret A. Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms."

India's pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for American consumers.

F.D.A. investigators are blitzing Indian drug plants, financing the inspections with some of the roughly $300 million in annual fees from generic drug makers collected as part of a 2012 law requiring increased scrutiny of overseas plants. The agency inspected 160 Indian drug plants last year, three times as many as in 2009. The increased scrutiny has led to a flood of new penalties, including half of the warning letters the agency issued last year to drug makers.

Dr. Hamburg was met by Indian officials and executives who, shocked by recent F.D.A. export bans of generic versions of popular medicines — like the acne drug Accutane, the pain drug Neurontin and the antibiotic Cipro — that the F.D.A. determined were adulterated, suspect that she is just protecting a domestic industry from cheaper imports.

"There are some people who take a very sinister view of the F.D.A. inspections," Keshav Desiraju, India's health secretary until this week, said in a recent interview.

The F.D.A.'s increased enforcement has already cost Indian companies dearly — Ranbaxy, one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store.
"If I have to follow U.S. standards in inspecting facilities supplying to the Indian market," G. N. Singh, India's top drug regulator, said in a recent interview with an Indian newspaper, "we will have to shut almost all of those."
The unease culminated Tuesday when a top executive at Ranbaxy — which has repeatedly been caught lying to the F.D.A. and found to have conditions such as flies "too numerous to count" in critical plant areas — pleaded with Dr.

Hamburg at a private meeting with other drug executives to allow his products into the United States so that the company could more easily pay for fixes. She politely declined.

India's drug industry is one of the country's most important economic engines, exporting $15 billion in products annually, and some of its factories are world-class, virtually undistinguishable from their counterparts in the West. But others suffer from serious quality control problems. The World Health Organization estimated that one in five drugs made in India are fakes. A 2010 survey of New Delhi pharmacies found that 12 percent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths there in recent years.

One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret for nearly a year while 100,000 useless pills continued to be dispensed. More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants.

"Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections," said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at the University of Kashmir. "That's very serious."

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare.

Satish Reddy, president of the Indian Pharmaceutical Alliance, said Indian drug manufacturers were better than the F.D.A. now contends. "More rigorous enforcement is needed, for sure, but this impression that India is overrun with counterfeits is unjustified," Mr. Reddy said.

But Heather Bresch, chief executive of Mylan, which has plants in the United States and India, said regulatory scrutiny outside the United States was long overdue. "If there were no cops around, would everyone drive the speed limit?" Ms. Bresch asked. "You get careless, start taking risks. Our government has enabled this."

For Dr. Hamburg, the trip is part of a long-running effort to create a global network of drug and food regulators to help scrutinize the growing flood of products coming into the United States, including 80 percent of the seafood consumed in the United States, 50 percent of the fresh fruit, 20 percent of the vegetables and the vast majority of drugs.
She has gone to conclaves of regulators from Europe and elsewhere to coordinate policing, but Indian officials have so far not attended such meetings.

Many of India's drug manufacturing facilities are of top quality. Cipla, one of

the industry's giants, has 40 plants across the country that together can produce more than 21 billion tablets and capsules annually, and one of its plants in Goa appeared just as sterile, automated and high tech on a recent tour as those in the United States.

Cipla follows F.D.A. guidelines at every plant and on every manufacturing line, and the company exports more than 55 percent of its production, said Yusuf Hamied, the company chairman.

But Benjamin Mwesige, a pharmacist at the Uganda Cancer Institute in Kampala, said in an interview in July that the institute had stopped buying cancer drugs from India in 2011 because it had received shipments of drugs that turned out to be counterfeit and inactive, with Cipla labels that Mr. Mwesige believed were forged.

He became suspicious when doctors began seeing chemotherapy patients whose cancer showed none of the expected responses to the drugs — and who also had none of the usual side effects. The drugs that had been prescribed were among the mainstays of cancer treatment — methotrexate, docetaxel and vincristine. Laboratory tests confirmed that the drugs were bogus, and Mr. Mwesige estimated that in 2011 20 percent of the drugs that the institute bought were counterfeit.

Enforcement of regulations over all is very weak, analysts say, and India's government does a poor job policing many of its industries. Last month, the United States Federal Aviation Administration downgraded India's aviation safety ranking because the country's air safety regulator was understaffed, and a global safety group found that many of India's best-selling small cars were unsafe.

India's Central Drugs Standard Control Organization, the country's drug regulator, has a staff of 323, about 2 percent the size of the F.D.A.'s, and its authority is limited to new drugs. The making of medicines that have been on the market at least four years is overseen by state health departments, many of which are corrupt or lack the expertise to oversee a sophisticated industry. Despite the flood of counterfeit drugs, Mr. Singh, India's top drug regulator, warned in meetings with the F.D.A. of the risk of overregulation.

This absence of oversight, however, is a central reason India's pharmaceutical industry has been so profitable. Drug manufacturers estimate that routine F.D.A. inspections add 25 percent to overall costs. In the wake of the 2012 law that requires the F.D.A. for the first time to equalize oversight of domestic and foreign plants, India's cost advantage could shrink significantly. Some top manufacturers are already warning that they may leave, tough medicine for an already slowing economy.

"I'm a great nationalist, an Indian first and last," Dr. Hamied said. "But companies like Cipla are looking to expand their businesses abroad and not in India."

American businesses and F.D.A. officials are just as concerned about the quality of drugs coming out of China, but the F.D.A.'s efforts to increase inspections there have so far been frustrated by the Chinese government.

"China is the source of some of the largest counterfeit manufacturing operations that we find globally," said John P. Clark, Pfizer's chief security officer, who added that Chinese authorities were cooperative.

Using its new revenues, the F.D.A. tried to bolster its staff in China in February 2012. But the Chinese government has so far failed to provide the necessary visas despite an announced agreement in December 2013 during a visit by Vice President Joseph R. Biden Jr., said Erica Jefferson, an F.D.A. spokeswoman.

The United States has become so dependent on Chinese imports, however, that the F.D.A. may not be able to do much about the Chinese refusal. The crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

- **Drug Quality Concerns Spur New U.S. FDA Oversight Effort**
  Bloomberg, February 15, 2014

Drug quality concerns, such as those that have banned U.S. sales of generic medicines from several Indian manufacturing plants, have spurred regulators to create a new unit to sharpen their oversight.

The Food and Drug Administration is establishing an Office of Pharmaceutical Quality to improve the agency's scrutiny of brand-name, generic and over-the-counter drugs, Janet Woodcock, director of the Food and Drug Administration's Center for Drug Evaluation and Research, said today at the Bloomberg health-care summit. The FDA is talking with the industry to develop data that may signal which manufacturing plants are straying from standards and need inspection, she said.

The agency now collects such information only during inspections. The thrust of the effort would be to head off potential concerns before the agency wields penalties such as banning products from troubled factories, Woodcock said. FDA Commissioner Margaret Hamburg has been in India the past week and met with generic-drug companies to discuss quality.

"We want to use leading indicators," Woodcock said in an interview after her appearance via webcast at the summit in New York. "These people aren't in trouble yet but they could be."

Ranbaxy Laboratories Ltd. (RBXY) and Wockhardt Ltd. (WPL) have been banned from selling drugs to the U.S. from some plants in India that

experienced quality issues. In the latest incident last month, a fourth Ranbaxy facility was banned from U.S. exports after FDA inspectors found drugs were re-tested to gain favorable results after initial analyses failed.

"All companies must understand that quality is the basis for the public's trust and confidence in their products and maintaining high quality standards is part of the cost of doing business," Hamburg wrote today in a blog post on her trip. Hamburg said the new office will "improve our oversight of quality throughout the lifecycle of a pharmaceutical product."

In addition to her discussions with drugmakers, the FDA chief signed an agreement with her counterpart in India to tell regulators there when agency inspectors are inspecting plants and allow them to join to observe U.S. standards.

In 2012, the FDA was given the power to collect fees from generic-drug makers in part to pay for an increase in inspections of facilities outside the U.S. The agency was also permitted to request records in lieu of conducting an inspection, Woodcock said.

The FDA is working with groups such as the Pharmaceutical Research and Manufacturers of America and American Association of Pharmaceutical Scientists to determine how often it will ask drugmakers to submit quality data, she said.

Lawmakers in Congress are scheduled to hear from doctors, researchers and patient advocates Feb. 26 in a briefing on whether substandard generic drugs are reaching the U.S. medical system from overseas. The briefing will feature Harry Lever, a Cleveland Clinic cardiologist who has said generic drugs for heart failure made by India-based companies often don't work the way they should.

❖ US crackdown on Indian medicines

www.bdnews24.com, February16, 2014

India, the second-largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by American regulators, says the New York Times.
The concerns range from safety lapses, falsified drug tests and sale of fake medicines.

Dr. Margaret A Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality of drugs produced by a handful of pharmaceutical firms."

India's pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased

scrutiny could have profound implications for American consumers.

FDA investigators are blitzing Indian drug plants, financing the inspections with some of the roughly $300 million in annual fees from generic drug makers collected as part of a 2012 law requiring increased scrutiny of overseas plants, the New York Times report said.

The agency inspected 160 Indian drug plants last year, three times as many as in 2009. The increased scrutiny has led to a flood of new penalties, including half of the warning letters the agency issued last year to drug makers.

Dr. Hamburg was met by Indian officials and executives who suspect she is just protecting a domestic industry from cheaper imports.

The Indian producers are shocked by recent FDA export bans of generic versions of popular medicines — such as the acne drug Accutane, the pain drug Neurontin and the antibiotic Cipro — that the FDA. determined were adulterated .

“There are some people who take a very sinister view of the FDA inspections,” Keshav Desiraju, India’s health secretary until this week, said in a recent interview.

The FDA's increased enforcement has already cost Indian companies dearly — Ranbaxy, one of India’s biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store. “If I have to follow US standards in inspecting facilities supplying to the Indian market,” GN Singh, India’s top drug regulator, said in a recent interview with an Indian newspaper, “we will have to shut almost all of those.”

The unease culminated Tuesday when a top executive at Ranbaxy — which has repeatedly been caught lying to the FDA and found to have conditions such as flies “too numerous to count” in critical plant areas — pleaded with Dr. Hamburg at a private meeting with other drug executives to allow his products into the United States so that the company could more easily pay for fixes. She politely declined.

India’s drug industry is one of the country’s most important economic engines, exporting $15 billion in products annually, and some of its factories are world-class, virtually undistinguishable from their counterparts in the West.

But others suffer from serious quality control problems. The World Health Organization estimated that one in five drugs made in India are fakes. A 2010 survey of Delhi pharmacies found that 12 percent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths

there in recent years.

One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret for nearly a year while some 100,000 useless pills continued to be dispensed. More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants.

“Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections,” said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at Kashmir University. “That’s very serious.”

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare.

Satish Reddy, president of the Indian Pharmaceutical Alliance, said Indian drug manufacturers are better than the FDA now contends. “More rigorous enforcement is needed, for sure, but this impression that India is overrun with counterfeits is unjustified,” Mr. Reddy said.

But Heather Bresch, chief executive of Mylan, which has plants in the United States and India, said regulatory scrutiny outside of the United States was long overdue. “If there were no cops around, would everyone drive the speed limit?” Ms. Bresch asked. “You get careless, start taking risks. Our government has enabled this.”

For Dr. Hamburg, the trip is part of a long-running effort to create a global network of drug and food regulators to help scrutinize the growing flood of products coming into the United States, including 80 percent of the seafood consumed in the United States, 50 percent of the fresh fruit, 20 percent of the vegetables and the vast majority of drugs.

She has gone to conclaves of regulators from Europe and elsewhere to coordinate policing, but Indian officials have so far not attended such meetings.

Many of India’s drug manufacturing facilities are of top quality. Cipla, one of the industry’s giants, has 40 plants across the country that together can produce more than 21 billion tablets and capsules annually, and one of its plants in Goa appeared just as sterile, automated and high tech on a recent tour as those in the United States.

Cipla follows FDA guidelines at every plant and on every manufacturing line, and the company exports more than 55 percent of its production, said Yusuf Hamied, the company chairman.

But Benjamin Mwesige, a pharmacist at the Uganda Cancer Institute in Kampala, said in an interview in July that the institute had stopped buying cancer drugs from India in 2011 because it had received shipments of drugs that turned out to be counterfeit and inactive, with Cipla labels that Mr.

Mwesige believed were forged.

He became suspicious when doctors began seeing chemotherapy patients whose cancer showed none of the expected responses to the drugs — and who also had none of the usual side effects. The drugs that had been prescribed were among the mainstays of cancer treatment — methotrexate, docetaxel and vincristine. Laboratory tests confirmed that the drugs were bogus, and Mr. Mwesige estimated that in 2011 about 20 percent of the drugs that the institute bought were counterfeit.

Enforcement of regulations over all is very weak, analysts say, and India's government does a poor job policing many of its industries.

Last month, the United States Federal Aviation Administration downgraded India's aviation safety ranking because the country's air safety regulator is understaffed, and a global safety group found that many of India's best-selling small cars are unsafe, the New York Times report said.

India's Central Drugs Standard Control Organization, the country's drug regulator, has a staff of 323, about 2 percent the size of the FDA.'s, and its authority is limited to new drugs.

The making of medicines that have been on the market at least four years is overseen by state health departments, many of which are corrupt or lack the expertise to oversee a sophisticated industry. Despite the flood of counterfeit drugs, Mr Singh, India's top drug regulator, warned in meetings with the FDA of the risk of over regulation.

This absence of oversight, however, is a central reason India's pharmaceutical industry has been so profitable. Drug manufacturers estimate that routine FDA inspections add about 25 percent to overall costs. In the wake of the 2012 law that requires the FDA for the first time to equalize oversight of domestic and foreign plants, India's cost advantage could shrink significantly.

Some top manufacturers are already warning that they may leave, tough medicine for an already slowing economy.

"I'm a great nationalist, an Indian first and last," Dr. Hamied said. "But companies like Cipla are looking to expand their businesses abroad and not in India."

American businesses and FDA officials are just as concerned about the quality of drugs coming out of China, but the FDA.'s efforts to increase inspections there have so far been frustrated by the Chinese government.

"China is the source of some of the largest counterfeit manufacturing operations that we find globally," said John P. Clark, Pfizer's chief security officer, who added that Chinese authorities were cooperative.

Using its new revenues, the FDA tried to bolster its staff in China in February 2012. But the Chinese government has so far failed to provide the necessary visas despite an announced agreement in December 2013 during a visit by Vice President Joseph R Biden Jr., said Erica Jefferson, an FDA spokeswoman.

The United States has become so dependent on Chinese imports, however, that the FDA. may not be able to do much about the Chinese refusal. The crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

❖ Spurious drugs in Kashmir panic US

Precious Kashmir, February 16, 2014

United States of America has taken serious note of infant deaths at a pediatric hospital in Kashmir (G B Pant in Srinagar) due to the alleged consumption of fake spurious drugs.

A few days ago, Dr Margaret A. Hamburg, the commissioner of the United States Food and Drug Administration, arrived in India to express her growing unease with the safety of Indian medicines because of “recent lapses in quality at a handful of pharmaceutical firms.”

USA has taken reports of falsified drug test results, safety lapses and selling of fake medicines very seriously given the position of India as the second-largest exporter of over-the counter and prescription drugs to their country.

“India’s pharmaceutical industry supplies 40 percent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for American consumers,” an American official was quoted by media as saying.

Reputed American news daily reported that deaths in Kashmir due to spurious medicines was one of the prime reasons which prompted the USA to increase safety regulation scrutiny of American companies.

Daily reported: In one recent example, counterfeit medicines at a pediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths there in recent years. One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret for nearly a year while some 100,000 useless pills continued to be dispensed. More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants.

“Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections,” said Dr. M. Ishaq Geer, senior assistant professor of pharmacology at Kashmir University. “That’s very serious.” Newspaper quoted

a local expert on the subject.

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare.
The F.D.A.'s increased enforcement has already cost Indian companies dearly — Ranbaxy, one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store.

"If I have to follow U.S. standards in inspecting facilities supplying to the Indian market," we will have to shut almost all of those." G. N. Singh, India's top drug regulator was earlier quoted in media as saying.

❖ Pharmaceutical Drugs From India Under FDA Scanner

Guardian Liberty Voice, February 16, 2014

The thriving pharmaceutical industry in India is now being closely watched by the world for all the wrong reasons: Lapses in safety measures, fabricated drug test results and the selling of counterfeit medicines has brought pharmaceutical drugs from India under the scanner of the U.S. Food and Drug Administration (FDA). With India being the second largest supplier of over-the-counter and prescription drugs to the U.S, the increased scrutiny signals profound consequences for consumers here.

FDA Commissioner Dr. Margaret Hamburg recently met with generic-drug manufacturers in India to convey her concerns over the safety of Indian medicines. Blaming a "handful" of pharmaceutical firms for the dip in quality, Dr. Hamburg felt it was unfortunate that the other Indian companies, which understood good manufacturing and quality processes, have been overshadowed by these findings. Ranbaxy, one of India's largest pharmaceutical companies, is a case in point. Last year, the company made history by pleading guilty to felony charges and paying $500 million fine, the largest ever to be imposed on a generic drugs company.

Many fear there is worse to come for defaulting pharmaceutical companies, with the FDA aiming to impose stricter norms and punishments. An Office of Pharmaceutical Quality is in the process of being set up by the FDA to improve the agency's inspection of brand name, over-the-counter and generic drugs, according to Janet Woodcock, director of the FDA's Centre for Drug Evaluation and Research. The announcement was made at the Bloomberg Healthcare summit held recently.

Referring to her visit to India in a blog post on the FDA's official blog, Dr. Hamburg wrote that all pharmaceutical drugs manufacturers must understand that "quality is the basis for the public's trust and confidence in their products and maintaining high quality standards is part of the cost of doing business."

The latest blitz of inspections of Indian drug plants by FDA investigators has

been funded by the approximate $300 million levied from generic drug manufacturers as annual fees. This follows a 2012 law that makes it imperative to increase scrutiny of manufacturing plants outside the United States. The 160 inspections in India, which were conducted in 2013, have brought under the scanner thrice as many pharmaceutical drug companies as in 2009. This has opened the floodgates on new penalties, more than half of which were warning letters issued to drug manufacturers by the agency last year.

The scrutiny, however, has not been received well in India, which supplies pharmaceutical drugs to over 200 countries around the world. Many of the Indian officials and executives who met with Dr. Hamburg felt that the U.S. FDA was safeguarding a domestic industry from cheaper imports. There is a very sinister perception of these inspections, said Keshav Desiraju, India's health secretary until this week in an interview. The Indian pharmaceutical industry is among the nation's premiere economic drivers, generating billions of dollars in revenue every year.

The increased FDA scrutiny is already costing the industry, which has flourished under the lack of an exacting quality control mechanism. While there definitely are world-class factories in India that are practically indistinguishable from those in the West, there are some that function despite serious lapses in quality control. A 2002 estimation by the World Health Organization states that one in five pharmaceutical drugs manufactured in India are counterfeit.

Also, a 2010 survey, conducted by International Policy Network, a non-governmental organization working along with Liberty Institute, Delhi revealed some startling realities in the Indian pharmaceutical market. The survey, which was supported by Legatum Institute, sampled drugs from New Delhi and Chennai and found that 12 percent of them were spurious. Instances of medicines being adulterated with chalk and talcum powder, mixed with pain killers; of antibiotics revealing no active ingredient whatsoever when tested; and of deaths being caused by fake medicines abound in India. In fact Ranbaxy, whose drugs manufactured in India are totally banned in the United States, still continues to populate the Indian market.

Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare. The Drug Controller General of India (DCGI), the top regulator of drugs in India, is vastly understaffed when compared to the U.S. FDA. In an interview to Business Standard, Drug Controller General G.N. Singh opined that the Indian pharmaceutical industry may collapse if the stringent norms followed in places like the United States are applied to it. The Indian market, he felt, was in all probability unready to follow global standards.

Representatives of the industry like the Indian Pharmaceutical Alliance (IPA) have however reacted defensively to India being brought under the scanner by the FDA. Satish Reddy, President, IPA has said that Indian drug companies were better than the image being created by the FDA. Though he

agrees that quality control measures must be implemented rigorously, he felt that the idea that the Indian pharmaceutical industry was dominated by spurious drugs wasn't justified.

❖ Unease growing in US over medicines made in India

Deccan Herald, Feb 17, 2014
Indian Express, Feb 17, 2014

The WHO estimated that one in five drugs made in India are fake. India, the second largest exporter of over-the-counter and prescription drugs to the United States, is coming under increased scrutiny by US regulators for safety lapses, falsified drug test results and selling fake medicines.

Dr Margaret A Hamburg, the commissioner of the US Food and Drug Administration, arrived in India this week to express her growing unease with the safety of Indian medicines because of "recent lapses in quality at a handful of pharmaceutical firms." India's pharmaceutical industry supplies 40 per cent of over-the-counter and generic prescription drugs consumed in the United States, so the increased scrutiny could have profound implications for US consumers.

FDA investigators are blitzing Indian drug plants, financing the inspections with some of the roughly $300 million in annual fees from generic drug makers collected as part of a 2012 law requiring increased scrutiny of overseas plants. The agency inspected 160 Indian drug plants last year, three times as many as in 2009. The increased scrutiny has led to a flood of new penalties, including half of the warning letters the agency issued last year to drug makers.

Hamburg was met by Indian officials and executives who, shocked by recent FDA export bans of adulterated generic versions of popular medicines - such as the acne drug Accutane, the pain drug Neurontin and the antibiotic Cipro - suspect that she is just protecting a domestic industry from cheaper imports. The FDA's increased enforcement has cost Indian companies dearly – Ranbaxy - one of India's biggest drug manufacturers, pleaded guilty to felony charges and paid a $500 million fine last year, the largest ever levied against a generic company. And many worry that worse is in store.

"If I have to follow US standards in inspecting facilities supplying to the Indian market," G N Singh, India's top drug regulator, said in a recent interview with an Indian newspaper, "we will have to shut almost all of those." The unease culminated Tuesday when a top executive at Ranbaxy - which has repeatedly been caught lying to the FDA and found to have conditions such as flies "too numerous to count" in critical plant areas - pleaded with Hamburg at a private meeting with other drug executives to allow his products into the US so that the company could more easily pay for fixes. She declined.

India's drug industry is one of the country's most important economic engines,

exporting $15 billion in products annually, and some of its factories are world-class, virtually undistinguishable from their counterparts in the West. But others suffer from serious quality control problems. The World Health Organisation estimated that 1 in 5 drugs made in India are fakes. A 2010 survey of Delhi pharmacies found that 12 per cent of sampled drugs were spurious.

In one recent example, counterfeit medicines at a paediatric hospital in Kashmir are now suspected of playing a role in hundreds of infant deaths there in recent years. One widely used antibiotic was found to contain no active ingredient after being randomly tested in a government lab. The test was kept secret for nearly a year while some 1,00,000 useless pills continued to be dispensed.

Sub-standard drugs

More tests of hospital medicines found dozens more that were substandard, including a crucial intravenous antibiotic used in sick infants. “Some of the fake tablets were used by pregnant women in the post-surgical prevention of infections,” said Dr M. Ishaq Geer, senior assistant professor of pharmacology at Kashmir University. Investigations of the deaths are continuing, but convictions of drug counterfeiters in India are extremely rare. Satish Reddy, president of the Indian Pharmaceutical Alliance, said Indian drug manufacturers are better than the FDA now contends.

Many of India’s drug manufacturing facilities are of top quality. Cipla, one of the industry’s giants, has 40 plants across the country that together can produce more than 21 billion tablets and capsules annually, and one of its plants in Goa appeared just as sterile, automated and high-tech on a recent tour as those in the United States. Cipla follows FDA guidelines at every plant and on every manufacturing line, and the company exports more than 55 per cent of its production, said Yusuf Hamied, the company chairman.

But Benjamin Mwesige, a pharmacist at the Uganda Cancer Institute in Kampala, said in an interview in July that the institute had stopped buying cancer drugs from India in 2011 because it had received shipments of drugs that turned out to be counterfeit and inactive, with Cipla labels that Mwesige believed were forged.

He became suspicious when doctors began seeing chemotherapy patients whose cancer showed none of the expected responses to the drugs - and who also had none of the usual side effects. Laboratory tests confirmed that the drugs were bogus, and Mwesige estimated that in 2011 about 20 per cent of the drugs that the institute bought were counterfeit.

Absence of oversight

India’s Central Drugs Standard Control Organisation has a staff of 323, about 2 per cent the size of the FDA’s, and its authority is limited to new drugs. The making of medicines that have been on the market at least four years is

overseen by state health departments, many of which lack the expertise to oversee a sophisticated industry.

Despite the flood of counterfeit drugs, Singh, India's top drug regulator, warned in meetings with the FDA of the risk of overregulation. This absence of oversight, however, is a key reason India's pharmaceutical industry has been so profitable. Drug manufacturers estimate that routine FDA inspections add about 25 per cent to overall costs. In the wake of the 2012 law that requires the FDA to equalise oversight of domestic and foreign plants, India's cost advantage could shrink.

Some top manufacturers are already warning that they may leave, tough medicine for an already slowing economy. "I'm a great nationalist, an Indian first and last," Hamied said. "But companies like Cipla are looking to expand their businesses abroad and not in India."

US businesses and FDA officials are just as concerned about the quality of drugs coming out of China, but the FDA's efforts to increase inspections there have so far been frustrated by the Chinese govt. Using its new revenues, the FDA tried to bolster its staff in China in February 2012. But the Chinese government has so far failed to provide the necessary visas despite an announced agreement in December 2013, said Erica Jefferson, an FDA spokeswoman.

The United States has become so dependent on Chinese imports. The crucial ingredients for nearly all antibiotics, steroids and many other lifesaving drugs are now made exclusively in China.

❖ Health Ministry asserts that no reports of rise in spurious drugs in India

Pharmabiz, February 21, 2014

Even as fresh reports appeared in the Western media about the rise of spurious drugs in India, the Government has categorically stated that there were no reports to substantiate the allegations coming out still about Indian industry.

"There are no reports to indicate that availability of spurious medicines is on the rise in the country," according to Union Health Minister Ghulam Nabi Azad recently in the Parliament. He also said the Government had taken several steps to check the problem of spurious and sub-standard drugs.

Very recently, a section of the US media had once again raised the issue of spurious drugs in India, in the backdrop of the visit of Margaret A Hamburg, the commissioner of the United States Food and Drug Administration (FDA), to the country. Indian Industry supplies 40 per cent of over-the-counter and generic prescription drugs consumed in the United States. The report had also claimed that World Health Organization estimated that one in five drugs

made in India are fakes. A 2010 survey of New Delhi pharmacies found that 12 per cent of sampled drugs were spurious.

"This had been cleared long back after the WHO formally informed Health Ministry that there was no such survey done by it in India. It is no more a debatable issue," a senior official from the Health Ministry told Pharmabiz about the report.

During the meeting with the US FDA Commissioner last week, the Union Minister had also clearly countered the allegations saying that "cheap drugs did not mean that they were spurious".

Detailing the steps taken to check the spurious drugs, the ministry sources said the States/UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far 16 States have already set up designated special Courts for trial of cases related to spurious and sub-standard drugs.

Guidelines for taking action on samples of drugs declared spurious or not-of-standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation. The inspectorate staff have been instructed to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country, sources said.

❖ U.S. not targeting Indian drug companies: FDA chief

First Post, February 22, 2014

The head of the U.S. Food and Drug Administration said on Friday it was not unduly targeting drug companies in India, which supplies a large portion of drugs used in the U.S., as the agency cracks down on substandard medication from abroad.

In recent months, the FDA banned drugs and drug ingredients from two Indian companies, Ranbaxy Laboratories Ltd (RANB.NS) and Wockhardt Ltd (WCKH.NS), citing quality concerns. Some Indian officials say the U.S. is disproportionately targeting Indian companies for enforcement actions.
FDA Commissioner Margaret Hamburg, who recently returned from a 10-day official visit to India, rejected those charges, saying that her agency was simply "undertaking our required regulatory activities" needed to protect public health in the United States.

India supplies about 40 percent of the generic and over-the-counter drugs consumed in the United States, making it the second-largest supplier after Canada. Yet quality control problems have long plagued India's drug industry, largely due to a weak regulatory system.

In 2012, a report by India's parliament alleged collusion between

pharmaceutical firms and officials at the country's Central Drugs Standard Control Organization (CDSCO), which oversees the licensing, marketing and trials of new drugs. It described an agency that was both chronically understaffed and underqualified.

The country is trying to improve but the task facing both local and overseas inspectors is difficult. The FDA has 12 members of staff in India, while about 500 Indian companies are registered to export drugs to the U.S.
The FDA staff is tasked with fostering communication with their Indian counterparts and can inspect facilities.

Dr. Amir Attaran, a professor of law and medicine at the University of Ottawa, noted that "even if you put a huge number of FDA staff in New Delhi, they have no legal power, no ability to do surprise inspections, no ability to issue subpoenas or take other measures to force a drugmaker to open its books." "They are foreign agents in a foreign land," he said.

During Hamburg's visit, the FDA and India's Ministry of Health and Family Welfare signed a statement of intent to cooperate to prevent the distribution of unsafe drugs.

The statement is not binding and has no enforcement power behind it. Among other things, the FDA agreed to inform India's regulatory authorities before inspections so that local inspectors can observe.

The ink on the statement was barely dry when the drug controller general of India, G.N. Singh, said in an interview that India would follow its own quality standards and that "the FDA may regulate its country, but it can't regulate India on how India has to behave or how to deliver."

Singh said his agency regularly inspects manufacturing facilities in India and that it plans to raise the number of inspectors to 5,000 in three to five years, from about 1,500. "We don't recognize and are not bound by what the U.S. is doing and is inspecting," he added.

Some observers are skeptical of India's commitment to improving quality standards. Last year, Ranbaxy pleaded guilty to felony U.S. charges of shoddy manufacturing practices and data falsification and agreed to pay $500 million in civil and criminal fines. Dinesh Thakur, a former Ranbaxy executive who blew the whistle on the company nearly a decade ago, said no one in the Indian government has contacted him about the matter."Clearly this is not a priority for the Indian government at the moment," he said.

The FDA may be able to ban products from individual facilities but its ability to impose widespread restrictions on India's drugs is limited, since the U.S. relies on them so heavily.

"The dirty little secret in all this is that we can't do without Indian products," said Roger Bate, an economist at the American Enterprise Institute who will moderate a congressional briefing on global substandard and counterfeit

medicines on Wednesday. "We have to negotiate and pressure because we can't boycott."

A group of critics, including Bate, Attaran and Dr. Harry Lever, a cardiologist at the Cleveland Clinic, plans to attend the briefing and hopes to put pressure on the White House to take up the issue of drug quality with the Indian government. Lever plans to discuss problems he is increasingly encountering with inferior-quality medicines. "The Indian government needs to feel some pain on this," Bate said.

Hamburg repeated a call she made while in India for Indian regulators to step up their participation in discussions about global collaboration on drug production. "India needs to be a full participant at the table," she said.

❖ 'MNCs and lobbyists campaign against Indian drugs industry'

Deccan Herald, February 23, 2014

A Fulbright scholar and a post-doctoral fellow at Harvard School of Public Health, Shaktivel Selvaraj is an adjunct assistant professor at the Public Health Foundation of India. He was a Health Economist at the National Commission on Macroeconomics and Health in 2004-05. Engaged in teaching and research at PFHI, Selvaraj spoke to Deccan Herald's Kalyan Ray on sub-standard medicine. Excerpts:

How serious is the problem of sub-standard medicine in India?

The term substandard is a catch-all phrase that captures any deviation from regulatory requirements. But not all sub-standard or spurious drugs pose a threat to life. From a public health perspective, only the drugs of 'non standard quality' pose the major threat. According to a 2009, CDSCO study, the extent of spurious drugs in retail outlets was only 0.046 per cent and the percentage of drugs failing chemical analysis was only 0.1 per cent (3 out of 2976 samples). In addition, sub-standard drugs accounted for 6-7 per cent of overall tested drugs (state drugs controller estimates). The problem of spurious drugs is nowhere as dire as has been claimed by unverified reports in media.

Is there an underlying Western campaign to malign the Indian pharmaceutical industry, which is a major player in global drugs export market?

There is certainly a campaign by multinational companies and their lobbies to undermine confidence in Indian generics. The chief tactic is to conflate the issue of 'counterfeit' which refers strictly to an intellectual property violation (an egregious trademark violation) with poor quality. The last few years have seen the emergence of an anti-counterfeiting agenda that focuses on misguided global enforcement mechanisms that have nothing to do with real

health concerns.

What is the size of the small and medium scale enterprise in the Indian pharmaceutical industry?

The Indian pharmaceutical industry is characterised as 'long-tailed' with approximately 5000 manufacturing units producing drugs, of which only around 250 and large scale units.

Do you think implementation of strict regulatory measures will be an expensive proposition for the SME unit?

Schedule M (good manufacturing practices-GMP) of the Drugs and Cosmetics Act has been implemented since July 2005. Firms were required to come into compliance and during this period several small and medium scale entities were impacted and had to shut down, particularly those producing bulk drugs. MNCs are engaged in attempts to leverage quality as a barrier to trade.

The main objective should be to aim for appropriate quality and regulatory standards and not only the highest standards.

Why Indian chemist shops don't have qualified pharmacists?

Under current rules, only qualified pharmacists are allowed and provided licences for setting up pharmacies. The lack of enforcement is certainly a challenge.

What are the flaws with the Indian drugs regulatory system? Why the Drugs Controller-General of India could not see these faults which American Food and Drugs Authority discovered with Ranbaxy?

Some of the current challenges facing the regulatory system include inadequate financing, lack of technical workforce and poor infrastructure and capacity for testing of drugs. But inadequate financial resources coupled with poor augmentation of testing laboratories and infrastructure, hiring of skilled personnel has crippled the CDSCO and state authorities' effective functioning. In the case of Ranbaxy, the complaints were related to violations of Standard Operating Procedures and not because of product quality defaults. India has the maximum number of FDA approved plants outside US.

Over 300 plus Indian pharmaceutical manufacturing units have EU mandated GMP certificates, while the largest number of DMFs (Drugs Master Files) approved in US are from Indian Generic firms. A large segment of our drugs manufacturing units are already qualified with Indian GMP.

❖ Stamping out spurious drugs

Deccan Heral, February 23, 2014

On November 25, 2013, Wockhardt group CEO Habil Khorakiwala received a

letter from the US Food and Drugs Administration flagging several shortcomings of the company's two drugs manufacturing units at Chikalthana and Waluj, both in Aurangabad district of Maharashtra.

The two units were inspected by an FDA team simultaneously between July 22 and 31, 2013, to prepare the warning letter on the deficiencies of the plants that manufacture drugs, which Wockhardt exports to the USA. The company is expected to comply with the FDA norms to remain in the US market.

The scanner on Wockhardt is relatively new but the production units of Ranbaxy at Paonta Sahib, Mohali, Tonsa and Dewas were under the FDA scrutiny since 2006 when the company consolidated its market in the USA. The US regulator issued several warnings and inspected the facilities before putting Ranbaxy on notice.

In May 2013, Ranbaxy pleaded guilty to felony charges relating to the manufacture and distribution of certain adulterated drugs made at the company's manufacturing facilities in Paonta Sahib and Dewas, and agreed to pay $ 500 million as damages.

In September 2013, Ranbaxy's Mohali unit too came under prohibition followed by the January 2014, ban on the Toansa facility, where the FDA inspectors, among other deficiencies, noticed flies too numerous to count in the sample preparation room. The firm is now left only with its Ohm Laboratories in Gloversville, New York, to cater to the US market, which constitutes almost 35 per cent of the Ranbaxy's global sale worth $ 2.3 billion.

“Ranbaxy was given a long rope. How can they be so casual when it involves thousands of crore worth of export market,” wonders S Srinivasan of the Vadodara-based non-governmental organisation Low Cost Standard Therapeutics (LOCOST). According to Margaret Hamburg, Commissioner of American drugs regulator USFDA, strong and smart regulation in a clear, predictable and transparent ecosystem creates a level playing field for all players in the market.

But why the Indian drugs regulator – Central Drugs Standard Control Organisation – or even the UK regulators could not pick up these flaws in Ranbaxy units? The difference, officials explain, lies in the inspection process adopted by different regulatory agencies. “For instance, let’s assume, there are 30 industrial processes to be followed while making a medicine named “A”.

Let us also assume the process involves initiating a particular step on the 15th day. Now, if a company does it on the 17th day after ensuring that the chemicals do not degrade in those two days, we will still get the drugs of right quality at the end. It will be all right for CDSCO. But the USFDA will call it an adulterated product because the process was not followed in toto,” explains an official of the union health ministry.

Officials and public health specialists hint at how the global pharma industry

pick up isolated cases and cleverly mix up separate issues related to spurious drugs, counterfeit or look-alike drugs and not-of-standard drugs to project Indian pharma industry in a bad light. “There are quality issues no doubt, but these should not be used as a non-tariff barrier targeting Indian products,” says Aradhana Johri, secretary in the department of pharmaceuticals in the Union Ministry of Chemicals and Fertilizers.

The multinationals, say industry sources, mix up intellectual property issues (trade mark violations), tax violations (inter-state movements) and technical issues (storage problems can make drugs sub-standard) with spurious drugs manufacturing to propagate a campaign which is seriously threatening the existence and credibility of Indian small-scale drugs manufacturing sector.

“Simply speaking, counterfeit refers to unlawful use of brand names that hurt commercial interests of a company while fake refers to products that do not contain any medicine or substandard ingredients and hence are harmful to public health,” explains C M Gulhati, a former consultant to the World Health Organisation and the editor of a pharmaceutical industry

journal. In a 2009 survey, CDSCO found only 0.046 per cent (11 samples out of 24,136) of drugs in retail pharmacy as spurious. These 11 samples were not accepted by the manufacturers as their genuine products. The government's own past estimates suggest 8-10 per cent sub-standard medicine that can happen for a variety of reasons including storage problem.
Storage problems

Improper transportation and storage of medicines is a serious problem in the country. Many quality products turn sub-standard by the time they reach consumers. “In the semi-urban areas, many retail chemists do not have functioning refrigerators. Most chemist shops sell chocolates and find it more profitable to stock them in refrigerators rather than medicines. Others switch them off on weekly holidays to save on electricity expenses. In many places power load shedding for 8 hours or more a day is a routine. Temperature sensitive drugs are bound to degenerate in such an environment,” says Gulhati.

Under the current regulations, manufacturers are hauled up for sub-standard drugs while the actual responsibility lies with either distributors or retailers or both. “There is a need to revisit the law,” he said.

The false propaganda leads to tightening of rules, which eventually come as an obstacle for small and medium scale industry. In the last decade, almost 40 per cent SSI units had been closed and setting up a new pharma unit now costs 10 times more than what was needed before these legislations.

“From the government, we have launched the cluster schemes in which Rs 20 crore would be provided to set up common facilities needed for quality control like effluent treatment plant,” says Johri. “Had we been so bad, we would not have exported medicine worth $ 15 billion to over 150 countries. As many as 360 manufacturing facilities are FDA approved, which is the largest outside

the USA," says the health ministry official.

In the presence of Hamburg, India and USA signed a statement of intent with the underlying purpose of improving the Indian drugs regulation standards using the US expertise.

One of the components of the agreement is FDA intimation to respective regulatory authorities before undertaking inspections, so that host-country inspectors may join inspections as observers.

"We are not here to tell the Indian regulator how to do their job. But for companies that want to sell their products in the US marketplace, they do need to comply with our standards and practices and expectations, and we think that through greater collaboration we can enhance understanding about what our standards and expectations are," says the FDA commissioner.

❖ Fake products in high demand

The Jakarta Post, February 28, 2014

The Indonesian Anti-Counterfeiting Society (MIAP), the Food and Drug Monitoring Agency (BPOM) and the US Embassy have stepped up efforts to raise awareness about the dangers of counterfeit medicine and cosmetics.

MIAP chairperson Widyaretna Buenastuti said such awareness was very important to stop the distribution of fake drugs and cosmetics as it could reduce the demand.

"When we reduce the demand, we automatically reduce the distribution as the producers stop producing them. This is what we will be doing so that fake products will have no place in the country," Widyaretna said.

BPOM chairman Roy Sparringa said he supported the MIAP campaign, since counterfeit drugs and cosmetics could be harmful to health and could result in death.

"We have conducted a number of operations against the products, including shutting down 129 websites selling fake medicine worth Rp 5.4 billion [US$464,400] last year and an operation in Jakarta and other locations where malaria is endemic, such as Papua and East Nusa Tenggara, to stop the distribution of counterfeit malaria drugs," Roy said.

US Ambassador Robert Blake said the campaign could also help protect intellectual property rights. Blake said that the US government and Indonesia had the same view on the issue as both nations were concerned with providing access to safe and original medicine.

❖ Is your medicine a fake? Government report warns counterfeit drugs are flooding India

Daily Mail, March 04,2014

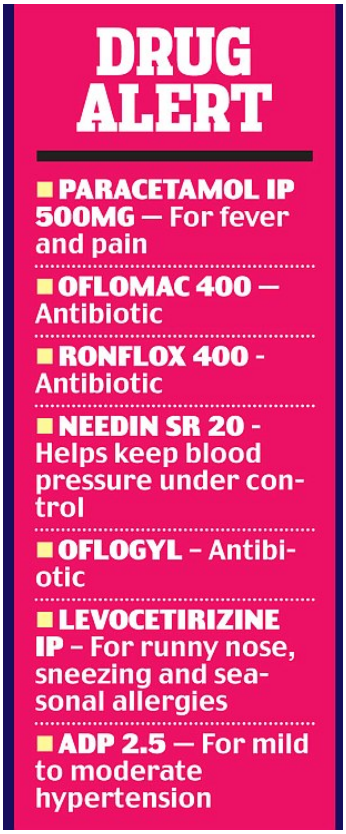
There is a high chance that the medicines prescribed routinely may not be helping people as they are just duds.

Drugs as common as paracetamol and certain antibiotics, readily available at chemist shops, may be fake and not of standard quality, a government report has warned.

In January 2014, at least 32 medicines sold in hospitals and chemist shops across India, including the national Capital, have failed government tests and have been declared 'not of standard quality' by the Health Ministry's Central Drugs Standard Control Organisation (CDSCO).

The ministry has recently put several medicines that are commonly sold in the market on high alert. Paracetamol tablet IP 500 mg, which is a widely used over-the-counter pain reliever and antipyretic (used to control fever), is one of them.

The drug commonly used for headaches and other minor pains, which is manufactured by a Chennai-based company, has failed the government test.
Similarly, Needin SR 20, which is used to control blood pressure, and RONFLOX, an antibiotic manufactured by a company in Himachal Pradesh, have been found lacking.



Another commonly-used drug Angizaar 50 tablets, prescribed for diabetes and hypertension, has been put on alert by the ministry.
"The drugs that failed different tests ranging from colour, weight to dissolution have been put on high alert.

"The drugs have been withdrawn from the market by the respective CDSO branches in the area where they were manufactured or were being distributed," said a senior health ministry official.
"Joint surprise checks are being conducted with the state drug controllers to check the quality of drugs on monthly basis. Under such checks, samples are drawn from government hospitals, retail and wholesale dealers having different pharmacological categories," he said.

The Centre tested around 2,000 drug samples in the last one year and found more than 180 drugs manufactured in different parts of the country to be substandard.

It immediately informed the drugs controllers of the states concerned to stop their distribution and to take action against the manufacturers under the drugs and cosmetics Act, 1940.

"We recently had a meeting to strengthen the drug control system in India. We are set to increase the number of drug inspectors in all zones. The drug inspectors will go to the manufacturing sites and check the quality of the medicines," said Dr Jagdish Prasad, Director General of Health Services, Ministry of Health. The Health Ministry has recently hired 200 drug inspectors to keep a tab on fake medicines. There are more than 10,000 drugs manufacturers in India, while there are more than six lakh chemist outlets.

❖ Govt counters allegations against Indian drugs, drug controller

WebIndia123, March 06, 2014

India today dismissed allegations of its pharmaceutical companies manufacturing substandard drugs and its national drug regulatory authority being corrupt and ineffective, saying these reports were motivated.

A section of foreign and Indian media were carrying out "factually incorrect and largely unsubstantiated news item about the Indian national regulatory authority and Indian drug industry," the Health Ministry said in a statement here.

The intention appears to be to malign the well-earned reputation of the Indian national regulatory authority that is the office of the Drugs Controller General (India) as well as the quality of drugs manufactured by the Indian pharmaceutical industry, the Ministry said.

It took particular objection to a statement attributed to Dr G N Singh, DCG (I) published in an Indian English daily, saying his statement had been distorted and quoted out of context.

Dr Singh was quoted as saying, "If I follow US standards, I will have to shut almost all drug facilities,".

"The manner in which the report has been printed appear to have completely distorted the factual statements made by the DCG (I) to make the news item highly sensational," the Ministry said.

There were adequate provisions under the Drugs and Cosmetics Act 1940 and Rules made there under for ensuring the quality, safety and efficacy of drugs manufactured in India for marketing.In fact, Indian drug products are accepted in more than 205 countries which include both developed and developing countries, the statement said.

The Ministry also questioned an article in New York Times which besides "wrongly" quoting Dr Singh also stated that "WHO estimates that one in five drugs made in India is a fake". The Ministry said the fact was that the WHO had clarified as recently as on August 31, 2012 that there was no such study carried out by the WHO.

"WHO has also regretted that occasionally some individuals in the media and the organisations use WHO references incorrectly and even irresponsibly."
The Ministry also rubbished a report by the author of a Washington DC think tank, the American Enterprise Institute, that termed the Indian Drug Regulator as corrupt.

❖ India needs US whistleblower policies to stop spurious drugs

Business Standard, March 6, 2014

Trade war between India and US refuses to settle down. It shifted to a higher gear during the Uruguay Round Agreement of 1994 and continues till date. It has only picked up speed after the Supreme Court judgement on Novartis over its anti-cancer drug Glivec, where the court declared that Novartis is only tweaking its existing product to gain more exclusivity.

Coincidentally even as the case was being argued in the courts, US FDA (Food and Drug Administration) seemed proactive in penalising a number of Indian companies. Some of the cases were settled out of the court while some attracted severe fines by the US FDA. Indian companies have complained to the Indian government, who are taking the case with US authorities that fine charged by the US authorities are too high.

Apart from these issues a new area of conflict has emerged especially after the Ranbaxy episode. A report in Economic Times says that India has called for a review of the US whistleblower policy as it feels that the generous incentives offered by the US FDA to reveal malpractices in their companies may encourage disgruntled executives to tamper with data to use against their employers.

Clearly there are more than one battle being fought by the two countries on the pharmaceutical front.

Arvind Panagariya, professor of Columbia University, in an article in Business Standard says that Big Pharma (a group of some of the largest pharmaceutical companies operating in the US) has convinced the US government that the country's interests are synonymous with its own. Big Pharma is currently using its considerable clout to pressure US government to designate India as a 'priority foreign country' in its 2014 Special 301 report due on April 30, 2014.

Their grouse is India does not respect the patent laws that are valid in US and most of the western world. But India is not supposed to follow their laws but has to align our laws with those dictated under TRIPS (Trade Related Aspects of Intellectual Property Rights) under the WTO agreement. Commerce and Industry minister, Anand Sharma, has rightly stated that India will never accept a 'TRIPS plus' arrangement. And why should it; just so that Big Pharma can make big money.

While India is on a strong footing on its patent battle with Big Pharma, that might not be the case with its fight with US FDA. The US drug authority has a right to check what enters their country and the process used to produce it. In most of the cases that have been raised by the US FDA, Indian companies have genuinely not followed the best trading practice. It is in the interest of the companies themselves that they follow the best practices that are globally accepted rather than the lenient ones followed in India. Indian companies however, have a point that their view should be heard before the US FDA pronounces its judgement.

However, it is on the whistleblower case that India is on its weakest wicket. Dinesh Thakur, the whistleblower in Ranbaxy's case walked away with a $48 million compensation for pointing out how the company falsified its test data. Indian companies feel that the compensation is too high which might prompt other employees to tamper with data.

It is very unlikely that this would happen. If we look at the Ranbaxy case, Dinesh Thakur noticed that same set of test numbers were reported by the third party which was conducting the clinical trials. These were tests that were not conducted by Ranbaxy. Even if an employee tampers with the data at the companies end a separate set of data is maintained at the third party which the company can produce in its defence. There are other checks and balances which prevents such an incident to take place.

In fact, if such violation of data is noticed then USFDA should be more stricter with its policy and ban the company from selling it product by using unethical means, but after giving the company a fair chance to protect itself. Moreover Indian FDA too should come out with similar policies to prevent spurious drugs that are flooding the market.

❖ Allegations of fake India-made medicines baseless: DCGI

The Times of India, March 09, 2014

The drugs controller general of India has contradicted a New York Times report reprinted in TOI on February 16 — 'India-made drugs trigger safety concerns in US'. The report made some "baseless, irresponsible and malicious" claims by stating that WHO estimates that one in 5 drugs made in India is a fake, a release issued by the public information cell of DCGI said.

The fact is that the WHO had clarified as recently as on August 31, 2012 that there was no such study carried out by the WHO. They have also "regretted that occasionally some individuals in the media and the organizations use WHO references incorrectly and even irresponsibly", the release said.

It said a section of the print media — Indian as well as foreign — has been publishing "factually incorrect and largely unsubstantiated" news "to malign the well-earned reputation of the Indian pharmaceutical industry".

India exports around $15 billion of pharma products, including vaccines to most of the countries in the world. There are about 360 USFDA-approved drug manufacturing units in the country. There are also over 150 European Directorate for the Quality of Medicines (EDQM)-approved drug manufacturing units. As recently as 2013, the WHO has declared the Indian national regulatory authority functional for vaccines against stringent international parameters.

The release said harmonization of regulatory standards has not yet been achieved even among the three major regions — North America, Europe and Japan. A product from India complying with the US standards would still have to comply with the regulatory requirements of Japan if it has to be exported to Japan. India has its own law governing the regulatory norms and standards. Manufacturers have to conform to these norms and standards. However, any Indian pharmaceutical product entering the US market complies with the US standards.

It added that Indian laws and India's robust regulatory framework ensure high standards of quality, safety and efficacy of drugs manufactured in the country.

❖ Only 2% of drug samples are of not-standard quality, says regulator

The Hindu, March 10, 2014

During nationwide surprise checks last year, Jammu region had the highest number of substandard drugs

A special nationwide drive to check the quality of drugs by the national regulator for pharmaceuticals and medical devices has found that just a little over two per cent of the drug samples were not of standard quality. No spurious drugs were detected.

The surprise checks, which the Central Drugs Standard Control Organisation (CDSCO) conducted together with the State Drugs Controllers to test the quality of drugs on a monthly basis, also showed that the Jammu region had the highest number of substandard drugs. Of the 156 samples collected from government hospitals and retail and wholesale dealers in April 2013, only 27

were not of standard quality. The State Drugs Controller has been asked to stop further distribution of these drugs in the market and initiate action against the manufacturers under the Drugs and Cosmetics Act, 1940.

As part of the surveillance of drugs made in India, the CDSCO collected 1,710 samples in December 2012 from the manufacturing sites falling within the zonal and sub-zonal offices nationwide. Of these, 1,123 were tested at its drug laboratories and only 26 were found to be sub-standard.

Of the 229 samples collected from the north zone, 219 were tested, and seven were found of sub-standard quality. The south zone collected 278 samples, and 112 of them were tested. All of them were found to be of the laid-down standards. The west zone reported seven cases of sub-standard quality out of the 161 samples tested. One sample from the east zone did not conform to the standards. A total of 73 samples were lifted from this zone, but only 27 were sent for testing, the surveillance report said.

❖ New tech can check whether your medicine is fake

Business Standard, March 10, 2014

The technology to differentiate between genuine and fake drugs would soon be at your disposal.

The move comes at a time when the domestic pharma industry is battling with issues relating to quality of drugs both within and outside the country.
While India is struggling to monitor counterfeiting, various government departments such as health, fertilisers, education and others are planning to adopt non-clonable identification (nCiD) technology in various projects and products, including medicines.

This technology will not only prevent duplication of identification or packaging, but will also enable consumers and regulatory agencies to test genuineness of a product.

Bilcare, the innovator of the nCiD technology, has licensed the same to public sector enterprises such as the Telecommunications Consultants India Ltd (TCIL) and Indian Telephone Industries Ltd (ITI) which are implementing it in government as well as private sectors. While the technology is already installed by many of the government departments and agencies such as the Delhi Police and Department of Fertilisers, TCIL is in advance talks with the health ministry to make nCiD labels mandatory on medicines, Bilcare Executive Director and Chief Scientific Officer Praful R Naik said.

According to Naik, some private sector companies such as Lupin and Biocon are already using the technology for their exports.

The nCiD technology was also used by the Delhi Police for identity cards for the entire force as well as for other staff deployed during the Commonwealth

Games. Besides, other departments such as the Election Commission, National Jute Board and Department of Supplies and Disposals are also evaluating proposals to induct the technology for various purposes.

The nCiD chips comprises nano-micro particles of diverse size of several metals. When a micro quantity of this metal composite is randomly embedded on to the chip's base, it creates a distinctly unique and non-reproducible pattern.

This pattern when scanned with a magneto-optic sensor results in generation of a complex magneto-optic digitised image information, which enables real-time communication through internet or mobile gateways. For instance, once nCiD chips are installed on medicine packs, consumers can access details such as its manufacturing site, date of manufacturing, expiry etc through a nCiD reader available with the chemist.

"Such a unique feature is completely non-reproducible even by the inventors themselves, and hence non-clonable. This unique feature of non-reproducible pattern which can talk and communicate sets the nCiD chip apart from other communicable embedded security measures like smart chips or non-communicable authentication technology," says Naik.

According to Naik, India has a potential market of over Rs 1,000 crore for nCiD technology. Bilcare currently has a manufacturing facility in Singapore, with a capacity to produce four billion chips. Apart from India, it is currently supplying to Indonesia, China and Australia from this factory. With a portfolio of 25 patents worldwide on the technology, Bilcare is planning to introduce the technology in many other countries.

❖ No ACs in pharmacies, drugs prove ineffective

The Times of India, March 12, 2014

'Store in a cool, dry place' is a standard prescription for storage of most medicines. At many pharmacies in the city, this often translates into tossing them onto racks that are exposed to dust and heat.

Recently, when a team from the Directorate of Drugs Control undertook a routine inspection in the city, they found a carton of anti-tetanus shots with a wholesale dealer stored without refrigeration. "This is shocking," said Dr Jacob John, a former virologist of the Christian Medical College, Vellore. "What officials were looking at was a box that carried potentially ineffective vaccines," he said.

According to the drugs and Cosmetics Act, vaccines should be stored in temperatures ranging between 2 C and 8 C. Incorrect storage could lead to vaccines being rendered ineffective.

While the carton of anti-tetanus shots caught officials' attention, poor storage of medicines is in plain sight at pharmacies across the city.

Close to five years after the Directorate of Drugs Control gave out a directive to pharmacies to equip themselves to provide optimum temperature for drug storage and began issuing licenses to only those that had airconditioners, several pharmacies continue to operate without proper storage facilities. When TOI visited a few pharmacies, it found that even those that had airconditioners had switched them off.

"It isn't a profit-making business anymore. I can't afford the electricity bill if the AC is kept on all day," said a local pharmacist in Arumbakkam.

While vaccines have to be stored in a refrigerator, most medicines can be stored in a room temperature of below 25C. Experts say that if this is not followed, the medicines will die well before the day of expiry. Their potency, stability and efficacy are directly related to temperature.

"Pharmacists fail to realise the importance of maintaining the temperature while storing drugs. Fluctuating temperatures could result in the medicines losing their potency," said M Bhaskaran, former director of Drugs Control. He said while many of the pharmacists store vaccines and sera in refrigerators, they ignore pills that need refrigeration.

"We need pharmacists who know their subject behind the counters, not those who are not qualified and fail to understand the seriousness," said Baskaran. "The Act may not say airconditioners have to be installed in pharmacies, but it is obvious drugs can't survive in our weather if stored without ACs," he said. Pharmaceutical experts say poor storage is a more serious problem than spurious drugs as more temperature-sensitive medicines are being introduced.

While loss of potency is an obvious outcome of poor storage, it could also result in allergic reactions, kidney and stomach problems, say doctors. "Many pharmacies don't have generators either," said gastroenterologist R Surendran.

Doctors caution that a patient may end up taking a large number of ineffective drugs to cure a disease, leading to substance abuse.

Officials maintain that all pharmacies set up post-2007 have airconditioners. "Licenses are granted only after we know they have a refrigerator and a cold room," said the director of Drugs Control, Abdul Khader S. "Every time we inspect a store, we also check the temperatures that medicines are stored at in the refrigerators," he said.

Druggist associations admit there are pharmacies in the city that operate without airconditioners. "We are in the process of identifying these and convincing them to get better storage facilities," said S Elangovan of TN Chemists & Druggists Association.

❖ 2.3% of tested drugs found to be of sub-standard nature: DGCI

Jagran Josh, March 20, 2014

Drug Controller General of India (DCGI) found that 2.3% of all the drugs tested by it were of sub-standard nature. This was revealed by the surveillance which DGCI carried out since December 2012. The results of the surveillance was released by the DGCI on 19 March 2014.

During the surveillance, DGCI collected as many as 1123 samples were collected and tested. Samples were drawn from government hospitals, retailers and wholesalers between April and December 2013 by joint teams of central and state drug controller officials.

The test revealed that of 1123 samples tested, 26 drug samples failed to qualify the test. Moreover, the highest concentration of sub-standard drugs was found in Jammu & Kashmir followed by Himachal Pradesh.

The drugs which have been identified by DGCI as sub-standard are: (i) Cefden-O (Cefixime & Ofloxacin Tab); (ii) Fixin IR-200 DT (cefixime Tab); (iii) Rabed; (iv) Kindac-P (Aceclofenac & Paracetamol Tab); (v) Biodox Bolus; (vi) Ranodom (Omeprazole Magnesium & Domperidone Tab); (vii) Orymox-250 DT Tab; (vii) Diclogold-M (Paracetamol, Diclofenac Sodium & Mag. Trisilicate Tab); (viii) Coldgard (Paracetamol, Phenylephrine HCl, Chlorpheniramine Maleate, Caffeine Tab); and (ix) Pre-MR (Diclofenacv Pot., Paracetamol & Chlorzoxazone Tab)

The results of the surveillance comes in the wake of regular ban on imports of Indian drugs by United States Food and Drug Administrators (USFDA). Recently, USFDA banned the import of drugs and drug ingredients from leading Indian manufacturers including Ranbaxy Laboratories and Wockhardt citing quality concerns.

The ban threatened the image and market share of 14 billion dollar of Indian pharmaceuticals sector in the United States. India is second only to Canada as a drug exporter to the United States, where it supplied about 40 percent of generic and over-the-counter drugs.

The DGCI conducted its last large-scale country-wide survey in 2009 for the period 2003-2008. It had collected over 24000 samples and tested them for genuineness amidst some allegations which termed India as a major source of fake drugs.

The study found that only 0.046% of the drugs in circulation were actually spurious and 6 to 7.5% of the drug samples tested failed quality standard tests annually.

❖ AIIMS life-saving drugs of poor quality: HoD to chief

Indian Express, March 29, 2014

The head of the department of anaesthesiology at AIIMS has written to the medical superintendent of the hospital over "poor quality of life-saving drugs" after her husband suffered reactions from two drugs provided by the hospital.

The second drug prednisolone was administered to control the reaction from the first drug. It is a common drug used to treat inflammatory and auto immune conditions.

In her letter to the medical superintendent on March 25, head of anaesthesiology department Dr Chandralekha quoted the brands of the drugs supplied by the hospital and sent samples of the drugs to the medical superintendent for testing.

"Such spurious life saving drugs should be withdrawn and banned immediately… in the "interest of patient safety. Prednisolone is a life-saving drug and used in emergency situations quite often. I am seriously concerned with substandard life-saving drugs,"she said.

In her letter, Dr Chandralekha said her husband first developed urticaria or deep rashes all over the body after taking amyril, a medicine to control blood sugar, "which he was taking for 3-4 years". "His diagnosis was "drug reaction" and for five days several anti-allergens, including prednisolone, were administered.

"Despite giving such heavy doses of anti-allergic drugs, response to treatment was not satisfactory, rather negligible," Dr Chandralekha wrote.

"It was decided to stop tablet amyril immediately which he was taking for the last 3-4 years and change the prednisolone brand. Advice was taken and the brand was changed and procured from the market," she said.
The same drug from a new brand procured from outside the hospital, and stopping the other drug, resulted in a "dramatic" response to the treatment within eight hours, she said.

"This problem was detected just because we are living on the campus with a pool of doctors around us, watching the patient personally," Dr Chandralekha.
The brand of the drug amyril, purchased by the hospital, was also changed recently, she said.

Sources said the supplier of the emergency drug predinsolone, which Dr Chandraleka quotes as having been given to her husband, has already been barred by the institute.

"We are investigating how a drug of this company still entered the hospital supply chain," an official said.

Medical superintendent of AIIMS Dr D K Sharma said while individuals can have allergic reactions to a variety of substances, including drugs, and, as in all such complaints, the drugs have been sent for testing.
"We have an elaborate drug safety mechanism… after the drugs come from centrally tested laboratories, we run our own tests. But whenever we get such complaints, we test the drug in question again," Dr Sharma said.

❖ Kashmir 'safe haven' for firms selling spurious drugs

Greater Kashmir, April 01, 2014

Putting lives of people to risk, the drug manufacturing companies operating outside the State have managed to sell large quantities of spurious drugs in Kashmir, reports suggest.

Documents available with Greater Kashmir show that Drug authorities of the states of Himachal Pradesh and Haryana have acted against some manufactures by suspending their product permissions.

Out of the 27 drugs found to be substandard here recently by state's Drug and Food Control Organisation (DFCO), majority of these drugs have been manufactured by companies from the states of Uttarakhand, Himachal Pardesh and Haryana.

Earlier this month, while taking a note of the spurious drug scam, the High Court in a public interest litigation filed by Dr Nisar-ul-Hassan through advocate Bhat Fayaz sought action taken report against the pharma companies found to have supplied substandard drugs in the state. The tests were conducted by the Central Drug Laboratory Kolkata and Regional Drug Testing Laboratory, Chandigarh.

The documents show that the product license for the sale and distribution of drug Traxol 100, manufactured by G.M.H Organics, Baddi Solan, was suspended for 45 days with effect from 8 January 2013 to 22 December 2013 after the drug with batch no 1012043A supplied here was found to be substandard.

The drug Dicloflam injection manufactured by M/S Visa Drugs and Pharmaceuticals Private Ltd, Sai Road, Baddi, bearing batch no VAI02K003 10/2014 earlier failed in the test of particulate matter following which the product permission was suspended for two months with effect from 8 November 2013 to 7 January 2014 by the Himachal Pradesh Government.
Also the drug Hope 1 of batch no 22446 Oct/2014 manufactured by R K G Pharma Private Ltd, 12-th Mile Stone Mathura Road, Faridabad, Haryana, was found to be substandard following which the product permission of the manufacturing unit was suspended by the Haryana government. The drug license of the manufacturer Orisiosn Pharmaceuticals, Ambala, Haryana, was suspended from 21 August 2013 after the drug Cureclox with batch no ORC-120 November 2012 was found to be not of standard quality.

The manufacturer Nitin Life Sciences Ltd, Karna, was issued show cause notice after the drug Nimeth-Inj manufactured by it turned out to be substandard.

State's Drug Controller, Satish Gupta, said, "The drug companies which have their manufacturing units outside the state have been selling substandard drugs in Kashmir. We have identified some of the companies and have written to the Drug Controllers of concerned states for taking action against those which have been found to be selling substandard drugs." Gupta added that the market vigil has been strengthened and large haul of samples has been made for testing.

❖ Self-certification for bar-coding for drug firms launched

Economic Times, April 06, 2014

The government has introduced self -certification for bar coding of secondary and tertiary level packaging of drugs in order to simply the export procedures. A barcode helps in tracking and tracing the origin of drugs which in turn helps in minimising chances of genuine drugs being considered spurious, sub-standard or counterfeit.

"A self-certification process on compliance of bar-coding requirement on secondary and tertiary level packaging of pharmaceuticals and drugs has been introduced. This will be effective from April, 1 2014," the Directorate General of Foreign Trade (DGFT) has said in a public notice.

The government had asked pharmaceutical companies to build track and trace capability for their exported medicines using barcode technology at three levels of packaging, primary, secondary (like packets) and tertiary (shipper or carton).

Primary level packaging is the first-level product packaging such as bottle, can, jar, tube that contains the item sold.

DGFT said that in this process, an exporter would be required to furnish a written declaration to custom authorities at the time of export regarding compliance of the relevant provisions of bar-coding on secondary and tertiary level packaging on the consignment.

India exports over USD 10 billion worth of drugs annually. The government wants to increase that figure manifold in the next few years. There is a big market for generics in the developed world. Industry experts say the only way Indian pharma firms can tap the market is by ensuring quality, and barcoding will help ensure that.

❖ CSFK concerned over substandard drug consumption

Rising Kashmir, April 07,2014

Civil Society Forum Kashmir (CSFK) Monday expressed shock and dismay over recent news reports making fresh disclosures about substandard drugs being consumed by the people in Kashmir.

A spokesman of the forum in a statement issued here expressed serious concern over government inaction in controlling and regulating the quality of medicines being consumed by the people. “The very fact that sale of spurious and substandard drugs is continuing unabated with full knowledge of the drug control officials is proof enough that government is taking Kashmiri people for granted as there is complete lack of accountability on all fronts particularly in matters related to health of the people at large,” the spokesperson said.

“Government of J&K has not only miserably failed in implementing the draft drug policy that was revised with due intervention of the subject experts of CSFK but has displayed total inaction in fulfilling its tall promises of upgrading drug testing facilities of the state and making alternative drug testing laboratory functional at Bemina, Srinagar for which a detailed proposal was also submitted to the government by CSFK,” the spokesperson further added. The statement read government’s face-saving measures taken at a time when spurious drug scam surfaced in the state like setting up of J&K Medical Supplies Corporation and streamlining drug procurement on the pattern of Tamil Nadu Medical Services Corporation have proved to be a damp squib and a non-starter in spite of the fact that more than a year has passed ever since this Corporation was set up but it is still quite far from being functional since no sufficient staff or funds have been made available to the said Corporation so far. Same is the fate of other provisions of the draft drug policy like implementing generic drug prescribing and sale within government hospitals and issuing drug licences to qualified pharmacists only. Government has miserably failed on every front.

“With this kind of pathetic state of affairs CSFK has threatened to come on roads and protest against the government inaction and dilly-dallying attitude regarding this vital aspect of public health. CSFK urges upon the concerned ministry and health authorities of the state to fulfill its promises made to the people from time to time and ensure sale of standard quality drugs besides implementing all provisions of the draft drug policy and issuing drug licenses to qualified personnel only. Registration of unqualified people as pharmacists and issuing drug licenses to them must stop forthwith and qualified pharmacists must be employed in all hospitals of the state,” reads the statement

The spokesperson said, “J&K Medical Supplies Corporation must be provided with all requisite facilities and made fully functional besides upgrading the drug testing facilities on a war footing basis.”

❖ North Korea's Illicit Economy Includes Fake Viagra and Smuggled Ivory

The Wire, April 15, 2014

North Korea, increasingly in need of cash to pay for things like armies, missiles, and food, has developed a rather healthy illicit economy that includes DVD trafficking and drug smuggling. A detailed new report from the Washington-based Committee for Human Rights in North Korea, "Illicit: North Korea's Evolving Operations to Earn Hard Currency," chronicles the various money-raising methods of Pyongyang, which have been crucial to the Kim regime's "self-preservation" since the 1970s.

The report looks at three stages of North Korea's illicit economy development, which began in the 1970s with government officials trafficking drugs and counterfeit cigarettes to diplomatic outposts, and later moved into counterfeit currency production. Today, a number of forces are threatening leader Kim Jong-un's grip on power, including brutal international trade restrictions that have only strengthened the power of the underground markets. Those markets originally developed as a "survival mechanism" for the most desparate North Koreans, but money and food became harder and harder to come by, the borders have become more porous and ability to earn money through the illicit economy has become more important.

Fake pharmaceuticals, counterfeit cigarettes, and products from endangered species like rhino horn and ivory are recent examples of the illicit trade. In fact, they have now surpassed North Korea's reliance on manufacturing knock-off drugs and counterfeiting foreign bank notes, reports Julian Ryall at The Telegraph. The global campaign of counterfeit distribution was potentially worth millions of dollars for the economy. A seizure of 3 million cartons counterfeit cigarettes was valued at $3 million, while the discovery of half a million tablets of Captagon, a synthetic stimulant, was estimated to be worth $7 million.

Other recent examples include the North Korean officials caught in 2004 smuggling 150,000 Clonazepam sedative pills through Egypt, and the production of fake Viagra tablets. Officials have also smuggled used cars and gems across international borders, trafficked DVDs, and sold pornography.

Tourism, while very limited and highly controlled, is one of the legal ways that North Korea generates income. Over the weekend, the country opened its marathon to foreign amateurs for the first time in 27 years, and the country has said it will complete a luxury ski resort to attract more tourists. But a bizarre story out of London today suggests that foreigners have the right to be wary. Police had to step in after North Korean embassy officials turned up at a North London barbershop that used an image of Kim Jong-un to promote a 15 percent discount on haircuts.

"I told them this is England and not North Korea and told them to get their lawyers," Mo Nabbach, who runs M&M Hair Academy, told the Evening Standard. "We did take it down but then some of our clients told me to put it

back up because we have a democracy here." Someone better tell Mike Huckabee.

❖ North Korea branches out into ivory, fake cigarette and pharmaceutical trade

The Telegraph, April 15, 2014,

North Korea has diversified its business model for earning hard currency, shifting from a reliance on manufacturing drugs and counterfeiting foreign bank notes to smuggling products from endangered species, fake pharmaceuticals and counterfeit cigarettes.

The details of Pyongyang's methods of earning the funds it needs to pay for its nuclear and missile programmes are spelled out in a study released on Tuesday by the Washington-based Committee for Human Rights in North Korea.

The 115-page report says Pyongyang has been producing narcotics and smuggling them abroad through the diplomatic bag and printing high-quality forgeries of foreign currency since the mid-1970s, all part of the Kim regime's "fundamental strategic objective" of self-preservation.

There has been a shift in recent years, however, with the emergence of a privatised market economy that the authors describe as "a criminal one that is feeding off the suffering and deprivation of the population".

The smuggling by North Korean diplomats of rhino horn and ivory also appears to be a more recent development, the report says, with a North Korean citizen arrested in 2012 in Mozambique as he attempted to smuggle 130 pieces of ivory, with an estimated value of $36,000, out of the country.

❖ Spurious drugs in J&K

Kashmir Times, April 15, 2014

Shortage of medicines and life saving drugs in the hospitals and basic healthcare centre across the length and breadth of Jammu and Kashmir speaks of the failure of the government in providing the basic facilities to its common masses. Moreover, it also speaks of government's apathy towards its people as a result of which spurious drugs and quacks are assuming alarming proportions not only in the urban centres but also in rural and far flung areas. In fact, sale of spurious drugs by the unscrupulous chemists and druggists in various parts of J&K are posing a serious threat to the lives of the innocent people. This is particularly so in the case of rural folks who find it difficult to locate a doctors in the health centres and trek long distances to the urban areas and land in the clinics run by quacks to fleece the innocent

people on the pretext of providing cheap medical treatment. In certain cases, the quacks are operating without any check from the health regulatory bodies of the government. Similarly, some of the clinics being run by unscrupulous people are cashing on the innocence of the people. As per government's own confessions majority of such clinics are neither registered nor recognized by the concerned authorities. These people are allowed to play with the lives of the people. So far as the sale of medicines is concerned, there are more than half the shops which are not having any license, a pre-requisite from the government agencies. These chemist and druggist shops are considered as the biggest culprits for the sale of spurious drugs to the people. The government's drive against such shops a few years lead to the cancellation of more than 50 percent licenses in the state and closure of their shops as they were fulfilling the required qualifications. Even the suggestions of the Indian Medical Association (IMA) for a ban on the sale of medicines and life saving drugs across the retail counters without any medical prescriptions have been ignored in the case of J&K. The problem has become acute due to free sale of drugs to anybody from these shops and without any check. The regulatory authorities are sleeping over these serious issues. It is only once in a blue moon that authorities wake up from their deep slumber to make a surprise check of these shops and everything is forgotten after a while. The unscrupulous traders in this sector are having field and making a quick buck in the whole process.

❖ North Korea diversifies drug smuggling, counterfeiting, study says

Fox News, April 21, 2014

The ruling family despots of North Korea, always desperate for hard currency to finance their lifestyle and loyalties, are now funneling increasing amounts of drugs, counterfeit goods and currency, as well as legitimate trade, through China, according to a study released last week that is sponsored by a committee that monitors the country's boggling human rights abuses.

As part of the change, blatant government-sponsored criminal activity appears to be shrinking in comparison to a combination of "quasi-private production and crony capitalism" focused largely on its expanding relationship with the Middle East, Africa and especially China -- but still backed by the full brutality of the regime, according to the report from the Committee on Human Rights in North Korea, a bipartisan group based in Washington.

In the process, the regime now dominated by third-generation dictator Kim Jong-Un is increasingly making its drug smuggling and other illegal activities harder to detect, as well as turning to a broad array of more legitimate ways to bring in the cash, especially an increase in trade with its huge neighbor.

The diversification includes the increased sale of natural resources, expropriation of the wages of North Korean laborers sent abroad to Africa and

the Middle East, and even profiting from the increased number of cellphones circulating in politically favored hands in Pyongyang and other cities.

Those changes call for new responses from Western countries that previously used sanctions largely to cut North Korea off from the international financial system, the report suggests -- though what those responses might be, it does not say.

“The case of human rights in the DPRK exceeds all others in duration, intensity and horror.” said Michael Kirby

Moreover, the study warns, “the North Korean regime will almost certainly see this as undesirable” -- a grim form of understatement when dealing with a saber-rattling power with nuclear ambitions that a U.N. human rights investigator called “a totalitarian state without parallel in the contemporary world.”

The report was prepared by Sheena Chestnut Greitens, an academic at Harvard and a senior fellow at the liberal Brookings Institution in Washington. Greitens told Fox News that one of the implications of her work is that the country’s economic changes “suggest it is not under as much pressure from sanctions as before,” and that the regime has proved to be “very good at adapting” to international financial pressure.

But even while noting that the regime has moved away from total control of all its cash-producing activities, and even, as the report puts it, developing a “symbiosis” between state-run enterprises and “essentially private” firms, Greitens warns that North Korea has a long history of camouflaging its activities, and that “we have possibly not figured out” how its older illicit activities are continuing.

“The U.S. and the international community need to do more research on all of this,” she says.

The study’s publication comes at another sensitive moment in the relationship between North Korea and the outside world, when the combination of its outlandish human rights behavior, belligerent nuclear ambitions and bloody internal purges have brought international concern to a simmering point -- but without much hope of resolution.

Last Thursday, the U.N. Security Council held a closed-to-the-press meeting to discuss the North Korean human situation at the behest of the U.S., France and Australia. Russia and China, tacit supporters of the Kim regime, did not attend the session.

Among other things, attendees were told by Michael Kirby, head of a U.N.-appointed commission looking into North Korean human rights abuses, that “the case of human rights in the DPRK”-- an acronym for the country’s formal self-designation as the Democratic People’s Republic of Korea -- “exceeds all others in duration, intensity and horror.”

Kirby says his commission recommends targeted sanctions "against those individuals most responsible" for North Korea's horrors, and referral of the atrocities to the International Criminal Court in the Hague.

According to Greitens' report, however, figuring out who to target, and how, could be more of a problem than ever before.

Among other things, due to its isolation from the West, North Korea is less vulnerable to general financial sanctions than other rogue states, such as Iran. "Unlike Iran, North Korea has no major foreign banks operating inside its territory," the study notes, "and its industries do not rely to the same extent on the dollar as an international reserve currency."

Indeed, the study says, "much of North Korea's banking today is done in China"-- and its increasingly complex relationship with its huge neighbor is one of the major reasons behind its new ability to tap sources of international cash.

The fact is that China is more North Korea's mainstay than ever, despite occasional signals from Beijing that it was joining in the pressure to squelch the Kim regime's nuclear ambitions.

"China's trade with North Korea dropped slightly in the first half of 2013, from $3.14 billion in 2012 to $2.95 billion," the study reports. But then it took off again, to reach an "all-time high of $6.45 billion that year, an increase of 10.4 percent over the previous year." In addition to raw resources for China's gaping industrial maw, the tally now includes manufactured goods such as clothing and textiles.

(Until recently all of that trade was managed for the regime by Kim Jung-Un's uncle by marriage, Jang Song-taek, who was suddenly executed late last year in a purge that has now extended to many other members of his family and following. The report cites experts concluding that Jang wasn't turning over enough revenues to the young dictator's own ruling clique.)

The same goes for North Korea's illegal exports, such as drugs, notably methamphetamines. Many more shipments are now being intercepted in China itself, or along the Chinese-Korean border, the study notes -- and North Korea itself has developed a significant drug problem among a population that is clearly able to bypass the government in accessing the drugs, perhaps because North Korean civilians also manufacture them to smuggle on a freelance basis.

A major result of the increased China trade, legal and illegal, is the development of more open consumer markets in North Korea, where the foreign currency most common by far is the Chinese yuan -- another sign of the growing economic integration of the two countries.

As a result, something akin to free enterprise has arisen: "In North Korea, it is now possible to operate a variety of businesses in a new business structure,"

the study says, in which private entrepreneurs take the earnings from technically "state-owned" enterprises in exchange for "revolutionary fund" or "loyalty offerings" of as much as 70 percent returned to the regime. This new arrangement, the study says, is "arguably, the basis of power in contemporary North Korea." The question is whether it makes the Kim regime likely to change further, or for the better, under new forms of pressure.

Andrew Natsios, former head of USAID in the Bush administration and co-chairman of the committee that sponsored the new study, argues that the changes are a sign that "the government is beginning to lose control." But that is not necessarily good news: "it could possibly increase the regime's panic; it depends on how threatened they are."

It also, he feels, increases the potential for Chinese involvement: "they are increasingly alarmed. They don't like the drug trade." But in the end, he admits, as does the study, that "our information is inconclusive. We just don't know a lot of things."

Except that the nightmare government in North Korea is murderous, unpredictable, and getting richer off its relationship with China, a country that seems to be doing the opposite of clamping down economically on its outlaw trading partner.

❖ Beware of counterfeit cosmetics

The Financial Express, April 27, 2014

Rapid Action Battalion (RAB) personnel raided a factory producing fake herbal cosmetics located at a building in city's Lalbagh area a fortnight ago. A photograph of the factory published in a contemporary showed how a young boy was engaged in preparing paste in large containers by mixing a variety of dyes for selling those as face cream of famous Indian brand Ayur. A mobile court which led the drive fined the factory owner Taka 0.1 million (1.0 lakh) for producing counterfeit foreign herbal cosmetics. It was revealed that the factory was making spurious hair gel and cream for skin care for the last two months.

This factory is not a lone small firm producing fake cosmetics. Earlier, we reported in this column that counterfeit cosmetics and toiletries are on sale in large quantities in Dhaka city and elsewhere in the country. Some traders have admitted that the packaging of these fake cosmetics and toiletries are so faultless that they themselves find it difficult to differentiate between the genuine and the adulterated products. They have claimed that though a number of manufacturers are not in the trade now, the products are on sale in the market under their previous brands.

An employee of a cosmetic shop at the city's Moulvibazar said the popular brand of cosmetics they sell are not original. He also stated that they "have to sell adulterated products because of their high demand in the market". The

trader has disclosed that the spurious cosmetics are produced mainly in Lalbagh, Hazaribagh and Kamrangir Char areas and also in some villages at Keraniganj across the river Buriganga.

The police are aware of such trade and crack down on the manufacturers from time to time. There are allegations that the manufacturers of fake products run their business with the help of a section of law enforcers.

Otherwise, how the supply of spurious items, one may assume, can be maintained when the sources of production are fully known to the authorities concerned.

The Bangladesh Standards and Testing Institution (BSTI) is assigned to check cosmetics, food items, beverages, etc., either produced locally or imported, and certify whether those are fit for human health. The use of spurious cosmetics may cause various skin diseases. It is advisable that the BSTI should look into the matter seriously and take measures to stop manufacturing of those counterfeit products with the help of law enforcers.

Reports reaching in Dhaka from various rural markets reveal that unscrupulous traders are again using red dye along with formalin in a variety of fish. They are doing it so that the buyers are attracted because of the fresh look of the fishes. The dye and formalin are mixed in the water in buckets and the new catches are immersed. The fish sellers are using formalin for quite a long time and now dye is added to allure buyers. Health officials at district and upazila levels, in many places, are aware of this unholy practice. But the trade continues unabated. In addition to formalin and dye, DDT is also being mixed in producing dry fish (Shutki), particularly in coastal areas of the country.

On the other hand, the Bangladesh Paribesh Andolan (BAPA), an environmental activists' association, has voiced concern over the bottled water and soft drinks. Most of the consumers are not aware of harmful effects of drinking water in plastic bottles, soft drinks and juices, BAPA says. Beverages in plastic bottles may impair body's immune system. An expert on soft drinks is of the opinion that these drinks contain acid, water and sugar and are not at all useful for health as consumers think. Soft drinks contain neurotoxin, compressed carbon dioxide which contribute to the damaging of nervous system. It is not true that the soft drinks quench thirst. Rather, they consume water from the body.

Such observation on beverages needs serious attention on the part of relevant authorities for the sake of protecting public health and the consumers have the right to know what they are actually drinking.

❖ Warning over low-quality malaria drugs

Myanmar Times, April 28, 2014

Health officials are to set up drug-testing laboratories at 15 border crossing

points in an effort to detect unregulated or low-quality anti-malaria medication entering the country. Last month inspectors found low-quality anti-malaria medication at Tamu in Sagaing Region, on the border with India, an official from the Food and Drug Administration's laboratory department said.
It was the first time the FDA had tested imported medication at the border using its own laboratory, said department director Dr Khin Chit.

"We tested eight kinds of malaria medicine imported from India, and found two kinds to be of low quality. One was FDA-approved and the other unregistered," she said.

She said the FDA plans to release the name of both medicines after the results are confirmed at their main lab in Nay Pyi Taw, adding that they are widely available in Myanmar and often used in private and government-run hospitals and clinics.

Dr Chit Khin said the FDA is planning to open testing labs at 15 border gates.
Deputy director of the health department's National Malaria Project U Thaung Hlaing told The Myanmar Times that the government had prohibited the importation of all types of mono-therapy malaria drugs on the recommendation of the World Health Organization, which instead advocates the use of artemisin-based combination therapy medication.

However, some companies that had already received a five-year approval from FDA when the decision was made have continued to import mono-therapy medication into Myanmar.

He said the health department authorised only the Padonmar brand anti-malarial drug for sale in the market because it is inexpensive and meets quality standards. But some doctors have still been recommending other drugs.

The push to combat fake and ineffective malarial medicine is being driven by the spread of drug-resistant malaria in south-eastern Tanintharyi Region, Kayin State and the highlands of eastern Shan State. About 52 townships are affected, according to health officials.

❖ Sale of spurious and substandard drugs is serious issue: Mirwaiz Umar Farooq

Current News Service, April 28, 2014

In connection with his ongoing antidrug addiction and social reform drive Head of Muthida Majlis Ulema and chairman of All Parties Hurriyat Conference Mirwaiz Umar Farooq Expressed deep anguish over the increasing drug menace among the youth of Kashmir and sought cooperation from all people and agencies associated with the trade of sale and distribution of medicine and drugs in Kashmir. Mirwaiz was addressing a

gathering of people engaged in the trade of medicine as well as the members of different chemist and druggist Associations. He stressed that in order to curb drug addiction it was necessary to curtail the easy acess to drugs and medicines used for this purpose and completely do away with the practise of selling drugs without prescription.

Mirwaiz also expressed his dismay that the serious issue of sale of spurious and substandard drugs, ever on increase in the valley, was not paid any heed to by the government nor did the Govt. have any effective drug control policy in this regard. He said continuous reports in media about the sale and cosumption of fake and substandard drugs specially in Govt. run hospitals was a matter of great concern.

Addressing the gathering, Mirwaiz said that our young generation was getting entrapped in drug addiction, drinking, gambling and other immoral activities and it was the duty of all sections of the society including persons associated with drug trade to understand their responsibility and duty towards the society. He said that these days' complaints about the supply of fake drugs, the nexus between doctors and medical represtatives, providing drugs without proper prescription and unnecessary clinical tests at the behest of unscrupulous doctors have become common practise and in such circumstances the cooperation of people engaged with medical profession and supply of medicines was very essential to stop this trend.

On this occasion members associated with the medical trade assured Mirwaiz of their fullest Cooperation and gave valuable suggestions. Disclosing that a number of government and other agencies were involved in the racket of fake drug supply, they said that there was no effective drug control system to check all this and a number of irregularities were going on in many Hospitals of the state. The participants included Mr. Fayaz Ahmad of JKCDA, Mr. Dilnawaz of JKCDA/SCDA, Dr. Fayaz Ahmad Dar of JK Doctors /Association, Mr. Umar Iqbal Dhar of Private Diagnostic Centre Association, Mr. Ghulam Nabi Shigan of Advisor Pvt. KPDC, Mr. K. M. Altaf Sheikh of Sheikh Pharmacy, Mr. Altaf Ahmad Khan of Eff Traders, Mr. Aftab Ahmad of M/s Kings Traders, Mr. Mir Abdul Majeed of Haya diagnostic Center, Mr. Raour Ahmad Rangrez Sec. of KPDCA, General Sec. KMRA Mr. Sajad Ahmad, Member KMRA Mr. Sadiq Ahmad Badoo, Treasurer KMRA Mr. Sarfaraz Ahmad Bhat, Member of Ambitious Med. Agency, Mr. Javed Ahmad and Arshad Ahmad of Yatoo Pharmacy, Mr. Syed Parvez President SCDA, Mr. Fayaz Ahmad Khan of Hadiqa Enterprises, Mr. Wasim Ahmad Dar of KMRA, Convener JKCDA Mr. Abdul Ahad Bhat, Mr. Mushtaq Ahmad of SCDA, Mr. Sheikh Abdul Rashid of JKCDA, Mr. Shakeel Ahmad of JKMSRA, Manzoor-ul-Haq, Mr. Fayaz Ahmad Azad, Mr. Raouf Ahmad Rangrez, Mr. Mushtaq Pakhta, Mr. Ajaz Ahmad Kachroo, Mr. Sajad Ahmad, Dr. Sajid, Dr. Umar, Mr. Altaf Ahmad Khan, Mr. Sheikh Abdul Rashid and Mr. Javed Ahmad Mattoo among others. Concluding the meeting,Mirwaiz said that the campaign against the social evil will continue and with the help and active cooperation of all sections of society will inshallah yeild results

❖ North Korea's economy pivots and grows under international sanctions

CNBC, May 01, 2014

Glimpses of a free-enterprise economy in North Korea emerged in the 1970s with the trafficking of goods, followed by the production of merchandise beginning around the mid-1990s, according to the report.

A third phase emerged around 2005, when the regime began to reduce its monopoly over some activities. Geographic distribution of goods has expanded to include maritime smuggling routes. It was around this time, the mid-2000s, that North Korea briefly was involved in manufacturing counterfeit pharmaceuticals.

In the summer of 2004, a South Korean man was arrested in Seoul for selling 4,000 pills of counterfeit Viagra that he claimed to have obtained from North Korea. There were some major discrepancies between the fake and genuine pills. Notably the fake pills were white and round, rather than blue and oval like the originals made by Pfizer. The fake pills were sold for 5,000 Korean won per pill, or roughly $5.

Fake Viagra is part of a decades-long legacy of drug-related activity inside the regime. State-sponsored production of drugs, particularly methamphetamine, appears to have increased in the mid-1990s, according to the report.

North Koreans sell drugs for money. And more people are turning to drugs as cure-alls in the absence of a modern health-care system. Drugs are used to treat chronic diseases and conditions including cancer, malnutrition and hunger, since methamphetamine curbs the appetite.

The new report by Greitens "is very useful in understanding the perverse transformation the country is undergoing," said Natsios, in a prepared statement.

How the regime makes money

Illicit activities such as drug production and trade are among eight key sources of hard currency for the regime, according to the report. Hard currency is important because it's used to support North Korea's development of long-range ballistic missiles.

The sale of arms and exports generates the largest share of hard currency for the regime, said Scarlatoiu. Other sources of hard currency include the Kaesong Industrial Complex, located north of the demilitarized zone that separates the two countries. The complex accounted for all of inter-Korean trade in 2012, a total of $1.97 billion, according to the rep.

❖ UK minister warns against 'dangerous' Indian medicines

Business Standard, May 01, 2014

A British minister has sought action against scientists in India and China who are allegedly producing dangerous new medicines called "legal highs" to be sold on UK streets.

Norman Baker, a UK Home Office minister, said that scientists in India and China are creating new drugs on a "weekly basis" and the UK government needs to find new ways to deal with them.

"We're in a race against the chemists of new substances being produced almost on a weekly basis in places like China and India," Baker told the BBC.

"They then come in here and are inaccurately and unhelpfully called 'legal highs' - some of them are actually illegal. They are certainly not necessarily safe and the word legal implies that they are safe. And people are consuming them and last year I think it was 68 people who died, according to coroners reports, from the ingestion of these substances.

"My objective is to minimise the harm from these substances to the public at large," Baker said.

The number of deaths from drugs known as "legal highs", such as mephedrone, known as "Miaow Miaow", reached the highest number ever recorded last year.

Ministers are consulting on ways to toughen regulation of the drugs.

"We're dealing with a situation where there's already a vast array of substances being sold on our streets, in our shops and that's what we have to deal with. Many of these are actually quite dangerous," Baker warned.

The UK's Office for National Statistics (ONS) said deaths linked with the psychoactive substances jumped from 29 in 2011 to 52 in 2012, an 80% rise.

Many of the so-called legal highs - which give the user euphoric sensations similar to the drug Ecstasy - have been made illegal by the Home Office but the law struggles to keep pace with a proliferation of different drug types.

❖ Govt to review 14000 pharma licenses

Rising Kashmir, May 04, 2014

In order to check the growing spurious drug menace in Kashmir, the government has decided to cancel the sale licenses not used by the proprietors as per the terms and conditions laid down by the government.

Besides cancellation, the government has also decided not to issue any further licenses to persons with matriculation qualification and instead the licenses will be issued to aspirants with bachelors in pharmacy.

Minister for Health and Medical Education, Taj Mohiuddin said that government will review 14000 licenses that have been issued 2001 onwards in Kashmir.

"We will see whether the license holders are using these licenses properly as per the guidelines set by the government. The problem of spurious drug menace is more rampant in small towns where the proprietors have either sub let their licenses or do not run the pharmaceutical shops themselves," Taj added.

The minister said his department will move a proposal when the cabinet meets next for issuance of an ordinance in this regard.

"We will press for an ordinance by virtue of which the pharmaceutical licenses would be issued only to applicants possessing bachelors in pharmacy and we will not entertain any of the applicant having matriculation qualification with five years of experience as was a norm in past," he added. "Till the cabinet meets next we have unofficially decided not to issue any license anymore." He said that samples of drugs are being lifted from nook and corner of the state especially from the rural areas and small towns. "We cannot check the medicine at the entry points because it comes in bulk so we will have to apply other possible alternatives to curb this menace," Taj said.

Pertinently, a government report on drug sample analysis submitted before the High Court last week said that 83 fresh samples, out of 3130 have been substandard. Taj said that various agencies including Central Drug Control Organization (CDCO) is on job lifting samples from the state to test their efficacy.

❖ Hotlines set up to check for counterfeit medicines in India, Nigeria

Thomson Reuters Foundation, May 13, 2014
First Post, May 13, 2014

Social enterprises in India and Nigeria have come up with text messaging services to help patients check that their medicines are safe and are not products of the counterfeit drugs industry, which kills many thousands of people annually.

From expensive pills used to treat life-threatening conditions like cancer to cheap painkillers, fake and poor quality drugs are entering the supply chain where unsuspecting customers risk their lives buying them over the counter or the Internet.

Experts say it is difficult to estimate fatalities caused by spurious drugs as it is an underground and highly organised global criminal activity. However, a 2007 study by the London-based International Policy Network said fake malaria and tuberculosis drugs alone accounted for 700,000 deaths annually.

To combat the problem, social enterprises such as Nigeria's Sproxil and India's PharmaSecure have partnered with drug manufacturers such as GlaxoSmithKline and Lupin, to print unique codes on the packaging and strips of medicines which can be verified by customers through sending a text message.

"Given the growing global counterfeiting problems, we wanted to develop a simple, efficient and cost-effective way for customers to verify the genuineness of their products prior to purchasing them," said Meliza Anne Mitra, Sproxil's global business coordinator.

"Additionally, given the prevalence of mobile technology throughout the world, it made sense to use a technology that was already in every customer's pocket."

Since it launched in Nigeria in 2010, Sproxil has responded to over 8.5 million verification requests from customers across the country, Mitra said.

DEADLY COUGH SYRUP

The World Health Organisation says the $75 billion dollar counterfeit drugs industry mostly impacts regions where regulatory and enforcement systems for medicines are weak such as in Asia, Africa and Latin America, but cases have been reported around the world.

Counterfeit cough syrups and other medicines laced with diethylene glycol have caused eight mass poisonings around the world, including one in 2006 in Panama where 100 people, mostly children, were killed.

In January 2012, 109 heart patients in Pakistan died after taking fake medicines. The same year, tainted steroids killed 11 people and left 100 more sick in the United States.

Both Sproxil and PharmaSecure work with dozens of pharmaceutical firms to print a unique, one-time use code on products. Consumers can then text the code to Sproxil's 38353 number in Nigeria or Pharmasecure's 9901099010 number in India.

Almost instantly, they receive an SMS response indicating whether the product is genuine, or fake. Codes can also be checked through the companies' websites, mobile apps or through a phone call to their customer service desks.

Two other social enterprises mPedigree in Ghana and Kezzler in Europe offer

similar services.

"A spurious drug could be anything from a drug that has lower quantities of the active pharmaceutical ingredient which would make the drug less effective, to drugs which have chalk or talcum power or substances which are actively poisonous in them," said Nakul Pasricha, PharmaSecure's chief operating officer in India.

"They are often made by shady contractual manufacturers who are duping the pharma companies while cutting corners in drug production, or by smaller fly-by-night unhygienic operations in warehouses who them sell them on to distributors who may or may not know the medicines are fake."

Pasricha said PharmaSecure, which started operations in India in 2009 and has since expanded to Nigeria, has placed unique codes on around one billion medicines so far.

Industry experts say the widespread manufacture of fake drugs is forcing authorities to take the issue more seriously.

Last month, French customs seized a stash of 10 tonnes of fake aspirin, erectile dysfunction medication and antti-diahorrea drugs from China in what is believed to be the European Union's biggest-ever seizure of counterfeit medicines.

In March last year, the International Police Agency, or Interpol, recognised the issue as a global public health issue and announced a deal with the pharmaceutical industry to crackdown on fake drugs.

Twenty-nine of the world's biggest drug companies agreed to provide $6 million over three years to help the agency tackle the crime.

- **Fake Medicines Worth $31 Million Seized in Global Crackdown**
  NDTV, May 22, 2014

Law enforcement agents have arrested 237 people worldwide in a 10-day crackdown on fake drugs, resulting in the seizure of counterfeit and unlicensed medicines worth 18.6 million pounds ($31.4 million), Britain's healthcare watchdog said.

The haul of 8.4 million doses of medicines included potentially harmful slimming pills, controlled drugs such as diazepam, anabolic steroids and anti-impotence pills.

The Medicines and Healthcare Products Regulatory Agency (MHRA), which was responsible for seizing products worth 8.6 million pounds, said on Thursday that the Interpol-coordinated operation was conducted between May

11 and 21.

The crackdown also targeted 10,603 websites, leading them to be closed down or suspended through having their domain name or payment facilities removed.

"The medicines recovered during these raids were being held in appalling conditions, such as a dirty old building with broken windows, with medicines lying on the floor in bin bags," MHRA Head of Enforcement Alastair Jeffrey said in a statement.

"Criminals involved in the illegal supply of medicines through the internet aren't interested in your health; they are interested in your money."

India was the source of 72 percent of the illicit medicines seized in Britain, while China accounted for 11 percent, the MHRA added.

❖ Selling expired drugs akin to murder

Ceylon Today, May 22, 2014

Our newspaper recently highlighted the case of the seizure of expired drugs and medical equipment from a warehouse in Grandpass worth Rs 60 million. Kudos to the Consumer Affairs Authority (CAA), for this timely detection, although it was on an anonymous tip off.

Rs 60 million may be the estimated market value or worth, but fraudulently selling such, as though it being within the stipulated dates of expiry, when in fact it's not, renders them wholly worthless. Worse still, being harmful to the body and mind, because certain pharmaceutical items, once expired, for instance cough syrups, could turn toxic if consumed after their stipulated expiry date, this is CRIMINAL!

Therefore, those responsible for such acts of treachery should be charged with attempted murder and nothing less than that, if the Penal Code so provides. Deterrence is the best form of punishment, thereby ensuring that such villainous acts will not be repeated.

It may instill fear into others resorting to such thoughtless criminal activity such as, of selling medications once their originally stipulated validity period had expired, and by fraudulently changing their dates of expiry, or of not abiding by the prescribed temperatures certain medications are required to be kept under. Hopefully, it would deter them from continuing with their dishonest activity.

The question that also begs an answer is what were the officials of the Cosmetics Devices and Drugs Regulatory Authority of Sri Lanka (CDDRASL), which comes under the Health Ministry, doing while this scam was on? Why is

it that they hadn't detected this criminal act at first, as such regulating directly comes under the CDDRASL?

Criminal, because the selling of expired drugs is toying with the lives of innocent, unsuspecting patients and is tantamount to premeditated murder.

CDDRASL like the CAA get their upkeep from public funds. If the CDDRASL is unable to do their job, then it's high time that the Government of Sri Lanka (GoSL) disbanded the CDDRASL and absorbed its residue if there be any into the CAA.

This will be a great saving of taxpayers' hard earned money. Such savings, GoSL may redirect, to bring down the present high cost of drugs. This will definitely benefit the poor. In a country like France, the State pays for the patient's drugs for non-communicable diseases such as diabetes and heart ailments.

Sri Lanka too should adapt laudable procedures like that as the costs of these drugs are so exorbitant that very few if at all could afford them. But in the case of the poor patient here, for all practical purposes they have no recourse to it.

Though healthcare in theory is free in Sri Lanka, more often than not, the government medical stores are out of stock of such drugs. If the patient has money, he may be able to buy the same from the pharmacy next door, if not, he may have to go through the ignominy of begging so that he could buy the necessary medicines, or, otherwise suffer in silence, and probably face death as a consequence, because he didn't have money to buy those life saving drugs.

Under the circumstances, the authorities should mete out the maximum punishment, as prescribed in the law, or enact stringent laws to deter those unscrupulous elements who sell expired drugs and associated ancillaries after alterng their dates of expiry. Such miscreants should be dealt with under the criminal law and not under civil law.

There is a mass movement against tobacco and alcohol in the country. What the country needs is a similar movement to rise up against vendors of expired medicinal drugs and ancillaries as well as of spurious drugs.
Sri Lanka is badly in need of strong institutions and not 'strong' individuals to combat this menace.

The integrity of the so called 'strong' individual is questionable when one considers the recent scams in the Colombo Stock Market, where the fraudsters got away scot free because of their 'strong' influential connections, while the poor man lost his life savings with no one to turn to, neither to institutions nor to 'strong' individuals, to grant him the much needed relief.
The plight of the poor suffering patient is no different.

❖ New quicker method to detect counterfeit medicines

Hindustan Times, May 25, 2014

Scientists have developed an improved chemical analysis method that is more efficient and five times faster in detecting counterfeit medicines such as Viagra, which have skyrocketed in recent years.

The method developed by the researchers at the University of Montreal identifies and quantifies the various compounds present in a pharmaceutical product, in a fifth of the time it takes governmental services to do the same job.

"Fake drugs are a scourge for public health," said Philippe Lebel from the university's Department of Chemistry. Once a simple artisanal activity, counterfeiting has become a global industry linked to organised crime and the mafia.

"According to the World Health Organisation, worldwide sales of counterfeit medicines reached $ 75 billion in 2010. Sildenafil citrate, better known by its trade name, Viagra, and the two other erectile dysfunction drugs, Cialis and Levitra, are among the most counterfeited drugs in the world," researchers said.

Lebel developed an analytical method to detect the 80 substances that may be substituted for the active ingredients in the three erectile dysfunction drugs on the market: Viagra, Cialis, and Levitra. Thirty pharmaceutical and natural products were then analysed to test and prove the potential of the new method.

"Our approach does not only target a medication's active ingredient," said Alexandra Furtos. "Rather, using a scanning technique, it also detects non-targeted compounds, some of them new synthetic analogs of the active ingredient. This is the originality of the method," said Furtos. "Our analysis takes ten minutes, whereas previously, it took up to fifty. In addition, our method identifies compounds that were not identified before, even in low concentrations," says Lebel.

Another sign that the approach is promising is that Health Canada has already incorporated it in its counterfeit monitoring process, researchers said. The threat of counterfeit pharmaceuticals is not new. But the growth of e-commerce has flooded the market with a wide range of both brand name and generic drugs, researchers said. The study was published in the Journal of Chromatography.

❖ Detection of massive haul of date expired drugs prompts probes on others

The Island, May 28, 2014

Following the detection of a massive haul of old medicinal drugs, fairness cream and vitamins repacked with fresh labels containing new expiry dates, at Attidiya on Tuesday, the Consumer Affairs Authority (CAA) yesterday said that it would inspect all drug stores run by private sector pharmacies countrywide. The consignment would have fetched as much as Rs. 500 mn if the racketeers had succeeded in releasing it to the market, the CAA said.

Addressing a media conference at the Sathosa Secretariat at Vaxuall Street, CAA Chairman Rumy Marzook said that the store owned by a well known chain of pharmacies was still under investigation and culprits would be produced in court soon.

He said that all pharmacies run by them would be inspected by CAA officials to check weather drugs, vitamins and cosmetics past shelf life had been released to their outlets after being repacked.

"Under the guidance of the Co-operatives and Internal Trade Minister Johnston Fernando, we decided to check all pharmacies countrywide," Marzook said.

Director General of the CAA J. M. A. Douglas said that law required pharmacies to be air-conditioned, but the large drug store raided on Tuesday had not even met that requirement.

He said that the CAA, together with the Health Ministry, would take action against pharmacies and drug stores that operated without air conditioning.

Consultant to the CAA Dr. Mahanama Rajamanthri said that consumers must be vigilant when purchasing medicinal drugs. They should not go by labels alone when purchasing goods, he said, urging the public to closely examine the packaging etc as well.

❖ The pills we take could kill us

Daily Mirror, May 29, 2014

While the proposed legislation for a National Medicinal Drugs Policy gets delayed, diluted and distorted by racketeer spin doctors, the yesterday revealed a shocking story about outdated drugs and fairness creams worth more than Rs. 500 million.

According to the Consumer Affairs Authority (CAA) its officers on Tuesday raided an Attidiya warehouse run by a private drug company. What they found was sickening and a shame to our society and a sign of the cancerous

corruption growing in our country.

The CAA officers found two million tablets of antibiotics, fairness creams, children's cough syrup, one million other tablets for various ailments and high protein weight gaining capsules. The officers believe that these drugs and fairness creams had reached their expiry dates in April this year and the heartless racketeers were apparently changing the labels to give a 2015 expiry date. We do not know how long this inhuman racket has been going on and how many millions of drugs and cosmetics which are ineffective or unfit for human consumption have reached hundreds of pharmacies.. The CAA assured tough action would be taken against the owners of the drug company and 200-square foot warehouse in Attidiya. We hope this will be done and that some high ranking politicians or officials will not be allowed to coverup what amounts to a huge crime. Tuesday's CAA detection was one of the biggest but we do not know how many more such racketeers operate such warehouses and sell ineffective or counterfeit drugs to millions of people including children.

While the detection is commendable and we need to be thankful for small mercies, these are only symptoms of a deadly, cancerous disease in the import, sale and prescription of medicinal drugs. At present, about 15,000 varieties of drugs are registered for import and because of this huge number—which may be a record of sorts. There is no way to maintain quality control or post-marketing surveillance.

More than 40 years ago Prof. Senaka Bibile, one of the most respected medical personalities in the world proposed a cure for this disease, but multi-million dollar transnational pharmaceutical corporations, Health Ministry officials and tragically even some medical consultants have blocked legislation for the implementation of Prof. Bibile's Essential Medicines Concept. In terms of this concept which has been hailed by the World Health Organisation (WHO) and implemented successfully in scores of countries including Bangladesh, the Government should reduce the number of drugs being imported to about 1000. If this is done, Sri Lanka could save millions of dollars it wastes in importing thousands of non-essential drugs under various names.

Equally important would the government's ability to check the quality of these drugs but this could be done only if the number is reduce to about 1000.

Prof. Bibile also proposed that the State should have a monopoly in the import of medicinal drugs because often it is a case of life or death. But at present the State Pharmaceutical Corporation imports only a limited percentage of drugs mainly for public hospitals.

On Tuesday the DRA officials on a tip-off raided Athurugiriya house of a pharmacist working in the Athurugiriya hospital and found medicinal drugs and equipment worth several lakhs. Making a mockery of this crime the female pharmacist has claimed her husband had given the tip-off to the drug regulatory officials because of some personal dispute with her. Whatever their

family problems are the fact is that hundreds of innocent patients were denied medicinal drugs and proper treatment. The medicinal drug issue has now become a crime against humanity including suffering patients and the government must act fast and effectively to cure this cancer.

❖ In North Korea, everyone is a doctor

News Focus International, May 29, 2014

In most countries, a person who is sick chooses to go to a hospital. They receive a diagnosis after relevant examinations are done. The doctor may then prescribe drugs or other kinds of treatment based on the results of the examinations.

In North Korea, those who are sick choose to see their local 'black market doctor' or head to private homes that sell black market medicine, instead of going to a hospital.

The ruling party in North Korea proudly boasts of its free medical care. There are indeed hospitals in every province, city, and county, and even in the outlying regions, there are maternity hospitals.

On top of that, each neighbourhood has a health clinic. There are even railway hospitals for railroad workers.

But since North Korea's economic collapse in the mid-1990s, drugs, medical supplies and medical equipment became the responsibility of the patients. A hospital could no longer offer more than a place to lie down and take body temperatures.

As the state ration system broke down, those who were in the medical profession had to resort, as with everyone else, to making a living through the underground economy. Some of them eventually set up business of selling medicine from their homes – neighbours could trust a former doctor over a random stranger who offered medicine.

These black market supplies are siphoned off from the military or smuggled in from China. Even medicine sent by the UN for specific illnesses can only be obtained by ordinary North Koreans via the underground economy, as the supplies must first pass through the hands of Party officials, who then sell them onto private drug peddlers and then into the underground economy.

North Koreans know it is better to go to an underground pharmacy and buy their drugs this way, than waste time by going to a hospital where there are no drugs.

In the outside world, medicine is normally prescribed by a doctor or pharmacist. But in North Korea, the burden of deciding on the diagnosis and treatment falls on the patient. But even after purchasing the relevant

medicine, its quality is not always guaranteed.

Park Sung-hye escaped from North Korea in 2013. She describes her experience: 'I bought penicillin from an underground pharmacy when my daughter had fever. But after she received the shot, pus started to form where the needle had entered. I bought the shot to reduce her fever, but as the pus began to grow in size, the fever increased.'

'When I went to a hospital, I was told that the medicine must have been a fake. My husband went back to the underground pharmacy and demanded that they pay for the cost of drugs that my daughter could use while in hospital.'

'But the pharmacy owner said that many people bought medicine from him, and not one person had come back to say the drugs were fake. I returned with a local security agent, but the owner said there was no evidence that I had bought fake medicine from his house." 'As there was no prescription or receipt, I couldn't do anything about my bad luck. In North Korea, anyone can sell fake drugs to earn a living.'

But ordinary North Koreans have no choice but to seek medical treatment in the underground economy. Not only do patients have to bring their own supplies when going to a hospital, they must offer cigarettes and food for the nurses and the doctors in charge. If it is winter, they must also offer firewood; going to a hospital is a desperate last resort.

And hospitals do not necessarily guarantee better standards of care. Kim So-yeon, who escaped in 2012, describes her experience: 'Many people see side effects after using IV drips in the hospitals. Why would you bother going to the hospital when you can use them in your own home?'

'Before our escape attempt, my mother-in-law came down with acute diarrhea, but we did not go to a hospital. We bought a 5% IV and contacted a local woman who was known to be good at finding a vein and giving shots. We brought her home, fed her a meal, and then had her administer the drip. We thought we could get rid of the diarrhea bacteria by flushing it out with an IV drip.'

She adds, 'It's normal outside North Korea for the symptoms of the patient to be examined first and then have a professional prescribe treatment. But because North Korean patients have to prescribe for themselves, they just rely on the informal advice given by those they know.'

❖ Majority of fake drugs in UK from India

The Times of India, May 31, 2014

An Interpol operation in the UK which seized fake and unlicenced medicines found that as much as 72% of the medicines originated from India.

Britain's Medicines and Healthcare Products Regulatory Agency (MHRA) confirmed on Friday that it seized £8.6 million such medicines in the UK, including slimming pills and controlled drugs like diazepam and anabolic steroids.

The most commonly seized drugs were: erectile dysfunction medicines (1.2 million doses), slimming products (383,000) and sleeping pills, tranquilizers and antidepressants (330,996 doses).

MHRA said, "The majority of packages seized that contained medicines supplied illegally originated from India and China, with 72% and 11% of seizures originating from these countries respectively".

❖ Police call for concerted effort to stop counterfeiting

The Jakarta Post, June 06, 2014

The National Police have called on the public to join the global fight against counterfeit goods, simply by thinking twice before purchasing fake products.

Secretary of Interpol's Indonesia National Central Bureau, Brig. Gen. Setyo Wasisto, said on Thursday that participation from the public in the fight against counterfeit products was crucial to deter the growing circulation of counterfeit goods in the country.

Setyo said that the fight against counterfeiting could be difficult as production and distribution was mostly run by international criminal syndicates.

"Today marks the launch of Interpol's Turn Back Crime campaign in Indonesia. In this campaign, we urge citizens not to commit or fall victim to organized crimes," he told reporters at National Police headquarters in Jakarta.

National Police spokesman Brig. Gen. Boy Rafli Amar said asking citizens to join the fight against counterfeiting was difficult given the cheap prices of fake goods, which, he warned, could sometimes be harmful to people's health.

Meanwhile, Food and Drug Monitoring Agency (BPOM) head Roy Sparingga said that the agency had identified 302 websites that apparently offered unregistered food products.

The BPOM determined that number during a week-long crackdown code-named The Pangea Operation in May. In the operation, the agency confiscated 1,385,440 units of illegal drugs, traditional medicines, cosmetics and food, comprising 868 types of items marketed online, worth in excess of Rp 7.47 billion (US$629,848).

"From the websites, we tracked down the production plants of the counterfeit

products — some are located in the country, while others are abroad," Roy said.

Aside from food and drugs, the police also urged consumers to buy only original electronic products and textiles.

In 2013, the National Police investigated 589 cases of intellectual property rights violations.

Between January and May this year, the police have handled 234 cases of intellectual property rights (IPR) violations.

Sr. Comr. Rahmat Sunanto, the deputy director of the National Police special economic crimes unit, said that among counterfeited electronic and automotive brands are Canon, Hewlett-Packard, Microsoft, Honda and Toyota. Fashion labels commonly ripped off include Louis Vuitton, Chanel and Gucci.

"Aside from conducting investigations in the country, we have also coordinated on these cases with the chambers of commerce from several countries, such as the US, Japan, South Korea and Italy," Rahmat said at the press conference.

Widodo, director general of standardization and consumer protection at the Trade Ministry, said that consumers could avoid buying counterfeit items simply by ensuring that a distributing license was printed on the product's label.

Widodo also suggested consumers choose local products that had obtained the Indonesian National Standard (SNI) certification.

Since March 2014, the Industry Ministry has imposed the SNI on 94 products, comprising agro-based products, foods, beverages, fertilizers, petrochemicals, shoes and textiles.

This year, the ministry is set to expand the mandatory use of SNI to 66 more products.

❖ Hidden menace of expired everything

Ceylon Today, June 08, 2014

A common complaint of the third world is that it is the dumping ground for what the rest of the world does not need or dare use. Almost like being given hand-me-downs as a kid – in this case, without the overtones of nostalgia of course. However, when a country seems to be gradually overflowing with food, cosmetics and medicine that are expired, the need for concern and urgent action cannot be more emphasized.

From expired medicine to fairness creams, vitamins, energy drinks and cosmetics (some of these items had outgrown their shelf-lives by as much as three years) to chocolates, Sri Lanka seems to be the latest destination for dubious goods. The sale of expired food or repacking expired goods and re-labelling them to be sold in the market, sadly, is not a new story. The fact that there seems to be an escalation of these incidents is.

Whilst the Consumer Affairs Authority (CAA) has been in the news recently regarding the almost daily haul of illegal goods, for businesses based in Colombo there is another authority, which could take further action with regard to this matter – the Colombo Municipal Council (CMC).

"People don't complain to us now, unfortunately even though there is a dedicated phone line for that purpose – 011-2676161. Once in a while we would get a call about a container of cheese or an issue with a small quantity of expired goods," stated Dr. Padeep Kariyawasam, Deputy Municipal Commissioner Health, of the CMC.

However, what the public may not know is that the CMC can impose fines and take the perpetrator to Courts. "The CMC has the authority to take legal action under the Food Act as well as the Consumer Protection Act. We can take samples, investigate and produce reports leading up to Court action," he added.

However, the biggest drawback in the system is that the fines levied are woefully inadequate. "The fines are very low, I don't think the laws have been amended for more than 15 years," Dr. Kariyawasam pointed out.

The Public Health Department of the CMC, which is the unit tasked with taking action on these issues is also severely understaffed.

"We have only one food inspector with two or three acting food inspectors. We should ideally have 12. We have about 40 Public Health Inspectors (PHIs) but the requirement is for many more," Dr. Kariyawasam further stated.
On the field, daily

According to Officer-in-Charge (OIC) of the Raiding Squad for Colombo, Pradeep Kalutaraarchchi, most of the raids involve complaints with regard to the non-disclosure of prices, spoiled food and date-expired products.

The CAA, which falls under the Trade Ministry, functions under the Consumer Affairs Authority Act and is able to file cases at the Magistrate's Court. The public has easy access to the CAA through their dedicated hotline – 1977. They could also contact the raiding squad on 077-1088922 or 077-1088907. From minor transgressions such as not displaying a price list, to serious offences such as mislabelling products or adulteration, the CAA would conduct a raid with the relevant District's raiding squad OIC and station officers in attendance. The Consumer Complaints Unit will attempt to negotiate a settlement in the case of minor offences with the replacement of an item for an item or compensation.

"Many cases are not easily settled because customers expect huge compensation. Ideally, the consumer should attempt to get the item replaced by complaining to the merchant first, and if he does not rectify the situation, the CAA. We will step in and negotiate and if needed, take the matter to Court," said Kalutaraarachchi.

Whilst appreciating consumer vigilance, he appealed to the public to provide 'tip-offs' under the condition of anonymity if needed, so that those responsible could be brought to book. He also appealed to the public to refrain from filing complaints out of desire to take revenge.

❖ Beware of fake drugs

The Telegraph, June 09, 2014

India has the largest "fake drug" industry in the world. The government estimates fake drugs to be four per cent of the total industry while media and the drug industry itself claims its closer to 30 per cent.

Drugs that are counterfeit, spurious, mislabelled, uplabelled (showing a higher concentration on the package) or illegal can be called fake. A drug is counterfeit if it is produced in a shoddy and unhygienic way. It may contain minuscule quantities or none of the genuine ingredient. The rest, (if you are fortunate) may be ingredients such as milk or starch powder or (if you are unlucky) rat poison or powdered glass. If a spurious drug is injected, it can produce abscess or fatal reactions.

The black market for fake drugs is very lucrative. They are manufactured for a fraction of the cost of the real medication, often in unhygienic factories but are sold at the same price.

Obviously, spurious medication does not work. The blame usually falls on the medical professional. Dissatisfied, the patient may begin to doctor shop. Expensive investigations -- often invasive -- follow as medical professionals attempt to arrive at a diagnosis. If the fake drugs were taken for an infection, the bug that caused the disease soon becomes resistant to the antibiotics. Expensive potent drugs are then given in an attempt to tackle the problem. The patient may succumb to the infection. Sometimes the patient recovers, but antibiotic resistant bacteria are released into the environment to attack other unsuspecting individuals.

Drug resistant TB is a major public health problem worldwide. Initially, it was blamed on the fact that patients did not continue with the treatment or finish the long time frame for which the medicine needs to be taken. Now, however, it has been found that fake and substandard medication for tuberculosis (TB) is in the market. Almost 10 per cent of the prescribed medication was faulty. It was apparently labelled correctly, but close inspection revealed faulty packaging, the drugs were pass the expiry date or "fake", with spelling

mistakes. Many batches were found to have been uplabelled.

The most lucrative market for spurious medication is in the treatment of infections, cancer, sexually transmitted diseases, impotency, glucose strips for the testing of diabetes and psychiatric medication.

Generic medication is much cheaper than branded products. They are stocked and used in government hospitals to provide effective but inexpensive treatment to the underprivileged. For the first four years after companies obtain a license to supply institutions, the products are checked by a central agency. After that it is the individual state's responsibility. The testing agencies are underfunded, inadequately staffed and overworked. It leaves many loopholes, which can be exploited and also provides scope for bribery and corruption.

In developed countries, the bulk of spurious drugs are sold through an unregulated Internet market, directly to customer. No prescription is required. We have not reached that stage in India yet. However, many friendly neighbourhood pharmacies do sell spurious and substandard drugs at rates lower than the MRP to unsuspecting customers. They often lure the customer with the argument that "this brand is cheaper!"

Stay safe
• Do not buy medication without a prescription and a bill. You might pay more as VAT (tax) is added. On the other hand, bills require that the batch number year of manufacture etc. be clearly recorded minimizing chances of fraud.
• Do not buy or use a medicine that has been substituted. If your physician has prescribed a medication take only that and not something "which is the same but is cheaper!"
• Check the expiry date and packaging. If it looks corroded, smashed or discoloured do not buy it. Other danger signals are spelling mistakes on the labels, with "e " instead of "i" etc.
• Vaccines should preferably be supplied and injected by the doctor. They may be fake or of reduced potency if bought from a pharmacy and then carried to the doctor's premises. The cold chain may not be maintained.

❖ India in the grip of fake drugs: RTI inquiry reveals 10-20 per cent of drugs found in major states are imitations

Daily Mail, June 11, 2014

Look carefully before you take that antacid tablet. Chances are, it could turn out to be spurious.

An RTI query revealed that between 10 and 20 per cent of drugs are fake in states like Uttar Pradesh, Tamil Nadu, Bihar, Gujarat and Maharashtra.
In smaller states like Delhi and Goa, the volume of spurious drugs may be just under five per cent.

But considering the amount of medicines sold, and that many of these are life-saving formulations, the fake drug menace is as scary as it gets for the common man.

The drugs found to be "not of standard quality" and "spurious" in sample tests conducted by the state drugs controller are some which we require for day-today use

"Some commonly-used daily drugs are Pantocid for acidity and gastro problems, Enalapril and Dopamine for blood pressure, Paracetamol for normal viral control to antibiotics like Ronflox and Oflomac. These adulterated drug samples are found across the country from Tamil Nadu to Sikkim," Delhi-based Raj Hans Bansal said, quoting the RTI reply.

In UP, nearly 130 drugs of 800 tested randomly were found fake to be this year. Last year, nearly 162 of 1,000 samples turned out to be fake.

ON HIGH ALERT:

- **Pantocid** - For acidity
- **Dopamine** - Anti-depressant
- **Enalapril** - For controlling high blood pressure
- **Paracetamol IP 500mg** - For fever and pain
- **Oflomac 400** - Antibiotic
- **Levocetirizine** – For runny nose, sneezing and seasonal allergies
- **Ambrid-T** - Cough syrup

In Tamil Nadu, for instance, nearly 210 samples tested fake out of the nearly 3,900 randomly checked last year, the RTI reply said.

CURBING THE MENACE

- Ministry has hired at least 200 drug inspectors in past one year and plans to hire more to curb the menace.
- Organisations working in pharmaceuti-cal industry have called for a better system to curb sale of bogus drugs.
- India Chapter of Partnership for Safe Medicines has been advocating for uniform standards for drugs and a drug tracking system.
- There is a need to sensitise consumers.

Officials in the Union health ministry said the quantum of fake drugs could be bigger as many North-east states, and Bihar did not provide the required data. They admitted that there was no complete control over the menace.

In January, at least 32 medicines sold in hospitals and chemist shops across India failed the tests and were declared "not of standard quality" by the Central Drugs Standard Control Organisation.

According to a Partnership for Safe Medicines India report on 'Patient Safety and Drug Detection Technology' released last year, India has more than 10,000 manufacturers of pharmaceutical products but very few qualify the standards of 'Good Manufacturing Practices'.

Most of the states were silent on the value of drugs seized, but the RTI reply added that at least 110 arrests have been made since last year in cases involving fake drugs seizure and trading.

❖ Fake drugs is a worry for Drug Controller General of India

Deccan Chronicles, June 16, 2014

Fake drugs is a major worry for the Drug Controller General of India as an estimated 10 to 12 per cent of medicines like paracetamol, dopamine (anti-depressant) and pantocid (acidity) in the market are fake.

Uttar Pradesh, Tamil Nadu, Bihar, Gujarat and Maharashtra have very high numbers while the other states have less than five per cent of these spurious drugs. The instances come to light only when complaints are registered by customers or when the state drug controllers carry out random checks and seize batches.

A senior drug control officer in Hyderabad said, “There have been demands for introducing uniform standards and also for a drug tracking system but the modalities are far from ready.”

The lack of complaints is seen as one of the weaknesses in curbing the entry of these drugs in the market. “If there is a noise made, then the supplier is alerted. But as the patients remain silent it becomes difficult to nail the culprits,” explained a senior government officer.

According to Partnership of Safe Medicines, very few manufacturers have “good manufacturing practices” certificates and till the government works towards ensuring their implementation, curbing the menace would be a difficult task.

❖ 'Unlawful' diet products

The Nation, June 17, 2014

The Food and Drug Administration (FDA) said "Fuco" diet supplements, including Fuco Pure and Fuco Burn, that are sold online violated the law for being extravagantly advertised and none of the brand's products have FDA approval.

FDA deputy chief Dr Paisarn Dunkum said, following complaints, FDA and police arrested a suspect last Thursday with Fuco products worth Bt300,000. He was charged with selling food supplements with fake labels that were not approved by the FDA (punishable with a fine up to Bt30,000) and for advertising food supplements without permission (punishable with a fine up to Bt5,000).

Paisan also warned that some pickled garlic and lime products have fake food product registration numbers (with the FDA approval mark). When added to a large amount of acetic acid, they could cause stomach irritation and severe ulcers. He cited the recent seizure of such products worth Bt500,000 from a Bangkok Phasi Charoen district warehouse.

"You can't just read the labels, as they might be fake. You should check the food product registration number, which you can then check with the FDA website (www.fda.moph.go.th)," he said.

❖ Maharashtra leads the rest in 'fake' drug sales

Metrognome, June 18, 2014

OTC vitamin supplements, cough syrups and pain killers are being manufactured, circulated freely, posing a huge risk to public health.

That spurious drugs have been doing the rounds isn't news but what's shocking is the way the felony has spread to everyday drugs too. Earlier, the 'faking' was restricted to costly and exclusive drugs like Viagra. But now, copies of over-the-counter pills like vitamin supplements, cough syrups and pain killers are being manufactured and circulated freely.

A Right to Information (RTI) application filed in 2013 revealed that that the problem of fake drugs in the country is much larger than we ever could believe. According to the reply provided by the Ministry of Health, a total of 345 cases of spurious drugs have been reported by Central Drugs Standard Control Organisation (CDSCO) between 2009 and 2012. Of these, 117 were reported in between 2009-10, 95 in between 2010-11 and 133 in 2011-12.

The data provided by the Health Ministry revealed, out of 1.37 lakh drug samples tested by CDSCO in the last three years, a total of 6,500 samples were found to be of sub-standard quality and 345 samples were reported

fake.

Contrary to the ministry's notion that rewarding whistle-blowers will affect the production of fake drugs, reality is quite the adverse and the number of fakes only seems to be increasing by each year. It was in 2009 that the Ministry had launched a scheme to reward those who give information regarding fake drugs.

Details provided through the RTI query revealed, in all, 37 complaints were received and investigated by the State Drug Controlling Authorities and CDSCO. However, none of the 37 complaints were found to be true and so far no one has been rewarded under the scheme.

An international newspaper had just recently carried a front page 'expose' about how India has been exporting fake drugs to Africa and endangering the lives of thousands in the process. In reply, India denied claims that it has exported counterfeit medication to Africa.

A spokesperson for ministry of external affairs was reported saying "No fake medicines have been sent from India to the continent of Africa." The article published in an English newspaper had reportedly cited concerns of experts and quoted NGO reports stating that almost one-third of the Malaria medicines imported to Uganda and Tanzania from India and China were counterfeit or of sub-standard quality. The drugs which looked identical to real ones could only be testified by laboratory tests.

It was not just malaria drugs, the newspaper had also claimed that antibiotics and contraceptives imported from India were fake. "Some pills contain no active ingredients; some are of partial strength and some have the wrong formulation entirely," it reported.

The fake medications have reportedly led to deaths, prolonged illness and increased drug resistance in parts of East Africa, the article said. Indian officials denied all the allegation adding this is not the first time that India has been accused of exporting counterfeit medicines.

A few years back, in 2009 too, there were reports of India supplying fake medicines to Africa. But investigations in the matter revealed that it was, in fact, China that had been supplying counterfeit drugs to Africa with a 'Made in India' tag to mar India's image.

Although India had not named any country, probes conducted by drug controlling authorities in Nigeria and other African countries proved that the counterfeit medicines were in fact produced in China.

India's pharmaceutical export to Kenya had almost doubled from Rs 292.94 crore in 2006-07 to Rs 543.86 crore in 2008-09.

The drug export to Uganda and Tanzania alone rose during this period from Rs 152.75 crore to Rs 290.76 crore and from Rs 152.24 crore to Rs 274.94

crore respectively. This time around, China too has denied charges of importing fake medicines to Africa. It has been reported that, last year, Chinese police seized £113m of fake pharmaceuticals in July alone and £19m worth in November. Many ingredients in the medicines were found to be harmful or toxic.

Earlier this year, China, after denying claims of exporting counterfeit drugs, appealed to India to deal with the menace of fake drugs, which had been marring images of both the nation, together. The Chinese newspaper had, last month, carried out an article about how smugglers from inside and outside Africa are responsible for the problem of fake drugs.

India has more than 10,000 drugs manufacturer and is the third-largest medicine producer all over the world. It has an estimated 5,000 production lines. To tackle the problem of counterfeit drugs, the Indian health ministry launched a huge campaign last month to check the quality of medicines manufactured across the country.

Several pharmaceutical companies are planning on using barcode technology to help distinguish the genuine from the fake. These companies are also urging the users to use mobile phones to verify the authenticity of medicines by sending SMS or checking on the internet. Although India is a major player in pharmaceutical sector, its image is at risk and also globally with the growing fake-drugs market.

A recent report showed how grave the situation really is when it comes to fake drugs in the Indian market.

Out of all the state in India, Maharashtra came out to as the worst affected with 23 per cent of the medicines in the state found to be 'not of standard quality'. In Tamil Nadu, the figures were a lot lower than Maharashtra at 13 per cent, Kerala was at 9.2 per cent, Gujarat at 8.5 per cent, Karnataka came to 7.2 per cent, Uttar Pradesh at 6.9 per cent, Jammu & Kashmir at 6.08 per cent and Rajasthan 5.8 per cent.

It's not just the 'inaction' of these fake drugs that is the matter of concern, many of these counterfeit drugs are also found to be dangerous and sometimes even fatal. A large portion of counterfeit drugs seized by the government were found to contain toxic chemicals like mercury and other heavy metals. These chemicals, when consumed, can be extremely dangerous. When taken in place of genuine medicines, spurious drugs can be fatal. The government, thus, seeing this dangerous trend, has started a campaign to implement bar codes on drugs, so as to distinguish the real ones from the fakes.

The global anti-counterfeit packaging market is expected to be worth $79.3 billion by 2014. This opens up a significant market potential for barcoding product authentication solutions for the pharmaceuticals industry. Hopefully, this would herald the end of counterfeit drugs that besides affecting India's image globally are fatal too.

❖ Fake Antibiotics Feed Growing Worldwide Superbugs Threat

Bloomberg, June 18, 2014

Antibiotics now rank among the most counterfeited medicines in the world, feeding a global epidemic of drug-resistant superbugs.

A new surveillance and reporting program in 80 countries led by the World Health Organization shows that counterfeit antibiotics are a growing problem in all regions of the world, rivaling fake versions of erectile dysfunction pills like Viagra. Infections become superbugs by gaining resistance when the treatments used against them aren't strong enough to kill them. It's a growing problem as substandard counterfeit drugs become more prevalent.

The threat is already spurring a strong response from drugmakers such as Pfizer Inc. (PFE), the U.S. maker of the Zithromax antibiotic, which has been focusing its anti-counterfeiting efforts on online pharmacies, collaborating with Microsoft Corp.

"Because the demand is so high for antibiotics, it's not unusual to see those who falsify these products concentrate on them," said Michael Deats, head of the WHO's drug safety and vigilance team, in a telephone interview.

Too Much of a Good Thing

Earlier studies have found that Southeast Asia is a particularly large source of the questionable drugs, trafficking mostly in penicillin and their derivatives. The WHO says the problem is more widespread. England's Chief Medical Officer Sally Davies has compared the gravity of the antibiotic resistance threat to climate change, requiring a similarly unified response from governments, industry and society.

With genuine medicines already losing potency against bacteria, the surge of counterfeits is particularly troublesome for public health leaders trying to curb the march to what the WHO has referred to as a post-antibiotic era in which everyday infections can kill.

Weaker Treatments

"Substandard medicines can create resistance such that the bona fide medicine can't treat the patient when he gets it eventually," said John Clark, chief security officer for New York-based Pfizer's fight against the counterfeit drug trade. "It's a horrific situation."

Part of the challenge is understanding the scale of the problem and where the fakes are coming from. Through the WHO's surveillance program, links can be made across borders to identify high-risk sources, Deats said.

Pfizer's effort with Redmond, Washington-based Microsoft seeks to identify

affiliated networks of counterfeiters by tracking down computer servers and banks tied to their websites, Clark said. That has allowed them to take down thousands of affiliated pharmacies in one fell swoop and prevent them from resurfacing, he said.

Indian Prescriptions

In India, widespread resistance to common antibiotics is forcing doctors to prescribe previously spurned drugs like colistin, said Abdul Ghafur, an infectious diseases physician at Apollo Hospital in Chennai, in south India. Even healthy individuals who have never visited a hospital carry drug-resistant bacteria, he said.

The situation led to India heeding the Chennai Declaration to tackle antibiotic resistance and adopting in March the so-called "H1 rule," where pharmacists must insist on prescriptions for 24 second- and third-line antibiotics.

Over the next two to three years, the list will be gradually expanded, and drug inspectors will help enforce the law, Ghafur said. "There are half a million pharmacies in India so implementation will take some time," he said in a telephone interview.

Worldwide Resistance

India produces about 40 percent of the world's supply of bacteria-killing drugs, according to Tim Walsh, a professor and infectious diseases researcher at Cardiff University in Wales.

The situation isn't confined to the developing world. "Very high rates" of resistance have been observed in all regions and in bacteria that cause common infections such as those related to wounds, pneumonia and urinary-tract conditions, the WHO said in its first global survey of antimicrobial resistance in April.

Similarly, fake antibiotics are just as likely to reach patients in the U.S. and Europe as in poor countries through online pharmacies. Of more than 10,000 online outlets surveyed last year by the U.S. National Association of Boards of Pharmacy, 97 percent were out of compliance with U.S. pharmacy laws and standards.

The fake drug challenge comes amid concern about the quality of real medicines, especially generics. The U.S. Food and Drug Administration has restricted imports of drug components made by India's Ranbaxy Laboratories Ltd. and Wockhardt Ltd. Now counterfeiters are adding to their woes.

"Generic-drug makers, just like research-based manufacturers, get just as concerned about their drugs becoming falsified," Deats said. "They can be the target just as much as anybody else."

❖ Nano tech to fight spurious drugs

The Times of India, June 21, 2014

India is the largest manufacturer of generic drugs in the world, and the pharmaceutical industry is worth billions of dollars in both domestic and overseas markets. Consequently, there has been a major issue with counterfeits of popular drugs and production of sub-standard drugs with similar-sounding names. Government agencies put the figure for such drugs at 0.4%, but independent agencies believe it could be as high as 12 to 20%.

A consumer in the large rural or even urban market may not be able to differentiate between the two, and this could even cause a patient's death. Law enforcement agencies have a tough task at hand — how to identify a sample as sub-standard or fake quickly and without doubt.

A project at Gujarat Forensic Sciences University (GFSU)'s Institute of Research and Development may have found the answer. The now complete project has employed nanotechnology to come up with cheaper, faster and more reliable detectors, which can tell the difference between a standard drug and the sample provided.

Rakesh Kumar, a student of GFSU, took up a project titled 'Applications of Molecular Imprinted Polymer Nanoparticles (MIPN) in Drug Anti-Counterfeiting' under the guidance of Professor Y K Agrawal. Kumar had received an Inspire Fellowship from the Department of Science and Technology, Government of India, for this.

"We developed a synthetic MIPN technology for a series of drugs like quinolone antibiotics, antiviral agents, or drugs to treat erectile dysfunction and so on. MIPN today is a viable synthetic approach to design robust molecular recognition materials that can mimic natural recognition entities, such as antibodies and biological receptors. MIPN is considered a versatile and promising technique, which can recognize both biological and chemical molecules, including amino acids and proteins, nucleotide derivatives, pollutants, drugs and food," said Prof Agrawal.

How does the detection work? Agrawal said they get 'control samples' of the drugs produced by various pharma companies. These provide the absorbent with 'memory' in the presence of the template molecule. When a sample is sprinkled on the detector, the bio-censors compare it to the template. If the pattern matches, the detector will give luminance. If the sample is sub-standard, the luminance will be weak and if it is fake, there will be no luminance at all.

The researchers said that compared to traditional methods, such as X ray fluorescence which cost lakhs, such detectors do not cost more than Rs 6,000 to Rs 7,000.

"This technology permits easy identification of all drugs with and even other new structurally-related substances, as it covers a wide range of polarities. All other analytical techniques need expensive instruments or gradient elution. Hence, in rural areas, where experiment conditions are not ideal, they cannot be employed to screen potentially counterfeit drugs," said Kumar.

- **Fake medicines threaten eradication of malaria in the Mekong Region: More research is needed!**
  www.Fightthefakes.com, June 30, 2014

http://fightthefakes.org/stories/more-research-is-needed/

My name is Marie Lamy and I am conducting a doctoral study at the London School of Hygiene and Tropical Medicine.

I am researching the institutional mechanisms to regulate and prevent the availability of fake medicines in the Greater Mekong Region of Southeast Asia, comprised of Myanmar, Thailand, Lao, Cambodia, Vietnam and parts of China.

My interest in fake medicines began when I witnessed the inequalities in terms of access to healthcare in Southeast Asia. After working as a researcher on global health governance at the Lee Kuan Yew School of Public Policy and subsequently as a project officer at i+solutions, a foundation specialised in the supply chain management of essential medicines, I gained a greater understanding of global health challenges related to access to medicines.

Why the problem of fake medicines must be taken seriously ?

Fake medicines are a worldwide threat. The challenge of fake medicines goes beyond matters of intellectual property, as fake medicines may contain none/inadequate quantities of the active ingredient or may contain harmful ingredients. Fake medicines are therefore a genuine threat to global health. The topic of fake medicines is very much under-researched from an institutional and governance perspective.

My project addresses the issue of fake antimalarial medicines through the lens of policy and regional governance, with a view to informing the development of more effective regional mechanisms to improve access to quality medicines. I am looking to see how countries in the Mekong Region can work together to prevent fake medicines from getting into the hands of patients.

A wide range of medicines are counterfeited worldwide – from lifestyle drugs to paediatric drugs and life-saving medicines like antimalarials, which are distributed on a wide scale and thus attract criminal groups looking to make the most profits. It is argued that 10% of all medicines worldwide are fake.

This estimate rises to over 30% in developing countries including countries of the Mekong Region.

The impact of fake medicines upon the global fight against malaria

Fake medicines pose a direct challenge to the eradication of deadly infectious diseases such as malaria, in part due to the risk of antimicrobial resistance. The Mekong Region has been identified as the basin of resistance to antimalarial drugs.

A great deal of research has been done and is still underway to find new testing methods to verify the quality of medicines, and to measure the extent of the spread of resistance. Yet, more research is needed to understand the structural reasons of why fake medicines enter the market in the first place, as well as to find effective collaborative solutions to curb this trend.

The regional dimension of this problem requires particular attention

While the illicit trade of fake medicines has reached a global scale and impact, the availability and sale of fake drugs tends to be concentrated in specific regional contexts. In the Mekong Region, where there is a high mobility of labour and goods across borders, regional solutions are needed to protect the lives of innocent patients.

Fake medicines are a threat to the effective supply chain management activities that procurement, donor and recipient organisations want to avoid. It is a threat that is looming, hard to quantify due to the fact that it stems from underground criminality, and difficult to eliminate due to the trans-border nature of the challenge and the lack of regulations and enforcement measures at the national, regional and global levels.

Large medical aid agencies, central medical stores, or any stakeholder at any point of the supply chain are at risk of getting their stocks stolen or diverted. At the same time, fake medicines are threatening to enter market illegally.

The question we must ask is what effective regional regulations and policies prevent incidents like these from happening?

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❖ PM warns action against food adulteration

New Age, June 26, 2014

Prime Minister Sheikh Hasina on Wednesday warned of tougher action

against those responsible for adulterating food items.

She gave the warning while replying to a question from ruling party MP Enamul Haq, on food adulteration, as the parliament session resumed with Speaker Shirin Sharmin Chaudhury in the chair, in the morning.

'The government has given highest priority to ensure good quality products and prevent adulteration of food items, for the sake of public health,' she said, adding, 'The government had launched mobile courts to prevent adulteration. More than TK 1 crore was realised as fine in the last five years.'

A total of 8,796 commercial entities were penalised for selling adulterated goods and spurious medicine, and they were fined over eight crore takas, said Hasina. Four hundred and sixty-three drug stores were fined for selling expired medicine.

She said at least 14 monitoring teams have been working across the country to check adulteration of seasonal fruits, using various chemicals.
`People are starting to benefit from the actions of the government over the past years,' said the premier, vowing to continue the drives.

❖ Fake drug poser on healthcare

The Telegraph, July 15, 2014

Next time you visit a medical store to buy medicines, don't assume that the expiry date written on the foil of the medicine would be right.

Reason: The medical store might be selling expired drugs with changed wrappers. On Wednesday, when the state drug control administration carried out a raid on an unlicensed godown on Govind Mitra Road, they found many expired medicines.

The unlicensed godown stored medicines worth around Rs 30 lakh and most of the drugs had expired. The drug inspectors found blades and erasers from the godown, which were allegedly used to change the expiry dates and price of the medicines. The medicines found were anti-snake venom serum, injectables and drugs related to cardiac ailments among others.

This was not the only time the state drug control administration found expired medicines during a raid. Sources from the state drug control administration said last year too many expired medicines were seized during a raid in Makhania Kuan, another locality of the state capital. "In that raid also, we found a large amount of expired medicines. It consisted mainly of antibiotics, calcium tablets and cough syrup," said Yashwant Jha, a drug inspector of Patna.

Subhash Chandra Roy, licensing authority, state drug control administration, also confirmed that expired medicines had been found on many occasions.

"We often find expired medicines during our raids but yesterday, we got a large amount of expired medicines. There is no denying that some medical shops are tampering with the expiry dates of medicines and selling those." Experts cautioned that popping expired medicines could be harmful.

Keshav Kumar Sinha, assistant professor in the pharmacology department of Patna Medical College and Hospital, said: "Expired drugs lose potency but it may also produce toxic effects. Drugs have a shelf life. When it ends, anything could happen. There are many medicines, which become toxic after they expire. Expired antibiotics can cause renal failure. Antibiotics, especially of terramycin group, can be very toxic after expiry. Expired drugs have a possibility of fungal growth. Popping expired vitamin tablets can cause liver problems, digestion ailments and gastrointestinal disorders."

Navneet Kumar, one of the drug inspectors of Patna, said: "Expired drugs don't dissolve properly in blood and thus cause problems. Some of the expired medicines also cause cardiac ailments."

State drug controller Hemant Kumar Sinha said selling expired drugs is considered equivalent to selling fake medicines.

"Expired drugs lose their efficacy. So we assume expired drugs to be fake. The drug control administration lodges FIR against any person found selling expired drugs. Imprisonment up to three years can be awarded to anyone found guilty," said Sinha.

❖ India's CDSCO to pay people who report fake drugs

www.in-Pharmtechnologist.com, July 17,2014

The CDSCO has accused international "vested interests" of labelling counterfeit drugs as "made in India" to damage the reputation of the country's pharmaceutical industry and launched a scheme to reward people who report fakes.

❖ India to Pay Whistleblowers for Info on Counterfeit Drugs

Wall Street journal, Pharmalot, July 18, 2014

The Indian pharmaceutical industry is already reeling from a series of manufacturing gaffes that have prompted a crackdown by the U.S. FDA. But Indian officials say some quality-control problems that have tarnished the collective industry image are actually not due to lax standards or malfeasance, but may be traced to "vested interests" that are distributing "spurious," or counterfeit, medicines near and far.

To combat the problem, the Indian Ministry of Health & Family Welfare is willing to reward "whistleblowers" that pass along information leading to a seizure. And informers stand to reap a bounty up to 20% of the value of any drugs that are seized. Government employees who similarly convey useful information may also be eligible to claim a reward.

"The country's hold on [the] international pharmaceutical market, especially the status enjoyed by it in providing high-quality drugs [for the] cheapest prices invited some unhealthy competition from various quarters," the ministry writes in a nine-page memo. "Internationally, the vested interests are supplying spurious medicines manufactured by them, but with 'Made in India' labels.

"…Since spurious or fake drugs is a sensitive issue affecting the health of the citizens, as well as the prestige of the country's pharmaceutical trade interests, there is a sense of urgency in taking on the menace on [a] priority basis."

Of course, counterfeit medicines are a global problem and the U.S. pharmaceutical industry is equally disturbed by the presence of phony drugs in the supply chain. The Pharmaceutical Research & Manufacturers of America, the industry trade group, for instance, recently lauded the U.S. FDA for proposing to destroy shipments of medicines worth less than $25,000 upon arrival in the country.

India, though, is particularly sensitive to any suggestion that the medicines made by its drug makers may be shoddy or worse. That's because so many domestic drug makers have been cited by the FDA. Since the beginning of 2013, the agency added 25 manufacturing plants in India to a list of facilities banned from sending drugs or ingredients to the U.S.

The FDA is bolstering its oversight in India in hopes of cracking down on wayward violators and, more importantly, elevate industry practices. The agency is in the process of increasing its staff to 19 inspectors from 12 in order to keep watch over some 600 plants. However, as Bloomberg News reports, the FDA is having trouble staffing its office there amid several recent departures.

"It's difficult to get people to stay there for long periods of time," Robert Pollock of Lachman Consultants and a former acting deputy director of the FDA Office of Generic Drugs, tells the news service. "It's so different than the U.S. The culture is different."

❖ Fake drugs in India may cross US$ 10 billion in next three years: ASSOCHAM

WebIndia123, July 18, 2014

Growing at a compounded annual growth rate (CAGR) of about 25 per cent,

the fake drugs market in India is likely to cross US$ 10 billion mark by 2017 from the current level of about worth US$ 4.25 billion, according to an ASSOCHAM recent analysis.

ASSOCHAM paper on "Fake and Counterfeit Drugs In India -Booming Biz" reveals that "India, the world's largest manufacturer of generic drugs, has become a busy center for counterfeit and substandard medicines which stuffed in slick packaging and often labeled.

The size of domestic drug market today is pegged at around $14-17 billion, ASSOCHAM sources here said.

The drives trade in fake drugs is a lack of adequate regulations, shortage of drug inspectors and a lack of lab facilities to check purity of drugs as the key reasons, adds the ASSOCHAM paper.

Shockingly, the biggest centre of spurious drugs seems to be the national capital region, which includes Delhi and its suburbs of Gurgaon, Faridabad and Noida. It is a growing problem and estimates indicate that (fake drugs) constitute nearly 1/3 of all drugs sold in NCR, adds the paper.

The concentration of fake drugs manufacturers can largely be found out in locations such Bahadurgarh, Ghaziabad, Aligarh, Bhiwadi, Ballabhgarh, Sonepat, Hisar and Punjab etc. Agra is also increasingly becoming a hub for fake drugs in India, adds the ASSOCHAM paper.

The fake drugs are available in the popular medicines like Crocin, Voveran, Betadine, injections of calcium and syrups like Cosavil. The fake drugs businesses are also turned into a massive racket and witnessed the availability of fake drugs to the extent of 25 per cent in India, reveal the ASSOCHAM recent paper.

The other key factors for the spread of fake drugs in India comprise the shortages of drug inspectors and proper lab facilities to check purity of drugs, storages of spurious drugs by the chemists, weaknesses in drug distribution system, plenty of uneducated workforces in India and lack of law enforcement. These all reasons have given the liberty to fake drugs manufacturers and druggists to supply the spurious drugs in the region, adds the paper.

The report also emphasises that the governance must work with industry and healthcare system to ensure the integrity of the supply chain system for pharmaceuticals. It is also important to strengthen legal and regulatory framework and provide penalties for convicted counterfeiters.

There should be public awareness campaigns to promote the importance of purchasing medicines through authorized and regulated distributors. Furthermore there should be coordination in intelligence sharing among the law enforcement agencies both domestically and internationally. It is a global problem that calls for a global solution.

❖ Spurious, substandard and date-expired medicines

The Independent, July 21, 2014

Adulterated and low quality medicines are being produced and sold in different places of the country, including the capital city, exposing the consumers to serious health hazards. This is an unholy marketing practice that should make our blood boil. People take medicines to get well. When they are not cured, rather their physical conditions deteriorate from taking medicines having no potency, or sometimes they even die from taking such medicines, then the outrageous aspect of it should be clear to all. Use of formalin and adulteration of food items have become a burning national issue in recent times. The government announced stringent punishment for the perpetrators of such activities. But the perpetrators are not confined to adulteration of food items alone, they have spread their grim claws also to medicine. Why they should not ? It is the gateway to become rich overnight. Why should they miss this golden opportunity ? In fairy tales, Aladin's magic lamp makes one rich in an instant. The manufacturers of fake medicines and distributors of sub standard and date-barred medicines can expect to become rich within a few months or years.

It is so unacceptable that what our people take as medicines sometimes pose serious threat to their life. Such medicines can drain a person's energy, sap his vitality, diminish his life force, dull his thinking process, and ultimately lead him to a point of no return.

Poverty, rising crimes, environmental pollution and political instability have made the lives of the people of this country unbearable. The quality of medicine likewise is also a concern.

Apparently, it is difficult to identify spurious medicines because they look all right. Owners of medicine shops without license located at different places of the country, particularly in rural areas, are mainly engaged in selling fake and poor quality medicines, exposing the consumers to serious health hazards.

The business of marketing fake and sub standard medicines began years ago. This practice is gaining strength with the passage of time. There are scores of dishonest traders and others who are controlling the business. Consumers are captive in the hands of these notorious elements.

According to doctors, consumption of such so called medicines causes havoc. After consumption of adulterated medicines people fall ill. Children are the worst affected. There has been a mushroom growth of private hospitals, clinics and diagnostic centres in Dhaka and other divisional and district towns during the last two decades. Taking the opportunity of this the producers and sellers of spurious medicines are doing roaring business.

The unearthing of fake medicine factories makes newspaper headlines at times. Members of the law enforcement agencies seize the factories and close them down, arrest some persons, realise fines of varying amounts and

that's all. In some cases, the perpetrators go scot free after greasing the palms of a section of dishonest members of the law enforcers.

In many cases fake medicines are wrapped with the labels of renowned pharmaceutical companies.

There are some business operators at the Mitford wholesale market in Dhaka who buy these spurious medicines and make windfall profits. On the other hand, import-banned medicines had been available in the Mitford market for a long time. The business is allegedly going on in connivance with a section of members of law-enforcement agencies. Sources said among the medicine markets in Babubazar and Mitford areas are Samiti Market, Yousuf Market, Ali Market, Nayna Market, Khan Market, , Dhaka Market, Sureshwar Market and Nupur Market.

Mitford is the country's largest wholesale medicine market and the nationwide marketing chain of medicine is controlled from here. According to a recent media report, date-expired and illegally imported medicines, with an estimated market value of around Tk 5 crore were seized from some shops and a total of 80 cases filed against the medicine traders for the possessing and hoarding of various fake, illegal and unauthorized drugs at Mitford.

There are 168 pharmaceutical companies in the country but only 62 follow the guidelines of the World Health Organization (WHO). Only twelve of them are manufacturing medicines as per standards laid down by WHO, and in most of the laboratories there is shortage of proper equipment and skilled personnel, mismanagement, lack of monitoring and illegal entry of banned medicines.

According to media reports only 50 to 60 pharmaceutical companies produce medicines of reasonably sound quality and 50 per cent to 60 per cent of the companies are producing medicines of low quality. In July 2009, consumption of spurious paracetamol tablets resulted in the tragic death of 28 children. The drug administration has probably taken only token action against some offending pharmaceutical companies. Besides, smuggling of banned medicines is going on unabated. There are about 2,25,000 medicine shops in the country, of which 82,000 hold valid license. Most of these medicine dispensing shops are run by inexperienced and unskilled personnel. Besides, there are quacks who play havoc with public health. There are only two government drug testing laboratories which can test only three to four thousand medicines yearly. At least ten more testing laboratories are needed to meet the demand. A national medicine policy was formulated in 2005 but it failed to make any satisfactory headway.

The government must take stringent measures to absolutely stop manufacturing and selling of fake medicines and the marketing of sub standard and date-expired medicines.

❖ Fake drugs in India may cross US $10 billion in next three years: ASSOCHAM

Elets News Network, July 22, 2014
Meri News, July 22, 2014

Growing at a compounded annual growth rate (CAGR) of about 25 percent, the fake drugs market in India is likely to cross US$ 10 billion mark by 2017 from the current level of about worth US$ 4.25 billion, according to an ASSOCHAM recent analysis.

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should be coordination in intelligence sharing among the law enforcement agencies both domestically and internationally. It is a global problem that calls for a global solution.

It has observed that intensification of the spurious drugs has not only severely impacted the original drugs manufacturers' annual but has hugely threatened the life of the patients. ASSOCHAM Health Committee has recommended review of the law to make stringent provision for punishment to the fake drug manufacturers.

"India is amongst the biggest exporters of illegal psychotropic drugs. This is possible because none of the Indian ports have the facility of required checks & balances and testing facilities. "Inadequate manpower, rampant corruption and the fact that only a handful of Government labs are functioning, is but an added advantage for the fly by night operators".
It also highlights that around 25 percent of India's drugs are fake, counterfeit or substandard. It mentioned the tricks of the trade include sticking fraudulent labels on expired products, filling vials with water, stuffing small amounts of real ingredients in packages of popular licensed brands and putting chalk power in medicine packets.

The Industry and the government should initiate a national campaign similar to the "Jago Grahak Jago" campaign and convince the citizens to insist on prescriptions and purchase receipts while making purchase of prescription medicines. ASSOCHAM suggested that government must make it a mandatory that all life saving medicines or high value branded medicines must have a tracing and tracking mechanism in place with use of modern technology.

Encouraging pharmaceutical companies to spend more on research and development and employing more in-house scientists can act as other safety mechanisms to discourage the manufacture and circulation of spurious drugs, adds the paper.

❖ All other drug adulterators must face justice

The Daily Star, July 24, 2014

In a welcome judgment a Dhaka drug court on Tuesday awarded the highest punishment under the law to a pharmaceutical company owner and her two staff members for manufacturing an adulterated drug for children. Being the first case of such conviction, the court has thus set the stage for holding to account other spurious drug makers, the deadly impact of whose products is yet to be unraveled.

The convicted drug manufacturer, as the case statement goes, was responsible for the deaths of some 76 children due to renal failure following application of their brand of paracetamol syrup that contained a highly toxic ingredient. Though the tragic incident took place between 1982 and 1992, a

nexus between the accused and the powers that be caused delay in the process of justice. Mercifully, it was an investigative report ran by this paper in 2009 that the case, which remained in hibernation for some 16 years, reopened leading to Tuesday's verdict.

The individuals punished were not the only ones dealing in deaths in the name of producing drugs. In fact, some five drug companies involved in producing such kind of spurious medicines were responsible for allegedly killing some 2,700 children under similar circumstances.

The government must now step in to expedite the process of justice for three other cases, too and sue the fifth such company still enjoying immunity from law.

❖ Market full with fake products

The Financial Express, July 25, 2014

It is indeed alarming to see that some unscrupulous traders are selling fake butter oil in the package of renowned companies and thus cheating common people. Eid-markets of the country are flooded with fake cosmetics, medicine and food items. Due to the laxity of the authorities concerned the profit-mongers are having a field day in their illegal business. Fake products are harmful for human consumption but it seems there is no one to see the interest of the consumers.

A few days back I bought a shampoo of a reputed company, but when I used it I found it spurious. The shopkeeper, however, changed it. Since then I buy foreign cosmetics only from reputed retailers, as I believe they do not sell fake products. Storing, selling and producing fake products must be discouraged and perpetrators must face stiff punishment so that no one dares cheat people. Fake cosmetic is very harmful for our body; so before buying anything we must exercise highest caution. We hope the law enforcing agencies will look into the matter and save us from this menace.

❖ Are cheap drugs really a bargain?

Pattaya Mail, Issue Vol. XXII No. 30, July 25, 2014

The Thai community must be very poorly. Well, if you go by the number of pharmacies in my street, you would imagine so. The only businesses with more outlets are beauty salons and massage parlors.

With so many pharmacies, the only way they can compete with each other is on price. So where do they get cheaper drugs in the first place?

A big money spinner are the drugs which can keep you in a state of perpetual priapism, a continuing (and painful) male erection and the term was coined

after the Greek god Priapus who is shown in paintings to have a central member like a third leg.

Cheap pills for Erectile Dysfunction (ED) that seem too good to be true, are usually just that - too good to be true! The chances are very high that they are counterfeit.

One of the patients showed me a box purporting to be genuine brand name Cialis tablets, which were not having the desired effect. I was immediately suspicious as the box was not all that well printed. I was quite sure they were counterfeit when I read the Patient Information slip. The English grammar was incorrect, and there were spelling mistakes. Eli Lilly, the 'real' manufacturer does not send out misspelled literature with their product.

Eli Lilly's website on Cialis confirms that there is fake Cialis in the marketplace. The website suggests you ask yourself these questions; any "yes" answers could mean that the Cialis being sold may be fake:

Is the price so much lower than the price at the hospital pharmacy that it seems too good to be true?

Does the pharmacy offer "soft tab" or "fast dissolve" Cialis? (Cialis only comes in tablets. There is no such thing as "soft tab" or "fast dissolve" Cialis). Does your local pharmacy offer "generic Cialis" or a drug with a name that is similar to Cialis? (Such products have not have been evaluated by the FDA for safety and effectiveness - they could be harmful.)

The World Health Organization puts the annual amount of counterfeit drugs sales at something like $35-40 billion per year. No wonder I (and you) get so many offers of drugs through the internet. That's a very large pie.

The World Health Organization also estimates that one in three drugs on the worldwide market today is counterfeit. Sometimes the fake drugs contain toxic substances from which you can die.

Pfizer's laboratories analyze the fakes and a representative stated, "We've seen boric acid, we've seen heavy metals, we've seen road paint, we've also seen floor wax to coat the pills and give them a shine. Obviously, they are detrimental to anyone's health."

It is not just Eli Lilly that is targeted. Pharmaceutical giant Pfizer (yes chaps, the makers of the Blue Diamonds of happiness) estimates its annual losses to counterfeit drug sales at $2 billion.

However, this is actually a serious situation. If specific drugs are only available through pharmacies, on the prescription of a doctor, is it safe to just buy over the counter (or the internet), without any doctor's advice?

The American Food and Drug Administration (FDA) says, "Patients who buy prescription drugs from websites operating outside the law are at increased

risk of suffering life-threatening adverse events, such as side effects from inappropriately prescribed medications, dangerous drug interactions, contaminated drugs, and impure or unknown ingredients found in unapproved drugs."

According to WHO, drugs commonly counterfeited include antibiotics, antimalarials, hormones, anti-diabetic medications and steroids. Increasingly, anticancer and antiviral drugs are also faked. And you can add to that, the 'Blue Diamonds' and all of the Indian knock-offs. Never forget the phrase "Caveat emptor" (Let the buyer beware).

If you receive a spam e-mail from someone who you don't know, offering you specific pharmaceuticals at a cheap price, that should be enough for you to go no further. If your local pharmacies will offer you 'name brand' medication that is supposedly prescription only at a very cheap price, that should ring alarm bells in your head too.

Get your medications on a doctor's prescription from a big pharmacy you can trust. Or suffer the consequences - which can be quite catastrophic if you are diabetic, for example.

- **Illegal, fake drug racket rocks Assembly; BJP for CBI enquiry**
  IBN Live, July 25, 2014

An illegal drug racket busted recently in the state capital rocked the Assembly on Friday with opposition BJP demanding CBI probe into it alleging involvement of health department officials.

Raising the issue during Question Hour, BJP MLA Vikram Kunwar asked how license was reissued to Hanuman Drug Agency in April when expired medicines were seized from it during a raid in September 2010. Kunwar said a raid in July 9 this year at the same agency had yielded a huge cache of expired medicines meant for use in state government hospitals, and demanded a CBI enquiry.

Rejecting the demand for a CBI probe, Bihar Health Minister Ramdhani Singh said the matter was under the jurisdiction of the state government and it would be investigated by his department's officials.

Supporting the demand for CBI enquiry, Leader of the Opposition Nand Kishore Yadav said, "This is a very serious issue as it concerns lives of poor people. The expired medicines recovered in raids are for government hospitals where poor people go for treatment."

Dates on these expired medicines were changed and then sent to places like New Delhi, Uttar Pradesh and even Nepal, Yadav said adding health department probe would not work as roles of health department officials were

questionable.

Congress Legislature Party leader Sadanand Singh also joined the issue asking who was the health minister when drug license of the agency concerned was renewed.

Treasury bench officials led by Finance Minister Bijendra Prasad Yadav said the crackdown on fake and illegal medicines was continuing with raids almost on a daily basis and "we should wait for the full report to come". At this, opposition members stood up shouting anti-government slogans and Speaker Uday Narayan Chaudhary ordered that the discussion on the issue would be taken up on a later date will all its supplementary questions.

❖ Copycat drug cos sprouting up on drug office inaction

The Financial Express, August 03, 2014

Many small pharmaceutical companies are allegedly involved in manufacturing drugs by using the labels of leading brands, wholesalers at the Mitford market, have said.

Abdul Hai, Vice President of Bangladesh Chemist and Druggist Association (BCDA), said while counterfeiters produce antibiotics and many other essential drugs, the drug office is playing the role a bystander, leaving the lives of people at jeopardy.

He said some small drug companies are manufacturing counterfeit products by copying packets, blisters and other labels for some running products manufactured by some pharma majors.

The BCDA leader said the drug office is not playing its due role to identify such drugs even though they know the companies that are manufacturing these.

He said there is a nexus between the wholesalers and some small companies that counterfeit some running products of leading companies.

Salim Barami, director of the drug administration office, said his office fined more than 300 companies about Tk 5.0 million for manufacturing and selling counterfeit drugs until last June.

He said, "We do not have adequate manpower and intelligence to detect counterfeit drugs or the factories which are resorting to this unethical practice."

He said in many countries there are intelligence tips for identifying smuggled or counterfeit drugs among the law enforcement agencies.

"But there is no such arrangement in Bangladesh and even many leading

companies do not inform us in fear of their reputation and the consumers' confidence," the drug official said.

Another BCDA office-bearer said there are more than 250 pharmaceutical companies in the country but only fewer than 40 companies hold almost cent per cent market share. "How do the rest of the companies run their business?" he posed the question.

He said some small companies are investing in counterfeiting leading companies' running products.

According to insiders, though the counterfeit drugs are being marketed mainly outside the capital city, many posh hospitals in Dhaka use foreign drugs using the local label.

By taking the low quality counterfeit drugs people are not getting the desired treatment and even in many cases it is leading to deteriorating health conditions of some critical patients, a drug office senior staff said.

He said, "As per complaints made by different sources we conducted special drives but as our power is limited; sometimes these drives do not become effective."

A senior official of a leading pharmaceutical company said, requesting anonymity, "We heard about many cases of counterfeiting our products and instantly we brought the matter to the notice of the drug office."

He said the drug office does not have adequate manpower and they are not empowered to punish offenders.

A drug office source said, "We are only empowered to file regular cases against counterfeiting and such other crimes verdicts of which take many years."

Citing an example of a closed pharmaceutical company, he said a case was filed against the company in the year 1996 but its verdict was finally delivered in the year 2014.

He said for effective punishment the drug office is currently conducting drives with support of the mobile court magistrates and law enforcement agencies.

❖ Draft policy to tackle advertisements for sub-par products

Myanmar Times, August 11, 2014

The Ministry of Information has proposed new rules for advertising aimed at cracking down on poor-quality products and fake promotions, but sources in

marketing and ad sales say they may prove difficult to implement and harm local businesses.

The draft advertising policy, which the ministry released on July 3 with an invitation for public feedback, instructs media organisations to accept only advertisements for products or services that have been certified by bodies such as the International Organization for Standardization or Myanmar's Food and Drug Administration.

Any statements or claims made in advertising must also be verified before being printed or broadcast, while ads should also include detailed information on how to participate in any promotional activities, such as competitions. Advertisements for products will also have to include an accurate retail price.
Daw Thidar Tin, director general of the ministry's Department of Information and Public Relations, said the policy was drafted in response to public complaints on misleading advertising.

"The purpose is to ensure the advertised price and actual market price are the same and also that the products are of genuine quality," she said.

"We've seen cases where the advertised prices are cheap but you can't actually buy them for that price in the market. And [advertisements] say the buyers will get additional presents, but they do not. We want to stop this from happening."

The rules, which will apply to all forms of media, including online, are likely to be introduced this year after public feedback has been received and assessed, and will come into force in April 2015.

"Manufacturers and other businesses need time to prepare to follow these rules – for example, they might need to improve the quality of their products. That's why we have set a gap between the date we issue the rules and when they come into force."

As well as those advertising products and services, the new policy could pose a heavy burden for media organisations, which would be responsible for vetting ads. It may also financially harm print publications – most generate the majority of their income from advertising – at a time when many in the industry are already struggling to survive.

As well as placing restrictions on how products and services are advertised, the draft would completely ban the advertising of alcohol, tobacco, gambling, unnatural therapies, pyramid distribution schemes and fake investments. It would also ban advertisements from political organisations if the content is not in line with existing laws.

Media organisations will be required to check educational providers have a business licence from the Ministry of Education, while ads for medicines, medical equipment or medical services can only be published or broadcast with permission from the Ministry of Health.

Advertisements for financial services and products have to disclose the degree of risk involved for investors, while non-commercial organisations, such as NGOs, can advertise only if they are formally registered with the government.

Ko Chanthar Oo, a deputy national sales director at Myanmar Consolidated Media, publisher of The Myanmar Times, said the policy would likely hurt ad sales, at least in the short term.

“If we have to ask for documents such as quality certification, the price of the product or permission from the Ministry of Health if it is a medical product when we sell advertising space, sales could go down,” he said.
“It will cause many difficulties for [our] customers. They have to pay money for the advertisements and at the same time they have to face these checks,” he said.

Others said the policy would impact most on smaller local manufacturers, who are less likely to be able to meet international standards. It may also give international brands an edge in the market.

“I don’t think the new policy will affect established brands and products because most already have those kinds of certification,” said Ko Wai Yan, a manager at advertising firm Mango. “But smaller manufacturers could be impacted.” He said the policy is unlikely to affect advertising spending. “Businesses need to advertise,” he said. “If they can only advertise with particular documents or accreditation then they will try to get them.”

U Hnin Oo, a central executive committee member of the Union of Myanmar Federation of Chambers of Commerce and Industry, welcomed the advertising policy on the grounds it would protect consumers and help them distinguish between products. While agreeing it might pose difficulties for businesses initially, he said it should be introduced as soon as possible.

“It should not pose difficulties for honest businesses,” he said. “Setting the real price actually just encourages competition. Consumers can then choose which to buy.”

Daw Thidar Tin said most of the draft advertising policy mirrored regulations in the Consumer Protection Law, which was approved in March and will come into force once by-laws are enacted.

While the policy will not contain any punishments, violations are likely to be in breach of the Consumer Protection Law.

“It will not be good for media organisations to accept advertisements that are not in line with the Consumer Protection Law,” she said. “So the media also need to know the do’s and don’ts to be on the safe side.”

❖ Hurriyat (G) concerned over supply of spurious drugs

Rising Kashmir News, August 13, 2014

Terming the supply of spurious and fake drugs to Kashmir as a serious issue, Hurriyat (G) Wednesday said the state government is playing with the precious human lives and they not only are responsible for this crime but some of their ministers are having partnership in this filthy trade.

In a statement Hurriyat (G) expressed concern and anguish over fake and substandard sprays supplied for orchards, which instead of benefit 'cause severe harm to the fruit production'

"The policy makers of India are working on an extensive plan to destroy Kashmiri nation on health, economic and moral levels and they want Kashmiris to beg for even a drop of water," Hurriyat (G) spokesperson said in a statement.

A high level delegation of All Kashmir Chemists and Distribution Federation (AKCDF) held a meeting with Hurriyat (G) chairman Syed Ali Geelani at his residence and revealed some alarming facts about the supply and trade of spurious and substandard medicine in Kashmir.

The delegation informed Geelani that all activities related to the supply of medicine were although shifted from Srinagar to Jammu in 90's, so the 'traders in Kashmir valley were not only left helpless but Jammu has been declared as the launching pad for making and supplying spurious and substandard medicines to the valley.'

❖ Congress demands MP health minister's resignation

Hindustan Times, August 14, 2014

The Congress has demanded resignation of health minister Narottam Mishra over the issue of sub-standard medicines in Madhya Pradesh. The party has also demanded a Central Bureau of Investigation (CBI) probe into it.

Leader of opposition in the state assembly Satyadev Katare alleged that due to the sub-standard medicines purchased by the state government, the death rate has gone up in the state.

He demanded action against those involved in the alleged scam and said that the government should curb the sale of such drugs.

Katare said, "Since it has been proved that the drugs were sub-standard, the health minister should resign. It is shocking that the government spends huge amount of money to bring movie stars to the state for events but when it comes to buying medicines, it purchases sub-standard drugs and plays with the lives of people.

Health and family welfare minister Narottam Mishra rebuffed Katare's claim. He said the medicines supplied under Sardar Vallabh Bhai Patel Scheme are generic and not sub-standard.

❖ Fake drugs constitute major part of medicine trade: Study

Drug Today Online, August 19, 2014

Growing at a compounded annual growth rate (CAGR) of about 25 per cent, the fake drugs market in India is likely to cross $10-billion mark by 2017 from the current level of about worth $ 4.25 billion, according to a study.

The study conducted recently by Industry body Assocham on "Fake and Counterfeit Drugs In India –Booming Biz" revealed that India, the world's largest manufacturer of generic drugs, has become a hub of counterfeit and substandard medicines stuffed in slick packaging and are often labeled. The size of domestic drug market today is pegged at around $14-17 billion.

The fake medicine trade is flourishing due to lack of adequate regulations, shortage of drug inspectors and a lack of lab facilities to check authenticity of drugs.

Ironically, the biggest centre of spurious drugs seems to be the National Capital Region, which includes Delhi and its suburbs, namely Gurgaon, Faridabad and Noida. It is a growing problem and estimates indicate that fake drugs constitute nearly 1/3 of all drugs sold in NCR, adds the paper.

The concentration of fake drug manufacturers can largely be found in locations such Bahadurgarh, Ghaziabad, Aligarh, Bhiwadi, Ballabhgarh, Sonepat, Hisar and Punjab etc. Agra is also increasingly becoming a hub of fake drugs.

Fake versions popular drugs like Crocin, Voveran, Betadine, injections of calcium and syrups like Cosavil are also available in the market. The fake drug businesses have turned into a massive racket, the study claims.

According to the study, the other key factors responsible for spread of fake drugs are storages of spurious drugs by the chemists, weaknesses in drug distribution system, plenty of uneducated workforces and lax enforcement of the law.

The report suggests that the governance must work with industry and healthcare system to ensure integrity of the supply chain system for pharmaceuticals. It is also important to strengthen legal and regulatory framework.

There should be public awareness campaigns to promote purchasing of medicines through authorised distributors. Furthermore there should be coordination in intelligence sharing among the law enforcement agencies both

domestically and internationally. It is a global problem that calls for a global solution.

It observed that the spurious drugs menace has not only severely impacted the original drug manufacturers' annual but also has hugely threatened the lives of patients.

❖ 'Fake drugs were sold in AIIMS': Sacked hospital vigilance chief makes explosive claims in wake of dismissal

Daily Mail, August 22, 2014

Former All India Institute of Medical Sciences (AIIMS) Chief Vigilance Officer (CVO) Sanjeev Chaturvedi was preparing to frame charges against officers and doctors when he was sacked.

His claims related to glaring mismanagement and irregularities such as the treatment of the dog of a senior official at the premier hospital. "A lobby of corrupt officials got me sacked. Leaders of Congress and BJP patronised the lobby. Fake drugs were sold in AIIMS and a former Congress MLA was behind the racket," Chaturvedi alleged.

Former AIIMS Chief Vigilance Officer Sanjeev Chaturvedi was preparing to frame charges against officers and doctors when he was sacked.

Making grave allegations against the Home Ministry, he said the former Congress MLA had the support of the government. "The lobby conspired to get me sacked after I raided a medical store," he said.

❖ THE DEADLY WORLD OF FAKE MEDICINE

The Daily Star, August 22, 2014

Rajib was only two-and-a-half years old when he was murdered. More than two decades later, his grief stricken mother tightly clutches on to his picture, almost whispering, amid her tears, "This is all I have left of my son."

Masud had just learnt to walk a few days before he was killed. His brother still can't believe that his younger brother was snatched away from them in such a manner.

Little Saima didn't even know the meaning of death, her world was limited to her parents, friends and her toys. When she was brutally murdered, her parents were left stunned, and 20 years on, are still not able to recuperate from their loss.

According to a survey by Bangabandhu Sheikh Mujib Medical University, as many as 2,700 children died due to renal failure after taking toxic syrup from 1982 to 1992. Rajib, Masud and Saima were among these numbers.

In 1991 child kidney specialist Dr Mohammad Hanif first rang the alarm over adulterated drugs. At that time he found many children suffering kidney failure and most of them consumed Paracetamol syrup. In 1982 when he was appointed a resident doctor at PG Hospital in Dhaka Dr Hanif experienced the sad death of at least 100 children suffering kidney failure. He says, "I remember, so many children dying! It was clear that we simply could not do anything to help the children recover. At the end of my shifts, the nurses would tell me again and again that I should just write death certificates for the children, as it was clear that during the night some of them would die. There was nothing we could do."

When he came back to Bangladesh in 1988 after completing his higher study in Australia he noticed that the situation did not change at all. Shishu Hospital had set up a committee with Prof Hanif as the chair to look into the matter. During his investigation he read an article on adulteration of paracetamol in Nigeria. He found that the cases that he observed as a doctor and the incidents that he had read about in the article shared similarities. He says," "Then I thought we had to find a totally independent and high quality laboratory to do the tests -- and so we sent a sample to a person I knew had worked in Massachusetts. He found a government laboratory willing to do the analysis. The test proved positive for diethylene glycol."

Ironically, the said paracetamol syrup, Flammadol, manufactured by the pharmaceutical company Adflame was distributed at the health facility set up for employees working at the President's office in Bangabhaban. Rajib's father, Mohammad Hadis, was the caretaker of the president while Rajib's father, Abdul Qader, was the head of state's cook. Most of the 2700 kids had minor colds and seasonal fever and were thus prescribed the medicine that would take their lives.

Rajib was only two and a half years old when he was murdered with toxic paracetamol syrup.

We might wonder about the delay in the court proceedings, as the cases against Adflame and four other pharmaceutical companies which manufactured syrups containing toxic chemical diethylene glycol, were stayed a number of times. But a father of one the children killed due to this medicine probably says it best, “Don't you think I would have seen justice long ago had the state's guardian [the President] cared for us at all?”

On July 22, this year, a court awarded ten years' rigorous imprisonment to the director of Adflame, Helena Pasha, its manager Mizanur Rahman and the production officer Nrigendra Nath Bala. They were also fined Tk 2,00,000 each under the Drug (Control) Ordinance of 1982. On the onset it may seem that justice has been served but at what cost? These families will never get back their children and even the Public Prosecutor Shaheen Ahmad Khan,

who valiantly fought on their side, stated that he was unsure about how long it would take for the case to pass through all the cases. “The accused might seek bail and thus delay the process,” he informed The Daily Star. “I cannot make predict anything.”

This is a widely publicised case against drug adulteration, and thus, most of us are aware of it. But what about the thousands of pharmacies that sell counterfeit stores to their customers and then have the audacity to protest when they are called out? In 2013, law enforcement officers seized around $640,000 worth of fake and unauthorized medicines from the central medicine sales hub, Mitford, and nearly 30 shops were closed down following the crackdown. But, the shops later reopened after the vendors protested.

These kinds of protest are not just limited to local markets, however. When the radical National Drug Policy (NDP) was drafted in 1982, the Bangladesh Medical Association (BMA), several larger national pharmaceutical companies and even representatives of many Western governments tried to undermine the policy that worked for the betterment of patients but apparently went against the vested interest of the said parties. In his academic paper, 'Bangladesh: A Tough Battle for a National Drug Policy', Dr Zafarullah Chowdhury, founder of Gonoshahthyo Kendro and the man responsible for the formulation of the policy, mentioned that on reading about the policy, then US ambassador to Bangladesh, Jane Coon, visited General Ershad to deter the implementation of the policy. “Her purpose was to convince him (Ershad) that the policy should not be implemented because it was unacceptable to the US. She insisted that at the very least, implementation of the policy should be postponed,” writes Dr Zafarullah.

The policy had called for the implementation of a generic drug policy that would deter medicine companies from manufacturing adulterated drugs. However, at a public hearing called by Ershad due to mounting international pressure, TNC representatives argued that the policy would “deter foreign investors,” making veiled threats to withdraw from the country.

“The small (pharmaceutical) companies took a more reasonable approach. Recognising that 90 percent of their products had no scientific validity, they argued that the fault lay with the Drug Administration which should not have permitted their products in the first place. They said that the negligence of the Drug Administration should not result in their financial ruin,” stated Dr Zafarullah in his paper.

The 1982 NDP ensured that the manufacturing and import of drugs were reduced to 225, and emphasised on the manufacture of generic drugs that could be manufactured locally, thus resulting in the wider availability of medicines at a significantly reduced price.

The comprehensive, people-oriented policy was amended in 2005 with some drastic changes. While the earlier policy stressed on the imposition of certain limitations on pharmaceutical companies, the policy amended in 2005 did not include such restrictions. “As the policy contains no obligatory provisions for

the pricing of necessary medicines, pharmaceutical companies tend to manufacture and sell higher priced necessary drugs, thus completely ignoring the needs of ordinary people. Moreover, it was mentioned in the 1982 drug policy that if the main ingredients of medicines were readily available and accessible in the local markets, these medicines (for example Antacid, Paracetamol and vitamin capsules) should not be imported. However, the amended policy has no clear provision for this," writes health service provide Mojnu-nul Haq in his book Tikto Oushudh, Rugono Chiktsha O Jimmi Jonogon.

Dr Muniruddin Ahmed, Professor, Clinical Pharmacy and Pharmacology, Dhaka University says that the medicines which have high commercial value are the ones that are most tempered with. "Lipito, a cholesterol lowering drug manufactured by the leading American pharmaceutical company Pfizer Pharmaceuticals, is the most widely sold medicine in the world, with around 160 billion pills sold every year. It's believed that this drug is the most counterfeited around the globe. Even in Bangladesh, you'll find adulterated versions of this drug. What I mean to say is that medicine tempering can be related to the demand for the particular drug, as pharmaceutical companies prefer to produce these medicines at a low price, thus combining harmful elements and turning them toxic," he adds.

According to a survey as many as 2,700 children died due to renal failure often taking toxic syrup.

Dr Ahmed adds that it's impossible for regular people to identify which drugs are genuine and which ones are counterfeit due to immense growth in technology in the field of medicine. However, there are some ways to know whether the medicines you are taking are genuine or fake copies. "The medicine packets often contain the name of ingredients and an instruction leaflet. If you notice any mistake in the name, ingredients, description or even language on these packets and leaflets, it is quite likely that you are holding a counterfeit drug in your hands," says Dr Ahmed. However, how many people have the patience or time to do this simple task? "Our ignorance will lead to our demise. We should at least be aware of the literature of some necessary medicines to ensure our safety," he cautions. He also adds that including generic name of medicines instead of brand names could actually help in combatting fake drugs.

Dr Ahmed argues that even though the National Drug Policy of 1982 was responsible for the emergence and growth of the pharmaceutical industry of the country, many companies took advantage of the law, as they laced their drugs with cheap, often fatal, alternatives of the main ingredients.

"I believe that the Directorate General of Drug Administration (DGDA) was responsible for this, as they were unable to monitor or prevent the production of such fake drugs," says DrAhmed. "Even now, this organisation plays an insignificant, often powerless role in monitoring the manufacturing of drugs. They are basically under the thumb of big medicine companies, and political parties. Thus, it's crucial for the welfare of our country to reorganize the

DGDA so that they can effectively stop the production of fake medicines," he adds.

Doctors often prescribe medicines of certain brands without even understanding whether the drug has genuine components or is a fake. A doctor of Dhaka Medical College Hospital, who is unwilling to publish his name, says that doctors should check whether the drug manufacturer has proper licensing or not. They should further check the literature of the medicines before accepting them from medical representatives of pharmaceutical companies," he says.

Child kidney specialist Dr Mohammad Hanif first rang the alarm over adulterated drugs.

He further adds that doctors usually prescribe the medicines found in the market but are not aware of whether the drugs have been tempered with. It's only when the patients return to the doctor with complaints of adverse reactions that they are fully aware of the state of matters, he says.

"The government's job is to ensure that the DGDA is not politically influenced or motivated. They should put pressure on the said organization to monitor the whole drug markets properly. All over the world there are examples of medicine tempering by big pharmaceutical companies. But steps are being taken to ensure that these culprits are brought under the law. The DGDA knows where and how fake medicines are manufactured and yet they fail to take any initiative," he concludes.

When we tried to contact Ruhul Amin, Deputy Director of DGDA, for his remarks regarding the increasing rate of drug adulteration, he declined to comment.

It's sad that the one basic right that every human being deserves is being denied to us because some fraudulent pharmaceutical companies feel that their profits are more important than the lives of a few millions. It's even sadder that even though the concerned authorities are aware of such fraudulence, they turn a blind eye to these crimes, thus inadvertently promoting this rampant trade of death.

❖ Mingalar market, an illegal medicine cabinet

Myanmar Times, August 25, 2014

Mingalar market in Tarmwe township is a maze; the four floors of the wholesale emporium are packed with clothes, fabric, toys, umbrellas, shoes and other consumer goods. There are more than 4000 stalls, each measuring just five feet (1.5 metres) in width. The four elevators in the building are normally full of boxes shuttling up and down the floors, so many customers instead choose to ascend and descend on foot.

The top level is home to more than 400 stalls selling medical products. Despite there being fewer customers than on the lower floors, this is the centre of a distribution network for both legal and illegally imported medicines that spans the entire country.

Medicines for sale on this floor come from wholesalers and what is known as the "line market" – products without Food and Drug Administration (FDA) approval imported illegally, said U Tun Aung, a shop owner at the market. Some are even brought into Myanmar on commercial flights in passengers' carry-on luggage.

The market, which was opened in 1990, has come under increasing scrutiny from the FDA, which works closely with the Customs Department, the Directorate of Trade and the police to stem the trade in black market medicines.

In 2013, after receiving complaints from the public, the FDA commissioned a survey that found many illegally imported antibiotics and malaria and urinary tract medicines were being sold in Myanmar.

In 2014 police charged 15 business owners who ran pharmacies in Yangon with selling illegal medicines.

And whilst the Mingalar Market Development Committee said no one had been prosecuted in the market, the FDA point to 40 prosecutions they made there in 2012, saying it has been the main focus of their investigations.
But despite that focus, FDA officials concede that their efforts have had little impact.

"We try to control the sale of illegal drugs at the market but we cannot stop all of it. When we go to these shops to inspect for illegal medicines, store owners move their stock before we come," FDA director Dr Theingi Zin told The Myanmar Times.

She said the medicines are often already approved for sale in foreign countries but agents do not want to spend the money to get them registered in Myanmar. In other cases the medicines are fake or substandard, which can cause more problems for those who take them.

It costs between US$700-800 to register a medicine for three years and so far 17,000 medicines have been registered. It's estimated that around 20 percent of medicines are illegally imported.

"These illegal medicines are not safe for people because they may be counterfeit or poor quality," Dr Theingi Zin said.

At best, the use of these products is unlikely to cure whatever ailment the patient has, and at worst they risk harming the patient.
"These medicines can cause drug resistance, the patient will not feel better and could have an allergy," said Dr Sid Naing, country director of Marie

Stopes International, a health NGO. “Resistance to antibiotics is particularly dangerous for people who have tuberculosis or malaria.”

The problems linked to the wide availability of illegally imported medicines are compounded by consumer habits that see many people take medicine unnecessarily or incorrectly. Instead of visiting a doctor, it is common to seek advice from staff at pharmacies or even grocery stores, who are usually not trained to administer the medicines they sell.

“This is a problem that many developing countries face,” Dr Sid Naing said.
Ma Poe Poe, who works for a medical distribution company and lives in North Dagon township in Yangon, said her mother still buys medicine in Mingalar market when she feels sick.

“If a customer tells the shop owner their symptoms the seller will give you medicine,” she said, adding, “I don’t think it is safe to take this medicine but my mother is still buying it.”

The illegal medicines are popular simply because they are cheaper than the registered imports, and are generally imported from China, India or Thailand.
But U Myo Zaw, a pharmacy owner from North Dagon township, said that without illegally imported pharmaceuticals some people would not be able to afford medical products.

He cited the example of oral contraceptives. In the past year, illegally imported contraceptives have spread widely because the state-produced contraceptive tablets are in short supply.

“Government clinics give free birth control pills to all women and sell them for K500 in the market. However, there are sometimes shortages and the legal drugs cost K2000 for one month’s supply, which is too expensive for most people,” he said. “So instead they buy one that costs just K300 and has come from China.”

U Myo Zaw sometimes buys illegally imported medicines from Mingalar market and Bogyoke Aung San market to stock in his shop but said crackdowns by the authorities are making it increasingly difficult to find wholesalers.

“They have been selling these illegal medicines for more than 10 years but nowadays the market is down because it is too dangerous for the wholesalers. But there is still demand, so some keep selling,” he said.

When The Myanmar Times visited Mingalar Market and inquired about the availability of illegally imported drugs, stall owners said they only sell them to regular, longstanding customers. Newcomers are unable to buy them because the wholesalers worry they could be working undercover for the police.

Mingalar Market Development Committee chair Dr Saw Hla Tun said the

market's management does not allow shops to sell unregistered medicines but conceded that the practice is common.

And it's clear to the authorities and many consumers too that, whilst there is a demand for cheap medicine, the supply of illegal medicines is unlikely to be stopped.

❖ Sushil Kumar Modi seeks CBI probe into drug buy 'scam'

Insight TV News, August 27, 2014

Former deputy chief minister and BJP leader Sushil Kumar Modi on Tuesday demanded a CBI inquiry into the purchase of drugs worth Rs 100 crore by the Bihar State Medical Services and Infrastructure Corporation Limited (BSMSICL), alleging involvement of top JD (U) leaders in the "scam".

Modi also demanded that the reports of two committees ? one headed by additional director (health services) Dr K K Singh and the other headed by director-in-chief (health services) ? be made public. The committees were formed in January to probe the purchase of substandard drugs and death of a patient following alleged administration of spurious drugs at the medical college hospital at Bhagalpur.

The BJP leader alleged the then CM Nitish Kumar, who held the health portfolio then, was aware of the irregularities in the purchase of substandard drugs at the rates higher than the ones decided by the State Health Society (SHS). The BSMSICL also purchased medicines from six blacklisted drug manufacturers.

JD (U) MLA Ravindra Rai had written a letter to the then CM, informing him about the affairs of the BSMSICL. The vigilance is probing the purchases made by the BSMSICL. The Union health ministry grants money for purchase of drugs and equipment under the National Rural Health Mission.

According to a letter submitted by the SHS's executive director to the principal secretary of the department on May 12 this year, a particular drug was purchased by the BSMSICL for Rs 58 per piece as against Rs 31.20 fixed as its price by the SHS. The officer had told the principal secretary that the revenue loss to the government should be prevented, said Modi.

The BJP leader also produced a letter written by an under secretary of the department to the BSMSICL's managing director, who is an IRS officer, that the BSMSICL should purchase drugs from approved vendors at the rates prescribed by the SHS in order to avoid objections from the CAG and Public Accounts Committee of the state legislature. However, Modi alleged, BSMSICL ignored the advices of both the officials.

Modi said on January 13 this year, the government set up a five-member

inquiry committee headed by Dr K K Singh to probe the drug and equipment buys. The committee was asked to submit its report within a week. Another committee was asked to probe the death of Arvind Shah, a patient admitted in Bhagalpur medical college hospital. Neither of the two probe reports has been made public, he added.

He said the rates of 31 drugs purchased by the BSMSICL were higher by 50% to 900% than the rates decided by the State Health Society. Some of the drugs purchased by the corporation were declared "batch failed" and found substandard in the labs. Sanjay Kumar, an officer of central secretariat services and belonging to Nalanda district, was the purchase committee's chairman, Modi alleged.

The police had recovered huge quantity of substandard and spurious drugs from different parts of Patna recently. Among the drugs seized were also those purchased by the BSMSICL.

❖ Spurious drug business an organized crime: DAK

Rising Kashmir, August 27, 2014

President Doctors Association Kashmir (DAK) today in a statement said that government has failed to curb the menace of spurious drugs in the valley.

“This illegal business in the valley is an organized crime supported by powerful vested interests. Everyday people die because of this criminal activity and masterminds are let off, DAK president Nisar ul Hassan said.

“There is a deep rooted nexus between shoddy pharma companies and some power houses that pumps massive quantities of spurious drugs in the valley,” he said, adding, “India is the capital of counterfeit drugs. According to WHO, India accounts for 35% of world’s spurious drug market. In an estimate 40% of Indian pharma market is under the grip of spurious drugs.”

The amended Spurious Drug Act 2008 contains stringent provisions such as maximum penalty of life imprisonment, making the offence cognizable and non-bailable and designating special courts so that judicial proceedings can be expediting, he said, adding, “The new law has provisions for reward to “Whistleblowers” who can take risk of providing information about the perpetrators of the crime.”

❖ ‘Jamu’ makers face losses of Rp 2 trillion to illegal products

The Jakarta Post, August 28, 2014

A business group has demanded that the government curb the increasing

sales of illegal herbal medicine, which could remove Rp 2 trillion (US$170.83 million) from the annual sales of local manufacturers making legal products.

Such illegal products — partly from imports — may contain prohibited medicine substances and chemicals that are made by firms operating without production licenses or distribution permits.

Imported herbal medicines, such as from China, India and neighboring nations, are sold either through the Internet or through multi-level marketing networks in the country.

Apart from its economic impact, the widespread presence of illegal herbal medicines has already made consumers restless due to fear of their low standards, according to the Indonesian Herbal and Traditional Medicine Association (GP Jamu).

GP Jamu chairman Charles Saerang said the Food and Drug Monitoring Agency (BPOM) and the Trade Ministry should take stricter action against illegal products that posed a threat to local manufacturers of herbal medicines, locally known as jamu.

“We’re worried that these illegal herbal medicines will have a negative impact on the development of our jamu industry,” Charles said during the opening of the cosmetics and herbs industry exhibition at the Industry Ministry on Tuesday.

The distribution of illegal herbal medicines in Indonesia had accelerated in the past five years, but the situation may pick up next year when the ASEAN single market, which would enable freer flows of goods, was established, he added.

Indonesia, home to a wide range of herbs, expects its domestic sales of herbal and traditional medicines to expand by 15 percent this year to Rp 15 trillion from last year, due to its increasingly health-conscious middle class, according to the association.

That will comprise Rp 3 trillion from the sales of jamu powder, Rp 3 trillion from food supplement and the rest from cosmetics, spa, aromatherapy, health food and beverages.

Such a sizeable domestic market will benefit 1,247 jamu manufacturers that employ a total of 15 million workers nationwide.

The BPOM recently stepped up its fight against the circulation of such unsafe products after finding a stable rise in the online marketing of counterfeit drugs, traditional medicines, cosmetics and food in past years, based on observations.

In May, the agency confiscated more than 1.39 million pieces of such illegal items worth Rp 7.47 billion, which were traded online.

Deputy Trade Minister Bayu Krisnamurthi said the key solution to this issue would be tighter supervision from the BPOM — the only body with the authority to do so.

"If the BPOM needs regulations to better supervise trade, we will respond to that demand," he said.

Bayu further said the ministry would be open to complaints from the business group, but required the submitting of accurate data on the issue.

❖ Spurious drugs an organised crime in Kashmir: DAK

The Greater Kashmir, September 02, 2014

Alleging that there is a deep-rooted nexus between some shoddy pharmaceutical companies and big power houses that pump massive quantities of spurious drugs in the valley, the president of Doctors Association Kashmir (DAK), Dr Nisar ul Hassan Monday said that the government has failed to curb this menace.

Quoting a report of Drug and Food Control Organization (DFCO), he said that the number of substandard drugs in the valley has increased to 138 in 2013-14 from just 21 in 2010-11. "This illegal business in the valley is an organized crime supported by powerful vested interests. Every day people die because of this criminal activity and masterminds are let off," Dr Hassan alleged in a statement.

Calling India as the "capital of counterfeit drugs", he added that the country, according to WHO, accounts for 35% of world's spurious drug market. "In an estimate, 40% of Indian pharma market is under the grip of spurious drugs," he informed.

Dr Hassan said the amended spurious drug act in 2008 contains stringent provisions such as maximum penalty of life imprisonment. The offence has been made cognizable and non-bailable and it asks for designating special courts so that judicial proceedings can be expedited, he said.

❖ Medicine scam culprits will not be spared: Manjhi

Business Standard, September 04, 2014

Bihar Chief Minister Jitan Ram Manjhi today said stern action would be taken against those found guilty in the medicine purchase scam.

"The probe committee report has come and it has revealed a scam of around Rs 15 crore. It is being analysed further. Those found guilty will not be spared.

We'll take stern action against them," Manjhi told reporters on the sidelines of oath taking ceremony for the 10 newly elected MLAs in the recent by-polls. Manjhi, however, evaded questions on former Chief Minister Nitish Kumar who was also holding the health portfolio during the period corresponding with the scam.

"I don't know about the situation back then," he said when asked about it. The health department had put the report of medicine scam probe committee, headed by Additional Director (Health) Dr K K Singh, in public domain yesterday. The report indicted Bihar Medical Services Infrastructure Corporation Limited (BMSICL) Managing Director Praveen Kishore and eight other senior officials for the scam and revealed that drugs worth Rs 14.4 crore out of total Rs 60 crore purchased during January and July this year were bought at inflated prices in comparison to the rate fixed by the State Health Society Bihar (SHSB).

Making the report public, Health Minister Ramdhani Singh had said, "action against the guilty will be taken within 48 hours." The report also said that drugs worth around Rs 20 crore had been bought from firms which were blacklisted in other states.

Apart from BMSICL MD, the government has decided to show cause eight members of the technical evaluation committee of the health department, which had screened the firms and recommended the prices suggested by them, the minister said. These include Joint Secretary (Health) Sanjay Kumar (since posted to New Delhi), Director-in-chief (Health) Dr Surendra Kumar, Deputy Director (Industries) Om Prakash Pathak, State Drug Controller Hemant Kumar Sinha, Patna Medical College and Hospital (PMCH) Deputy Superintendent Bimal Karak, SHSB Assistant Director Dr D K Raman, UNFPA representative Haider and BMSICL General Manager (Finance) Tripurari Kumar. The minister said his department was also considering action against specially invited members to the purchase committee.

Apart from financial irregularities, the purchased drugs were also of substandard quality. Some drugs were also misbranded with double labels. These cases came to light in July this year when two persons in different districts lost their lives allegedly due to substandard medicines administered to them at government hospitals. The state government cracked the whip after the opposition parties raised the issue vociferously in the state legislature and demanded CBI enquiry into the scam. The functioning of state Assembly and Council was disrupted over the issue for four days during the Monsoon session.

❖ Playing with lives

State Times, September 05, 2014

As per details provided by the Drug Controller of the State to a news agency 12,534 samples of drugs were collected in the State since the year 2010 while

prosecution proceedings have been initiated against 175 drug suppliers so far.

During the year 2012-13, some 2,365 drug samples were collected and 87 found not having the standard quality and 24 misbranded. Out of the samples collected, 63 were found sub standard and prosecutions against 52 drug suppliers have been launched. During 2013-14, in all 4,874 drug samples were collected and 151 were not of standard quality, 13 were misbranded. Out of these samples, 138 were found sub standard and prosecution against only 62 drug suppliers were initiated. Meanwhile, the drug department has stated that for the ongoing year, 1,722 drug samples have so far been collected and the investigations are going on.

Drugs play as crucial life savers for restoring health, preventing diseases and epidemics. When drugs itself are counterfeit, these pose addictive danger to patients by forced over dosage. Counterfeit medicines are difficult to detect. Fake drugs generally contain the same salts but their purity and quantity is suspected. As a result, patients need to consume more amounts of drugs for relief without desired result. Fake drugs can escape controls hence counterfeiting has become a global problem, which has drawn attention of medicos.

According to the WHO reports, India accounts for nearly 35 per cent of world's spurious drugs market. It is estimated that 40 per cent of the pharma market in our country, i.e. Rs 8,000 Cr is infested with spurious and black marketed drugs. Not only the people's lives are at stake but also there are serious losses to the exchequer of both Central and State Governments on account of huge revenue of sales tax and excise duty. The Indian pharma industry has a domestic turnover of more than Rs.20, 000 Cr and exports over Rs.10,000 Cr. Unfortunately, our successive state governments busy in self praise and fighting phantoms with Centre and opposition and in slogans of appeasements to a limited section, are missing this vital issue of social welfare. Present dispensation with limited shelf life left could at least punish the booked culprits before the elections are announced.

❖ Indian pharmacologist charged with smuggling fake drugs

IBN Live, September 13, 2014

An Indian pharmacologist and an American pharmacist have been charged with smuggling four million misbranded and counterfeit pharmaceuticals into the US, federal prosecutors said.

Indian Balbir Bhogal, 67, from Las Vegas, and Wisconsin-based pharmacist Marla Ahlgrimn, 59, were arraigned on an indictment in federal court in Central Islip, New York, before US Magistrate Judge Gary Brown.

In a 10-count indictment, the duo was charged with importing and distributing

controlled substances and misbranded drugs, trafficking in counterfeit drugs, mail and wire fraud, smuggling and money laundering.

According to the indictment and information presented at the arraignment, from June 2007 to May 2010, Ahlgrimm and Bhogal, who allegedly arranged for the manufacture in India of millions of tablets of controlled substances, including alprazolam and phentermine, and prescription drugs, including carisoprodol and counterfeit Viagra.

Although they did not hold an importer's license from the Drug Enforcement Administration, the defendants allegedly arranged for the importation of the same drugs into the US.

Neither the incoming packages nor the tablets themselves were labelled or identified as controlled substances or prescription drugs, federal prosecutors alleged.

The drugs were allegedly intended to be supplied to an online pharmacy, based in Costa Rica that catered to customers within the US, including Brooklyn and Queens, New York.

The online pharmacy used call centres and websites based outside the US, but filled the orders from inside the US using individuals who were not licensed pharmacists to bottle, label and drop-ship the drugs.
To facilitate the operation, the defendants allegedly wired money from Costa Rica to the US and then to India, federal prosecutors said.

❖ When Counterfeit and Contaminated Drugs Are Deadly

Pacific Standard, September 18, 2014

For Food and Drug Administration and law enforcement officials with a special interest in cracking down on counterfeit and contaminated pharmaceuticals, September has already proved to be a very busy month.

Last week, a pharmacist in Wisconsin and a pharmacologist in Nevada were both charged with supplying “at least four million misbranded and counterfeit pharmaceuticals to an illegal Internet pharmacy based in Costa Rica that catered to U.S. customers,” according to a Justice Department press release.

Marla Ahlgrimm and Balbir Bhogal have been accused of masterminding a scheme to manufacture imitation versions of drugs like Xanax and Viagra in India, smuggle them into the U.S., and then arrange for Costa Rica-based call-centers to fill orders to American customers. Everyone involved was unlicensed, and the packages were not labeled according to FDA or Drug Enforcement Agency standards. Oh, and most importantly, the drugs were fake. Madison.com reports that the pills were found to either contain lower dosages of medicine than what they claimed, or else no real medication at all.
The prospect of millions of Americans being disappointed with the potency of

the Viagra they illegally purchased from online pill peddlers is, perhaps, not the most sympathy-rousing "buyer beware" tale out there. But another legal case also developing now involves a darker tragedy. Earlier this month, agents arrested a (former) pharmacist, Glenn Adam Chin, as he was attempting to board a plane to Hong Kong at Boston's Logan Airport.

In 2012, a damning report in the Lancet announced that a third of all anti-malaria drugs for sale in Asia and Africa, when tested, were found to be either fake or expired.

Chin was the head pharmacist of the New England Compounding Center—since closed—which sent a batch of contaminated drugs to pain clinics across the country in 2012. The medication, meant to alleviate back pain, had not been properly sterilized, and when doctors injected it into their patients, it caused an outbreak of fungal meningitis. In all, 751 patients got sick from the tainted vials, and 64 people died.

The compounding center was shut down, and its staff has been under investigation by the U.S. Attorney's office ever since. Chin is the first person to have been arrested so far. (Chin's lawyer told the Boston Globe last week that his client has been made a "scapegoat," adding, "I am sure that someone needs to be blamed, but I am not sure it is him.")

Rogue compounding centers aside, counterfeit, contaminated, and otherwise compromised medication is a worldwide problem. In 2012, a damning report in the Lancet announced that a third of all anti-malaria drugs for sale in Asia and Africa, when tested, were found to be either fake or expired. "Because malaria infects so many people, often in poor countries, margins are low and competition between legitimate brands of medicine is fierce," as Marc Herman explained. "At the same time, the disease is so common, medicine to treat it is sold over the counter in many regions, and much of it taken without proper medical oversight."

The consequences are deadly: When drugs aren't potent enough, they don't just fail to treat the patients taking them; they also contribute to the increasing resistance of malaria to drugs overall. One researcher writing in the Malaria Journal this year called the manufacture and sale of counterfeit anti-malaria drugs "a crime against humanity."

Europe has its share of problems in this area as well. Just this month, counterfeit versions of Roche's cancer treatment MabThera were discovered in Germany. European authorities say drug-theft and -counterfeiting is rife in Italian hospitals. And in 2012, authorities in England and Spain busted an extensive crime ring that was selling fake erectile dysfunction drugs that the gang had imported from China and Singapore.

The World Health Organization has said in recent years that about half of all drugs bought and sold on the Internet are fake, and that a tenth of all global pharmaceutical commerce worldwide involves counterfeits. The WHO has cited INTERPOL raids throughout Asia, the Middle East, and Africa that

uncovered counterfeit drugs ranging from antibiotics to birth control, from organ transplant drugs to medicine for schizophrenia.

In fact, even the worldwide proliferation of counterfeit Viagra is no joke. Counterfeit drugs can have less-potent dosages than they are supposed to, but they can also contain entirely different, harmful ingredients. The WHO reported an episode in 2008 in Singapore in which drugs purportedly meant for erectile dysfunction actually contained glyburide, a medicine typically taken by diabetics. The drug sent 150 people to the hospital with severe hypoglycemia; seven patients suffered brain damage and four people died.

Those who work to stem the flow of fake drugs around the world have a set of complicated obstacles before them. As economists Erwin Blackstone, Joseph Fuhr, and Steve Pociask succinctly put it in the journal American Health & Drug Benefits in June:

Internet pharmacies, which are often the source of counterfeit drugs, often falsely portray themselves as Canadian, to enhance their consumer acceptance. Adding to the problems are drug shortages, which facilitate access for counterfeits. A long and convoluted supply chain also facilitates counterfeits…. Trafficking in counterfeits can be extremely profitable; detection of counterfeits is difficult, and the penalties are modest.

The researchers recommend that the punishments for manufacturing and selling counterfeit drugs should be much harsher, and authorities should put more resources into educating the public about the dangers of ordering drugs from online pharmacies.

Most surprisingly, the authors also suggest that the tech world could join the fight, by helping to "construct Internet search algorithms so that legitimate online pharmacies appear first."

❖ No quality control for life-saving generic drugs, govt apathetic

The Times of India, September 16, 2014

While the Indian government is pushing generic drugs as they are cheaper and, therefore, more affordable, there seems to inadequate attention on ensuring that the quality protocol of these drugs is properly observed.

A case in point is a life-saving drug, Liposomal Amphotericin B, which is used to treat fungal infections in critically-ill patients. Several doctors say while the need for the drug is obvious, the drug controller general of India (DCGI) has failed to ensure that pharmaceutical companies manufacturing the generic version of this drug carry out proper tests.

In fact, a government-appointed expert committee had recommended action against the erring pharma companies.

TOI also has a copy of a letter from VM Katoch, the director general of Indian Council of Medical Research (ICMR) to the DCGI on June 4, calling for action against companies manufacturing and marketing untested Liposomal Amphotericin B.

"The quality of these preparations will immensely affect the efficacy and toxicity," the letter states. Katoch told TOI that he wrote this letter in response to complaints received by him.

When contacted, DCGI GN Singh said the matter was forwarded to the state authorities for necessary action. "I am not aware of the present status of this particular case but licenses are given for the manufacture and marketing of generic drugs after detailed examination of the risk factors," he said.

Doctors say the obvious risk of Amphotericin B is its high toxicity, which can lead to kidney failure and death. However, given that it's a life-saving drug, used when patients are in terminal decline, they have little option but to use the generic version, especially for poor patients. "It's an unsatisfactory situation, but we monitor toxicity closely to see that it doesn't go out of control," said a doctor.

"Liposomal Amphotericin B was included in the Indian Pharmacopoeia — the standards setting institution for drugs in India — in the year 2010 and a number of licenses for the manufacture of generic versions of the same drug were granted without clinical trials. It was removed later when a senior official from the department of biotechnology raised objections. But the companies are still selling them," said one of the experts.

TOI spoke to cancer specialists and transplant surgeons who use the anti-fungal medicine frequently. They said the current controversy is symptomatic of the real problem facing the health system. "The government is right in promoting generic drugs but where is quality control? There is no limit on the number of companies that can be allowed to manufacture the generic version of a drug and the amount they can charge. In case of Liposomal Amphotericin B, over a dozen pharma companies have been awarded the licenses," said a senior doctor.

Dr AS Soin, liver transplant surgeon at Medanta Medicity, Gurgaon, said fungal infections are common in terminally-ill patients and transplant cases. "Though there are advantages of a pioneering drug but we tend to use the generic ones because the former is simply unaffordable to many. The research molecule of Liposomal Amphotericin B is two to three times costlier as compared to the generic version," he said.

A senior AIIMS doctor, who did not want to be quoted, added: "Generic drugs are by definition as effective as branded ones. But the problem lies in poor regulatory mechanism that allows the manufacturing and marketing of spurious drugs in the name of generic versions."

Health ministry officials point out that while tests are conducted to check chemical composition of a generic drug, there are none to ensure "bioequivalence" or its efficacy compared to the pioneer drug.

Dr AK Dewan, medical director of Rajiv Gandhi Cancer Institute, regulators should allow limited branded generics of a particular compound and ensure quality. "The generic version costs Rs 7,000 per month. Another branded drug for lung cancer and head and neck cancer earlier cost Rs 80,000 per month for 100 tabs but with generic medicines available, it has come down to Rs 7,500. Even original manufacturers are forced to reduce prices to remain competitive," he says.

❖ Some Indian Drug Makers Send Low-Quality Meds to Africa Deliberately?

Wall Street Journal-Pharmalot, September 18, 2014

Do some Indian generic drug makers deliberately send low-quality medicines to Africa?

An analysis of 1,470 samples of two antibiotics and two tuberculosis drugs that were labeled as made in India, and then sold in Africa, India, and five middle-income countries elsewhere, found that more sub-standard drugs were purchased in Africa by the researchers. The drugs were made by 17 different Indian manufacturers, none of which were named in their analysis.

For instance, the researchers found that 17.5% of samples of the rifampicin tuberculosis treatment that were purchased in Africa were substandard, which meant there was less than 80% of the active pharmaceutical ingredient found. By contrast, 7.8% of the samples of the same medicine obtained in India were substandard.

Another example: the researchers found that 8.6% of samples of the ciprofloxacin antibiotic that were purchased in Africa by the researchers were substandard, compared with 3.3% of those purchased in India. There were no instances of substandard samples purchased in other countries, including China, Brazil, Turkey, Thailand and Russia.

The analysis appears in the National Bureau of Economic Research, and was funded by The Legatum Institute, a public policy think tank, and the Social Sciences and Humanities Research Council of Canada, a government agency that supports research.

Overall, nearly 11% of the medicines that were bought failed a basic assessment of active ingredients and most of those – 7%, to be exact – were found to be substandard, since these contained some amount of the correct active ingredient, but were essentially under-dosed versions of the medicines.
“What we are seeing are companies willfully selling worse-quality medications where they suspect those medicines will not be found,” Roger Bate, an

American Enterprise Institute scholar who led the research, tells us. "It was not all companies and not all products… But statistically speaking, what we're seeing is some level of intent. The worst products are going to markets where they are less likely to be caught."

We asked the Organization of Pharmaceutical Producers of India for comment, but have not yet received a reply. A spokesman for Sun Pharmaceuticals, which was not named in the paper, declined to comment. Sun Pharma is in the process of buying Ranbaxy Laboratories , which has had numerous quality-control problems. A Ranbaxy spokesman has not responded to our questions.

Several Indian drug makers, in fact, have been on the regulatory radar over the past couple of years due to manufacturing woes. The FDA has banned products made at three dozen plants run by different Indian drug makers amid a crackdown in response to concerns about the veracity of the pharmaceutical supply chain.

"There's a problem with oversight in India," says Bate. "It's incumbent on regulators to do their job. But regulations within these countries must be taken more seriously than they currently do. These companies save a lot of lives around the world, but they could save more lives if the quality of their medicines was higher."

One expert, however, questioned the conclusions. Vince Suneja, chief executive of TwoFour Insight Group, a consulting firm that works with Indian drug makers, says the analysis is largely anecdotal. He notes the report concedes the findings are based on "crude" assessments of active pharmaceutical ingredients of product samples, suggesting the results could not be generalized to future research.

Moreover, he notes that not all of the drugs were registered for marketing authorization in the countries where they purchased. But the sample size data indicates that products registered in African countries have the same statistical passage rate of products in India and other countries. This implies the issue is with drugs that are not registered for marketing authorization.

"This tells us there's a supply chain problem," says Sunejga. "So the question becomes is India intentionally exporting lower-quality product or is Africa accepting product that isn't registered?" As a result, suggesting that lower-quality drugs are intentionally sent to Africa "unfairly categorizes all Indian companies as the same, when this conclusion is not supported in the paper."

❖ Bhopal: Whistleblower doctors allege witch-hunting by health dept

Hindustan Times, September 19, 2014

Two senior doctors, including the president of Madhya Pradesh Medical

Officers Association, who had raised the issue of supply of substandard medicines, alleged on Thursday that health department was indulging in "witch-hunting of the whistleblowers," instead of taking action against those who supplied substandard medicines in the first place.

MP Medical Officers Association president Dr Ajay Khare told HT that he along with Dr Padmakar Tripathi, medical officer at Government TB Hospital and Arun Diwedi, non-medical assistant at JP Hospital, who is also the president MP Class-III Employees' Association, have been served charge sheets, accusing them for conspiracy and defaming government's scheme for free medicine distribution.

"I have received a copy of the charge sheet, while Dr Padmakar Tripathi and Diwedi are yet to receive a copy. But charge sheets have been put on the state health department's website since September 16," Khare said.

He claimed that instead of exposing the suppliers of substandard medicines and where such medicines have been supplied in last few years, the department was baying for their blood because they dared to raise this issue which could make a difference of life and death in some cases.

Dr Padmakar Tripathi said while working at Government TB Hospital, he found that one antibiotic Ofloxacin was having no effect on the patients despite being a life saving drug.

"After that I filed an RTI at the controller food and drugs, where I got the reply Ofloxacin was substandard. The officials also informed me that in last two and half years. Besides, the testing lab had found 147 substandard medicines. Now, if the health department is claiming that these medicines were sourced from private medical stores, the question arises is whether it was private or government, it is the moral responsibility of the authorities and doctors to stop and raise a hue and cry about," he said, adding that if the need arises, they will approach the court.

When HT contacted principal secretary health Praveer Krishn said whatever the department felt against the doctors is in the charge sheet and he has nothing more to say regarding the issue.

❖ Youth Cong stages demo in Bhopal to protest 'fake drug' distribution

Hindustan Times, September 24, 2014

Continuing their protest on the issue of distribution of sub-standard and fake medicines in the state, the Youth Congress (YC) activists staged demonstration at the Satpura building here on Tuesday.

The YC activists had gone to lay siege to the health directorate. The police officials present on the spot asked them to take a delegation to the

commissioner, health. Though the activists gave the memorandum, they weren't satisfied with the reaction of the official.

"We went to Satpura building and sat on a dharna. We were not at all satisfied with the response of health commissioner Pankaj Agarwal as he took our memorandum and was going back immediately without even listening to us. It is a serious issue and the CAG report has mentioned how sub-standard medicines were distributed in hospitals in the state", said Monu Saxena, YC leader.

Saxena said that in order to highlight government's inaction and indifference, the YC will stage a major protest at the JP Hospital on Wednesday morning. "The government and officials are all busy, trying to hush up this issue", he further said. "Medicines worth Rs. 29 crore were distributed without the quality check in order to provide benefit to certain private companies", he further added.

Congress leader Atul Sharma has said that the issue is about deep rooted corruption in the system, as due to 'commission', the sub-standard and fake medicines are being purchased and sold across the state.

❖ Government study on spurious drugs to gain momentum

The Hindu- Business Line, September 26, 2014

The Government's study on spurious drugs in the country is set to gain momentum in the next few months, a senior Government official said.

The Central Drugs Standard Control Organisation (CDSCO) in consultation with the Indian Statistical Institute and other partners, including the State drug controllers, have put in the basic framework on how to carry out the study, including details on the category or medicines to be covered, said Bangarurajan, Deputy Drugs Controller, CDSCO (West Zone).

With the basic framework in place, the study will be rolled out in terms of actually picking up samples from across the country and analysing them before coming out with a final report, he said, speaking on the sidelines of a pharmaceutical industry event organised by the Indian Drug Manufacturers' Association. About 15 categories of medicines, such as anti-malarials and antibiotics, have been identified to be surveyed, he added.

Former Drug Controller-General of India, Surinder Singh, who is now Director of the National Institute of Biologicals, heads this committee that is studying the prevalence of spurious drugs.

The study gains in significance against the backdrop of quality questions being raised on Indian medicines by overseas regulators. The Indian drug regulatory representative, however, added that local authorities were also

keeping an eye on local pharmaceutical products and their quality has been improving over the years.

A similar study on spurious drugs was conducted in 2009, where 24,000 samples were picked up from across the country. The prevalence of spurious products was found to be about 0.04 per cent, he said.

Various numbers are discussed when it comes to the prevalence of spurious drugs in India, including numbers attributed to the World Health Organisation, that have in fact been denied by the WHO, he said.

Meanwhile, the Government is also expanding the number of Adverse Drug Reaction (ADR) centres in the country to record incidents of reactions related to medicines. From about 150 now, it would go up to over 380 by 2015, he said, adding that all Government medical colleges would have an ADR centre. This expansion comes even as the Government doubles its drug regulatory personnel from about 1,500 at present.

The drug regulator is already collaborating with foreign regulators during inspections of local drug plants, he said, on the steps being taken by India to harmonise its drug regulations with international laws.

At a recent conference on drug regulations in Brazil, he said, regulators were concerned with the uniformity of Good Manufacturing Practices norms across different countries. The thinking was on whether inspections done by one regulator could be picked up by others to avoid multiple inspections, he said.

On harmonisation of regulations across countries, Ronald Piervincenzi, Chief Executive Officer of the US Pharmacopeia, said it would benefit industry as it makes them more efficient with a single approach on quality standards across markets, even as it eliminates multiple testing.

❖ Fake drugs and certificates

The Independent, September 27, 2014

Two news items of forgery, one about a fake drug factory and other about a pernicious racket making false certificates and mark sheets, must not be taken casually, because these are related to public health and the image of the concerned educational institutions as well as the nation. In the former case, it was found that a drug factory in the port city of Chittagong prepared medicine in an unhygienic atmosphere. But a drug factory always demands certain standard of cleanliness for the production of drugs. More seriously, this drug factory was marketing date-expired drugs in new packages as well as producing unauthorised items.

The busting of this recent drug factory in Chittagong is not unique. In fact, we often come to know about these fake drug companies and that also for a long time. This means that the patients in our country are continuously consuming

substandard drugs or unknowingly swallowing capsules or tablets containing flours in the name of antibiotics or other life saving drugs.

There are many problems that are plaguing the health sector, and the presence of fake and spurious drugs on the market is greatly taxing public health. Many a time we also come by news of fake doctors also. We cannot lift the standard of the health service, public or private, unless we are able to contain people who are involved in foul business of making fake or substandard drugs and treating patients without having genuine medical degrees.

Producing fake papers of recognition of educational institutions such as certificates or mark sheets, like forging bank notes, is also a very serious problem. According to the Independent report in the recent case, the persons arrested confessed that obtaining certificates produced at Neelkhet in the capital, people are serving in different government organisations whether they have the required ability or not. This involves tarnishing of image not only of the relevant educational institutions, the nation may also suffer image crisis, if persons going to foreign countries for the purpose of education or job are found with fake certificates.

Therefore, it is expected that the country's various law enforcing agencies as well as the relevant government entities would take these matters seriously and do the needful on a sustainable basis. These fake businesses also reflect the overall moral degeneration of our society. If the people who are caught with forgery are meted out exemplary punishment for their crimes in all the cases, the punishment itself can act as a deterrent against the crimes.

❖ Rise in sale of fake cosmetics and drugs in Rangoon.

Democratic Voice of Burma, October 02, 2014

Rising sales of fake cosmetics and drugs have been reported in Rangoon, where unidentified people claiming to be staff members of reputed cosmetic companies are selling fake goods to retail shops. Incidences have been reported in North and South Dagon, Tamwe and Thaketa Townships. The Ministry of Health, earlier in August, identified and listed nine cosmetic brands made in Thailand with carcinogenic components leading to skin cancer.

❖ ALL INDIA SURVEY OF SPURIOUS & NOT OF STANDARD QUALITY DRUGS

Twofour Insight Group, October 20, 2014

Over the past several weeks, industry media outlets have been reporting on the Union Ministry of Health & Family Welfare (the "Health Ministry") announcement that it would be conducting a so-called "All India Survey" to

determine the extent of spurious[1] and not of standard quality ("NOSQ") drugs in India (the "2014 Survey"). The objective and history behind this survey reveals the current priorities of the Indian government for its pharmaceutical industry as it has come under considerable scrutiny both domestically and by developing and developed countries. However, the seriousness of the Indian government in changing the reputation of the Indian pharmaceutical sector will be ultimately determined by the results of the 2014 Survey. If the results are similar to the survey that was conducted in 2009, which concluded that the extent of spurious drugs in the country was an absurdly low 0.046%, the new survey may raise additional red flags about the Indian government's underlying goals in allocating significant resources to carry out the 2014 Survey.

The genesis of the 2014 Survey goes back to a petition filed on December 19, 2011 with the Committee on Petitions of Rajya Sabha (the "Committee") by Shri Rahul Gaur, r/o Noida (UP) (the "Petitioner"). In his petition, the Petitioner raised several concerns with the manufacturing and marketing of drugs in India, including, the extent of spurious drugs prevalent in the market, re-usage of expired drugs, high patient risk in certain clinical trials to the excessive cost of drugs in the country. As a result, the petitioner requested the following actions to be taken:

- Changes in the law to curb spurious drugs
- Mandating prescription under "generic" name only
- Consumer awareness
- Controls on clinical trials
- Uniform pricing throughout the country

The Committee heard from several stakeholders, including, Secretary of the Health Ministry and the Department of Pharmaceuticals and various organizations, including industry and non-governmental organizations ("NGOs"). After hearing their views, the Committee made the following key finding with respect to the prevalence of spurious drugs in the country: "spurious drugs cannot be merely gauzed through statistical information provided by various States based on analysis of the samples, as the number of samples taken for analysis is minuscule vis-à-vis the number of manufacturing units multiplied by the products and number of batches released into the market and the available inspectorate and the capacity to analyze the samples in each state". According to the Committee, the following factors have contributed to the availability of spurious drugs in the marketplace:

- Increase in licensing of drug manufacturing facilities
- Permitted use of third party products manufacturing
- Absence of a defined distribution system
- Indiscriminate issuance of licenses to sell drugs
- Lack of a defined tracking system of distribution of drugs
- Availability of multiple brands for the same generic molecule

As a result, in the 148th Report of the Committee that was presented on February 7, 2014 (the "148th Report"), a key recommendation made by the Committee was for States and the Centre to conduct a pan-India Survey to identify the geographical areas where spurious drugs are more prevalent in order to allocate resources to monitor for such activity and elimination of the same by the regulatory authorities.

47th Meeting of the Drugs Consultative Committee

In less than five months of the issuance of the 148th Report, the Drug Controller General of India ("DCGI") Dr. G.N. Singh ("DCGI Singh") convened the Drug Consultative Committee (the "DCC") to review a proposal for the 2014 Survey. The powers of the DCC are outlined in Section 7 of the Drugs & Cosmetics Act, 1940 (the "D&C Act" or "Act"), as it was established to ensure consistency of implementation of the Act in the country. The DCC includes nominated representatives from both the Central and State Governments.

The 47th Meeting of the DCC took place on July 30-31, 2014, to discuss, amongst other topics, the recommendation made by the 148th Report for the so-called All India Survey. Notably, the "inaugural deliberations" highlighted in the meeting minutes reveals the uniform concerns of various key government officials in the need to reform the drug regulatory system in India. For example, the following key observations were made:

- "Even though India has over 10,000 drug manufacturers in the country, the quality of the drugs is not well regulated" (Dr. Jagdish Prasad, Director-General of Health Services, Health Ministry)
- "Complaints have been received from Sri Lanka and Vietnam regarding supply of substandard drugs" (Lov Verma, Health Secretary, Health Ministry)
- "The perception of the Drug Regulatory Authorities is not good in the country" (DCGI Singh)
- "The central government expects that within a span of three to five years there will be [a] change in the face of the Drug Regulatory System of the country" (DCGI Singh)
- "Drugs in the country are required to be made available at affordable prices" (Injeti Srinivas, Chairman of the National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizer)
- "The industry can only provide drugs at affordable prices if the earnings from exports provide internal subsidy for activities of research and development and improving the quality of drugs manufactured in the country" (Sudanshu Pandey, Joint Secretary, Ministry of Chemicals and Fertilizers,)
- "There should be no compromise [on] the quality of the drugs manufactured for export" (Joint Secretary Pandey)
- "The Chemists and Druggists Trade Associations some time practice monopolistic and restrictive trade practices

in the sale of drugs" (Mahesh Zagade, Commissioner, Food and Drug Administration, State of Maharashtra)

- "There is no assessment of adverse impact of non-implementation of the statutory provisions of the D&C Act" (Commissioner Zagade)

After these quite insightful, yet concerning, remarks on the state of the drug regulatory system in India and the need for reform, the DCC considered the proposal made in the 148th Report by the Parliamentary Committee on Petitions to conduct an "All India Survey". The Health Ministry made its recommendations known at the meeting, including conducting the survey to encompass both spurious and NOSQ drugs in the country. In addition, the Health Ministry noted the following attributes of the survey that would allow it to be significantly different than the 2009 Survey that was conducted in the country:

- Sample size of ~ 42,000 drawn from across the country; exact size to be finalized after discussion with the Indian Statistical Institute ("ISI") Hyderabad and the Ministry of Statistics and Programme's National Sample Survey Office ("NSSO"), Delhi.
- 15 therapeutic categories of drugs that are listed in the National List of Essential Medicines, 2011 ("NLEM")
- The Health Ministry has set aside Rs. 8.5 crores (US$1.5 million) to conduct the survey
- Survey to take place in late 2014 through February 2015

The NSSO also outlined to the DCC the need for the following information from the States in order to determine the statistical design of the survey:

- Number of retail outlets in each state (by District)
- Information with respect to the maximum number of prescription drugs that are covered in each of the 15 categories in the NLEM, including their trade name (by District)
- Number of civil hospitals stores (by District)
- Number of central medical stores (by District)
- Number of CGHS dispensaries in the country

As a result, the DCC recommended the survey to be conducted and requested the States and/or Union Territories that have not already provided the information requested by the NSSO to provide the information as soon as possible.

All India Survey v. 2009 Survey

The last time the Health Ministry attempted such a comprehensive survey was in 2009 when it was announced that only 0.046 percent of samples (11 of 24,136) in the country were found to be spurious. In the 2009 Report on Countrywide Survey for Spurious Drugs ("2009 Survey"), the Health Ministry

focused on 9 therapeutic categories and 65 specific brands and limited its analysis to "spurious" drugs. Nearly 25,000 samples were collected at retail pharmacies across the country. Samples were collected and sent to the various manufacturers of the 65 specific brands which conducted a physical (visual) exam of the packaging of each the samples to determine if it was spurious or not. All but two manufacturers reported that 100% of the collected samples were indeed their product. While little of the methodology for the 2014 Survey was shared, the NSSO comments indicate that they intend to collect samples from a wider array of sources than just retail pharmacies. In addition, given the mandate to test for quality as well as to determine whether the product meets the definition of spurious under the Act, the new samples should be subjected to quality testing requirements outlined in the Act and the Drugs & Cosmetics Rules, 1945, as amended.

The impetus for the 2009 survey was quite similar in many ways to the 2014 Survey; however, the Indian drug regulator and the local Indian industry have been under heightened pressure since the release of the 2009 Survey. Originally, the Health Ministry conducted the 2009 Survey to ease the concerns of the international community with respect to the extent of spurious drugs produced in India. Immediately prior to the 2009 Survey, India had faced considerable pressure in the media as a result of a World Health Organization ("WHO") report which concluded that ~35% of the available spurious drugs globally are produced in India. Similarly, the 2014 Survey was proposed in light of recent reports of spurious drugs with "Made in India" label found in certain markets.

Also, since the 2009 Survey, the focus of international pressure on Indian generics has now turned to quality in addition to spurious drugs. Consumers, politicians and media in developed countries such as the United States have been starting to question whether the recent flurry of warning letters issued by the United States Food and Drug Administration (the "USFDA") to companies in India is representative of the overall quality of manufacturing in India. This has also led to U.S. Congressional hearings on the topic and an increase in the number of USFDA inspectors and frequency of inspections in India. Of course, part of this renewed focus has been a mandate to inspect more frequently domestic and international suppliers of generic medicines using the resources available via the Generic Drug User Fee Amendments of 2012 ("GDUFA").

To what extent the 2014 Survey results will be similar to the 2009 Survey will be watched very closely by stakeholders around the world, especially markets that are significantly reliant upon low-cost Indian generics to manage their healthcare costs. One interesting area to watch will be whether the 2014 Survey will highlight issues at global pharmaceutical companies operating in India to serve the domestic and export markets or implicate drugs that are being manufactured in facilities in India under a license from a Western company. Since the 2009 survey, the number of non-Indian companies with a presence in the India has grown considerably as a result of several high profile cross-border transactions.
To learn more about initiatives of the Indian government such as the 2014

Survey that have an impact on the Indian pharmaceutical market, contact us at info@twofourinsight.com. Receive the latest Client Alerts and stay on top of the latest news of India's life science industry by signing up for "Saturday Morning Catch-Up", a weekly newsletter from TwoFour Insight Group.

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[1] Spurious medicines are defined in Section 17B of the Indian Drugs & Cosmetics Act, 1940, as amended in 1982, as a drug manufactured under a name which belongs to another drug, if it is an imitation of another drug or if it has been substituted wholly or partly by another drug or if it wrongly claims to be the product of another manufacturer.

❖ Centre to finalise modalities for nationwide study of spurious, NSQ drugs at DCC meet on Oct 27

Pharmabiz, October 21, 2014

The Centre has called an urgent meeting of the Drugs Consultative Committee (DCC) on October 27 to fast-track its ambitious project of generating national data on quality of drugs manufactured and marketed across the country. The main focus behind this single agenda meeting is to finalise the matters in consultation with the state drug controllers for initiating the whole process at the earliest.

This meeting is perceived to be strategically very important for the pharma industry, as it will set the ball rolling for a very extensive and well organised effort by the government to have India's own official report on spurious drugs. Through this joint effort between the state and the centre, India will now be able to project a clear statistics on spurious drugs, thus clarifying India's stand on the same with scientific evidence.

Dr G N Singh, drug controller general of India (DCGI) informed that they have already formulated a plan through consultation with National Institute of Biologicals (NIB) for conducting a scientific study on the extent of problems of spurious drugs and drugs not of standard quality (NSQ).

He said, "We have already devised a survey plan to develop statistical drug sampling and a methodology, which we will appraise it to the state drug controllers and others stakeholders. In fact this meeting will be exclusively held to discuss about the design and modalities to be adopted for such a study at the national level and to assess the extent of the problem of spurious drugs and NSQ. Once we are through this study India will be able to scientifically prove that India manufactures and produces only standard quality drugs unlike claimed by vested interest. It will also finally help in

addressing all the doubts and lack of confidence in the effectiveness of the Indian regulatory system and capabilities the drug regulators."

It is understood that the government is very keen on pushing this initiative to ensure that the Indian pharma industry will get the resultant boost of confidence. As a follow up of this meeting the Centre had already asked the respective state licensing authority(SLA's) to submit a detailed report on the number of chemist and pharmacy shops in the state, number of drug testing labs along with data on samples collected, number of manufacturing units, licences issued etc.

Dr H G Koshia, commissioner, Gujarat Food & Drugs Control Administration (FDCA) stressed that from a regulators point of view this is a huge pro active step towards strengthening the credibility of Indian pharma industry further through a dedicated scientific based evidence. "Not only will this study help in positioning India as a strong pharma leader globally, as we will have strong data to support our point. It will also help putting a lid on all the detractor who try to malign the interest of the country through unjustified data and sources."

❖ SURVEY OF SPURIOUS DRUGS

Pharmabiz, October 29, 2014

The Centre has decided to conduct an all India survey on the extent of availability of spurious and not-of-standard quality drugs in the country. It is expected to be a broad-based survey covering 42,000 samples belonging to 15 therapeutic groups drawn from across the country listed in National List of Essential Medicines. The last nationwide survey of spurious drugs was conducted in 2009. The Union health ministry designated Dr. Surinder Singh, director, NIB, Noida, as the convener of the survey and a fund of Rs.8.5 crores has been allocated for the purpose. The survey is scheduled to be completed by February 2015. The survey is expected to help in identifying the geographical areas where spurious drugs are available which may help authorities to have a focused monitoring of this activity. The National Survey Sample Office (NSSO) of the Ministry of Statistics and Programme has already started working on the project by approaching the state governments to provide necessary information to arrive at a statistical design for the survey. Drug Control Departments of the state governments have a decisive role in tracking down the spurious drug units and eliminating them with their inspection staff. The joint efforts of the state governments and the Centre can only help the country to project clear statistics on spurious drugs and clarifying India's stand on the same with scientific evidence.

The government initiative in this regard has to be seen in the context of attempts by certain vested interests to tarnish India's image as a reliable exporter of cheap generics to the global markets. India's position as a strong player in the global pharmaceutical market had been under attack for some time by spreading rumours that Indian drug makers also produce and export spurious drugs. The survey is an attempt to disprove this false propaganda

and strengthening the credibility of Indian pharma industry further through a dedicated scientific based evidence. It can help to position India as a strong pharma leader globally with reliable data to support. In fact, the Central health ministry has been attempting to improve the drug manufacturing standards on a regular basis for the last ten years by making GMP mandatory in 2005 and introducing Spurious Drugs Act from 2009. India has already proven its international quality standard capabilities with a large number of ANDA approvals, DMF filings, US FDA/UK MHRA approved manufacturing facilities which are considered as key indicators for assessing the capabilities of any national pharma sector. This fact is further demonstrated by the trends in the number of product approvals received from various major drug regulatory authorities of the world.

❖ Menace of fake drugs

The Financial Express, October, 2014

http://www.thefinancialexpress-bd.com/2014/10/31/63733

The busting of the dens of spurious medicines by the law enforcers has been on a sharp rise for some time. It readily points to the fact that the syndicate of fake drug manufacturers is becoming stronger day by day in the country. Despite the increased surveillance by various monitoring authorities and striking forces, they remain undeterred.

In a country where food adulteration is widespread, the practice of making spurious medicines is nothing unusual. Perhaps Bangladesh is one of the countries, where this crime is resorted to so nonchalantly. The fake medicine manufacturers have little prick of conscience as they flood the market with even spurious life-saving drugs. These drugs usually go to the city suburbs and the vast rural area. Some unscrupulous local physicians even prescribe them for innocent patients. Many drugs enter these areas as over-the-counter medicines. It may remind one of the tragedies which occurred in the country following the taking of a fake fever-remission drug by hundreds of babies around two decades ago. One cannot say people are not dying these days upon taking fake life-saving medicines.

Manufacturing spurious drugs lead to the highest forms of punishment in many civilised countries. In our case, the heinous practice is generally taken lightly, and sometimes swept under the carpet. It seems the fake medicine syndicate adopts devices of outdoing the law enforcement and monitoring authorities.

There is little doubt that the common people will endorse any harsh measure that will be taken against the fake medicine manufacturers.

❖ Chemists illegally selling cough syrup to be arrested: Maria

The Times of India, November 06, 2014

Police commissioner Rakesh Maria has ordered city cops to register FIRs against those who illegally sell and purchase cough syrups or tablets for addiction. Chemists who violate the Food and Drug Administration (FDA) guidelines will be arrested under this order.

"Certain syrups and tablets do not fall under the ambit of the Narcotics and Drug Psychotropic Substances (NDPS) Act. However, several youth are procuring them illegally and are addicted to them. We have started a drive today against these drugs which are a factor in street crimes," said the 57-year-old police chief.

Maria has asked police stations to register offences under section 328 (causing hurt by means of poison, etc, with intent to commit an offence) of the IPC against medical shop owners and buyers who purchase these drugs illegally.

The police commissioner also identified video parlors screening porn movies as a big menace. "To a considerable extent, offences against women in slum areas are committed due to these factors. We will seize equipment of the video parlors and arrest them," he said. The drive will continue for three months.

Besides, a special drive to trace missing children has also been started. "We have formed five-member teams in each police station that will be supervised by an inspector rank officer. We conducted meetings with the DCPs and additional commissioners of police and decided that the five-member team will not be given other work unless in an emergency. Their job will be to trace missing children. Last year, 300 boys and 200 girls who went missing are yet to be traced," said Maria.

❖ NIB forms 2 Core Groups to study spurious, NSQ drugs, ISI to help sampling plan

Pharmabiz, November 09, 2013

National Institute of Biologicals (NIB) has issued a circular for the constitution of two Core Groups for conducting a scientific study on the extent of problems of spurious drugs and drugs not of standard quality. For the core group to plan and devise the survey plan, NIB has identified Terms of Reference (TOR) to develop statistical drug sampling and a methodology in consultation with Indian Statistical Institute, New Delhi.

The meeting is to be convened on November 15, 2013 to discuss the design and modalities to be adopted for such a study at the national level and to

assess the extent of the problem of spurious drugs and NSQ stated the circular issued by Dr Surinder Singh, director, NIB and nodal officer of the project who was the former Drugs Controller General of India (DCGI).

The circular issued via No. N1-26/2013 NIB Drugs, stated that first core committee for planning and designing the survey plan and its implementation would be chaired by Dr B R Jagashetty, former drugs controller, government of Karnataka.

The second Core Committee would identify the National Accreditation Board of Laboratories (NABL) led by Dr N Murugesan, director, Central Drug Testing Laboratory, Chennai coming under the Central Drugs Standard Control Organisation (CDSCO).

The action plan for the Core Committee 1 would also be to identify the fast moving drugs from the National List of Essential Medicines (NLEM) and market for drawing of the samples under the survey. It would oversee implementation of the survey and coordinate its various activities.

The terms of reference for Core Committee 2 are identification of NABL approved and government and private Dugs Testing Labs. It will negotiate with NABL approved private Dugs Testing Labs on the fee to assess the samples in accordance with the Schedule B of the Drugs & Cosmetics (D&C) Act and Rules.

Further the Core Committee 2 would also propose testing fee justification for the analytical assays for the drug samples for which testing fee is not provided in the Schedule B of the D&C Act and Rules.

The Committee would also have the responsibility of projecting the budgetary allocation for drawing of the drug samples, transportation, storage and shipping to the Drug Testing Labs, testing fees and other miscellaneous expenses related to the same.

While the other members of the Core Committee 1 are Dr S K Gupta, Prof. Emeritus and head, clinical research, DIPSAR, New Delhi, Dr Urmila Thatte, head, Clinical Pharmacology department, KEM Hospitals, Mumbai and president Indian Society for Clinical Research, Bijon Mishra, founder, Partnership for Safe Medicines, India, MC Deka, drugs controller, government of Assam, DK Shringi, former drugs controller , government of Rajasthan, Dr N Murugesan director, CDTL, Chennai, Dr S Manivannan, deputy drugs controller (India), CDSCO, sub zone, Bengaluru, Dr Madhur Gupta, technical officer, WHO-India, nominee director, Indian Statistical Institute, New Delhi, Dr Robin Kumar, senior scientific officer, IPC and Akanksha Bisht, scientific assistant, IPC is member –secretary.

There would be a few members from Core Committee 1 who would work in a similar capacity along with Dr R A Singh, RDTL, Chandigarh, Dr K Bangarurajan, DDC(I), CDSCO, north India, Dr Sudha Swami, chief scientific officer, DTL, Bengaluru, Chandan Kuamr, finance officer, IPC, Ghaziabad, Dr

Bikas Medhi, additional professor pharmacology, PGI, Chandigarh, Lotika Khajuria, DDC, Jammu, Navneet Marwah, DC, Solan HP.

❖ Experts discuss methods to check spurious medicines

Tribune, November 09, 2014

Experts from medical, health, social organisations, government and NGOs discussed how to provide safe medicines to patients at a seminar organised by social foundation, The Partnership for Safe Medicines in India. They stressed on taking stringent action against those who were involved in production, marketing and selling of spurious medicines in the country.

The venue of the seminar was Radison Hotel, Roshanabad, 12 km from Haridwar city. The participants indulged in productive interaction at the seminar.

Bejon Kumar Mishra, founder director of the Partnership for Safe Medicines, India, said the primary objective of the conference was to initiate a discussion on the new health policy for India and National Health Assurance Mission. The main focus was on providing universal affordable health care to all and sundry.

An oulay of action plan on how to tackle the menace of substandard, spurious, wrongly labelled, falsified and counterfeit medical products found in the medical supply chain in India and globally, was also considered on the occasion.

VK Subburaj, secretary, Government of India, Ministry of Chemicals and Fertilizers, said there was a need for implementation of insurance cover for all and accessible medical facility for the poor and common man.

Keshav Desi Raju, Secretary, Minister of Consumer Affairs, Uttarakhand, said patient's safety as well as affordability and providing good quality drugs worldwide was desired. In the Indian context, the government was committed to this aspect, added Raju.

He said as the population level was rising sharply, health facilities needed to be upgraded and spread in that perspective.

Referring to states like Andhra Pradesh and Kerala, Raju said health assurance was being provided to all the residents of these state, which should be implicated by other states too. The state governments should allocate specific budget annually for the health insurance, he added.

Dr Linda M Distlerath, a delegate from International Alliance Development PSM, Washington DC, USA, stressed on the need of having a global forum and cooperation by respective nations to counter spurious drug menace.

Anil Khaitan ,chairman of Indian Pharma Forum, said stringent legal penalty clauses for defaulters should be enacted. Asha Gambhir, secretary general of the All India Women Conference, stressed on the need of having high standard labelling and checking facilities so that spurious medicines could be detected prior to their supply or sale at chemist shops or medical centres.

Laxmi Kanta Chawla, former Health Minister, Punjab, advocated for reining in pharmaceutical companies as well as doctors, who prescribed drugs or medicines of a specific company.

Other topics, which were discussed during the convention, include "need for enhancing patient safety and quality medicines", "global initiative on pharmacovigilance", "patients–consumer right to universal access" and "coverage to quality health care".

❖ India takes action on spurious and sub-standard drugs

The Pharma Newsletter, November 10, 2014

An American pharmacist and an Indian pharmacologist charged with smuggling four million fake pharmaceuticals into the country earlier this month may have been the last straw for the Indian government battling counterfeit drugs.

Summons have been issued to carry out an all-India survey on the availability and the extent of spurious and sub-standard drugs in the country, while law enforcement agencies have been ordered to aggressively pursue counterfeiters and put them behind bars, reports The Pharma Letter's India correspondent.

Fake drugs, that treat everything from cancer to erectile dysfunction, are a multibillion dollar industry. With many accusing fingers pointing to India, the country has decided to don battle gear against sub-standard pharmaceutical products.

With Wisconsin pharmacist Marla Ahlgrimn and Indian Balbir Bhogal from Las Vegas arraigned on an indictment recently in a federal court in New York, the spotlight has shifted once again to the distribution of spurious drug emanating from India.

From June 2007 to May 2014, the duo allegedly arranged for the manufacture of millions of tablets in India of controlled substances, including phentermine and alprazolam, and prescription drugs, including counterfeit Viagra (sildenafil) and carisoprodol. The recent instance has highlighted a major issue that has plagued the Indian drug industry.
MAIN HUB

India, the world's largest manufacturer of generic drugs, has become a beehive for counterfeit and sub-standard medicines. Slick packaging is often

labelled with the names of legitimate companies such as Abbott, Pfizer, GlaxoSmithKline and Novartis, and the spurious drugs are marketed in India as well as sold across the globe.

While erectile dysfunction medication tops the list of most common fake drugs, treatments for chronic ailments like HIV, diabetes and Alzheimer's, painkillers and weight loss medications, cardiovascular medications, and even cancer drugs could be spurious.

“The World Health Organization has noted that one in five drugs made in India are fake. The Office of the United States Trade Representative (USTR) has recently highlighted the serious issue of export of counterfeit drugs from India," said SV Veeramani of the Indian Drug Manufacturers' Association.

Worried about the many reports that indicate India is spearheading the $75 billion global fake pharmaceutical industry, Mr Veeramani said the Indian government has launched a reward program offering $55,000 to those who provide information about syndicates dealing in fake drugs.

“The government is doing all it can to clamp down on the illegal trade. Last year, the Health Ministry had strengthened its drug laws and speeded up court trials. Life imprisonment awaits suspects found guilty of manufacturing and selling spurious drugs," he said.

Mr Veeramani added that the spread of spurious drugs is also actively being controlled through the upgrading of appropriate laws. “Since these drugs are said to cause the death of almost 1 million people a year globally, the issue cannot be ignored. Fake drugs also tend to contribute to a rise in drug resistance," he added.

BIGGER ISSUES AT HOME

Counterfeit medicines are a huge problem in India as well. A recent report by the Regional Drug Testing Laboratory in Guwahati noted that North East India has the highest number of spurious drugs in circulation in the country.

In its September list of misbranded drugs, released early this month, the Central Drugs Standard Control Organisation (CDSCO) declared 45 drugs, cosmetics and medical devices as sub-standard.

AK Pradhan, Deputy Drugs Controller of India said close to 20 products were manufactured in Assam (in NE India) alone, while Kokrajhar, West Bengal, Himachal Pradesh, Indore, Andhra Pradesh, Jammu, Goa, Punjab and Uttarakhand were the other states rife with fake drug production.

A recent analysis by the Associated Chambers of Commerce and Industry (ASSOCHAM) has also pointed to the growing industry. It has said that the fake drugs market in India is likely to cross the $10 billion mark by 2017, from the current level of about $4.25 billion.

Growing at a compounded annual growth rate (CAGR) of about 25%, the analysis has put Delhi, the national capital, including the nearby suburbs of Gurgaon, Faridabad and Noida, at the heart of the spurious drugs manufacturing issue.

The ASSOCHAM analysis has said that popular medicines like Crocin (acetaminophen or paracetamol), Voveran (diclofenac sodium enteric coated tablets), Betadine (povidone iodine), and injections of calcium and syrups like Cosavil (paracetamol, pheniramine maleate) were regularly found to be fake.

GROWING MENACE

The issue is being tackled on a war footing in India. Dilip Shah of the Indian Pharmaceutical Alliance (IPA) said India was running a drug counterfeit campaign with a current batch of 22 inspectors. “The team is headed by Drug Inspector Prakash Singh in Uttar Pradesh, and Julio Ribeiro, former Director General of Police, for the All India campaign. We have covered more than half of the country and are getting monthly reports from various quarters," he said. Adding that the experts on the job were “either from the Research and Analysis Wing (RAW, the primary foreign intelligence agency of India) or Intelligence Bureau (IB)," Mr Shah said, “they are the best in their field in intelligence gathering. They have many teams that buy samples from chemist shops and investigate almost each packet."

Since spurious drugs is a sensitive issue affecting the health of citizens as well as the prestige of the country’s pharmaceutical trade interests, he added that there was a sense of urgency in taking on the menace on a priority basis. “In Punjab, we have a former Director General of Police, in Bihar we have appointed two senior IB people. Most of the people on the team are from the police or IB. As an industry, we are extensively concerned about this. Our name (India's) should not be used to supply sub standard products across the globe," he said.

UPPING THE ANTE

The CDSCO has also upped the ante to scan drug samples across the country, in a bid to assess quality. HG Koshia, Commissioner of the Gujarat Food and Drug Control Administration, said that the CDSCO periodically collects data and samples from different zones for analysis.

He stressed that the government measures to tackle the situation would be pro active, and would further strengthen the credibility of the Indian drug industry. Through the joint effort between each state and the Centre, India would soon be able to project clear statistics on spurious drugs, and would be able to clarify its stand with perfect scientific evidence, he added.

“The nation-wide study on spurious and not-of-standard quality drugs instituted by the government will help in positioning India as a strong pharma leader globally, and the strong data will support our point. It will also help put a lid on all the detractors who try to malign the interest of the country through

unjustified data."

Through consultation with the National Institute of Biologicals, the Indian government has already formulated a plan for conducting a scientific study on the extent of spurious drugs and drugs not of standard quality, said GN Singh, Drug Controller General of India (DCGI). The nation-wide study would set the ball rolling "for a very extensive and well organised effort by the government to have India's own official report on spurious drugs," the DCGI added.

As IPA's Mr Shah noted, there are distinct aspects to decipher and de-complexify the counterfeit pharmaceutical supply chain. High technology is being enabled, like tamper-evident packaging, bar codes, holographics, and the more recent RFID.

"We have anti-counterfeit primary level packaging in the drug industry now. Every tertiary and secondary product has a 2D barcode, to allow for easy storage and tracking. Every primary packaging, that means each vial, will henceforth carry a barcode," he said.

He added that the global drug market was attractive to criminals who sought to exploit weaknesses in global supply chains, which could be vulnerable. "We aim to plug all the holes soon," he said.

❖ Bad drugs, unsafe surgeries: Deaths highlight India's healthcare woes

Los Angles Times, November 15, 2014

India produces world-class doctors and lifesaving generic drugs, but the deaths last week of more than a dozen women who underwent sterilization surgeries have refocused attention on the less exemplary aspects of the country's health system.

Activists have called for an end to the government-backed sterilization operations, a harsh form of population control still widely employed in rural India. The procedures are often carried out in assembly-line fashion at unsanitary and poorly equipped public "health camps" that result in scores of deaths every year.

For the Record:

India sterilization: An article in the Nov. 16 Section A on India's healthcare system incorrectly stated that between 2002 and 2012 an average of 12 Indian women a week died due to complications from tubal ligation surgeries. On average 12 women died a month.

The challenge before the government is to raise the standard of living of the poor districts and not indulge in short-term goals like sterilization. While the

doctor who performed last week's surgeries in impoverished central India is behind bars, authorities are also investigating whether women at the clinic were given antibiotics that contained traces of rat poison – underscoring how easily fake or tainted drugs can enter India's health system.

Preliminary tests of pills handed out at the clinic in the state of Chhattisgarh found that they include zinc phosphide, a compound often used in pest control chemicals, officials said Saturday. Police have arrested the director of the drug manufacturer, Mahawar Pharma, a small, family-run company that supplies the state government.

State and local health officials continued to buy drugs from the company even though a court found in 2012 that it had sold fake generic medicines, The Indian Express newspaper reported Saturday. Chhattisgarh's food and drug controller even gave Mahawar Pharma a certificate last year for maintaining "quality standards," the newspaper said.

India exports $15 billion in pharmaceuticals annually, including 40% of the prescription medications used in the United States, but fake or faulty drugs are a major concern in the domestic market. There are no reliable estimates of the number of spurious medicines in circulation nationwide, but in a 2010 survey by nongovernmental organizations of pharmacies in the capital, New Delhi, 12% of drugs purchased were found to be substandard. Most contained either no active ingredients or nonlethal components such as chalk or talcum powder.

Cases of drugs tainted with poisonous compounds are rare, but when deaths are blamed on such drugs, authorities frequently arrest manufacturers to deflect attention from problems in the supply chain. The process of buying drugs is plagued by corruption and collusion between state-level officials – who are responsible for implementing health policies – and middlemen who secure favorable prices without regard for quality control, experts say.

"The government tends to buy from intermediaries because of cuts and commissions, and that is where the fault is," said Bejon Misra, founder of the Partnership for Safe Medicines India, an advocacy group.

"It's not that the states don't have the budget. They have enough money to buy quality products – it is just their intent to prop up intermediaries for their own benefit."

The effect of bad drugs is compounded, Misra said, when state health officials conduct mass clinics for procedures such as sterilizations, which often bring in hundreds of patients in quick succession.

Most of the 4 million Indian women who undergo tubal ligations every year – the highest number in the world -- are poor, uneducated and from rural areas. The "health camps" are heavily promoted by local health workers, often to meet quotas encouraged by state officials, critics say.

India, which launched a campaign of state-backed sterilizations under Prime Minister Indira Gandhi to curb population growth in the 1970s, has officially abandoned national quotas for the procedures. In reality, however, activists and patients say that state officials still set targets and offer cash and other incentives to lure patients.

R.K. Gupta, the doctor arrested last week for performing the surgeries on women in the town of Bilaspur, said that he was a “scapegoat” and faced pressure from supervisors to meet targets.

The state health minister, Amar Agarwal, denied setting targets but said the sterilization camps “are held in the interest of people, to keep the population in check” in a nation of 1.2 billion people.

Official statistics show that between 2002 and 2012, 1,434 women died due to complications from tubal ligation surgeries – an average of 12 every week. In 2012, three men were arrested in the northern state of Bihar for operating on 53 women in two hours in a field without using anesthesia. Health officials say that Gupta performed more than 80 surgeries in six hours last weekend at the clinic in Bilaspur.

Aarti Gorwadkar, a doctor who has attended sterilization clinics in the western state of Maharashtra, said that basic hygiene procedures often aren’t followed. Surgical tools are rudimentary, doctors conduct only cursory evaluations before operating and women are sometimes left to recover on dirty floors. Sometimes, she said, surgical implements aren’t sanitized before being used on the next patient, raising the risk of infections. “I have seen them being cleaned in a hurry under running tap water,” Gorwadkar said.
Although vasectomies are a much safer procedure, few men are sterilized, owing largely to patriarchal traditions. Often, husbands pressure their wives to undergo sterilization to grab the cash incentives. “Most of the time, women are kept in the dark about the details of the procedure and consequences of it,” said Abhay Bang, an activist in Maharashtra.

Many activists question why the surgeries are being performed at all, given India’s declining fertility rate. In 1971, the average Indian woman had 5.1 children, but that rate has fallen to 2.4, just above the level at which a population stabilizes. Yet growth rates remain relatively high in India’s poorest areas, such as Chhattisgarh, where sterilization drives continue.

“It cannot be a coincidence that the more prosperous regions of the country have less fertility rates,” said Kiran Moghe, secretary of the nongovernmental All India Democratic Women’s Assn. “The challenge before the government is to raise the standard of living of the poor districts and not indulge in short-term goals like sterilization.”

❖ India's struggle with faulty drugs exposed

Health 24, November 18, 2014

http://www.health24.com/News/Indias-struggle-with-faulty-drugs-exposed-20141118

The Indian government underestimates the number of fake drugs produced in the country, commonly passed off to Indian consumers as genuine and sold around the world.

The recent deaths of 15 people linked to a small pharmaceutical factory in the eastern city of Raipur have highlighted how easily adulterated drugs can enter India's huge healthcare system.

Substandard drugs

Experts say the government is underestimating the scale of the problem, hampering efforts to rein in abuses in one of the world's biggest markets for counterfeit and substandard drugs.

Stuffed in glossy packaging and sometimes labelled with the names of legitimate companies, fake drugs are commonly passed off to Indian consumers as genuine and sold in developing nations around the world.

Estimates vary of the number of fake drugs in India. According to an estimate from the World Health Organisation, one in five drugs in India is fake or faulty. The Indian government, by contrast, says the figure is closer to 0.3 percent.

Regulating a sector beset by bribery, collusion, cartels and other coercive practices poses a challenge for Indian government officials when selecting which manufacturers to buy from, a 2013 report by the United Nations Office on Drugs and Crime found.

India's drug regulator was criticized for only having 124 employees, according to a parliamentary report two years ago. By comparison, the drugs regulator in the United States, where the population is four times smaller, has about 14 500 employees.

"States procure medicine through a tender and the manufacturers that bid the lowest quote win the order to supply, regardless of their manufacturing process or distribution systems," said Bejon Kumar Misra, head of Partnership for Safe Medicines India, a non-governmental organisation.

Complacency a factor

But G.N. Singh, the Drugs Controller General of India, said quality and safety came before price in the tender process.
"If the drugs are found to be substandard, we will suspend the license of the manufacturer," he said.

Some experts fear complacency is a factor.

"There is a lack of regulatory oversight and if you are cutting the costs right down to the bone, then sometimes you are cutting too far," said Roger Bate, an academic at the American Enterprise Institute in Washington.

"I don't see it getting better, because the government doesn't admit there is a problem, let alone trying to address it," he added.

The central government might be spurred into action by the latest scandal which has hit headlines at home and abroad. Thirteen women who attended a squalid sterilisation camp in eastern India last weekend have died, and the prime suspect is a batch of pills supplied by a small drugs factory, Mahawar Pharmaceuticals, located in Raipur, state capital of Chhattisgarh, one of India's poorest regions.

Poor people

The owners of the plant deny all wrongdoing. Two more deaths underlined suspicions that it was drugs, not dirty equipment or botched operations, that were to blame.

One of the two, 80-year-old Anjori Maheshwari, arrived at a hospital complaining of fever and dizziness. He was clutching a strip of pills from the same batch of antibiotics used by the women at the sterilisation "camp". A day later he was dead.

"The doctor said my father died because of this medicine," Chuni Lal, the man's 38-year-old son said, as he wept on the veranda of his home. "What can we do, we are poor people?"

The state government has banned the sale and distribution of all medicines from Mahawar.

Reliable estimates of the number of fatalities from tainted drugs are hard to come by. In one of the worst cases, counterfeit drugs were blamed for contributing to the deaths of more than 300 infants in Kashmir in 2012 after they were given medicine at the state's main paediatric hospital.

"It is an easy crime because it is impossible to tell there is a problem with the drugs just by looking at them," said Anil Bansal, a doctor at the Delhi Medical Council. "As the industry becomes more lucrative, the problem is getting worse."

❖ Warning on herbal sex drugs

The Bangkok Post, November 20, 2014

Some herbal sexual supplements sold for men have been found to also contain the drug aildenafil, a chemical compound similar to the anti-impotence

drug Viagra but it is not approved and could pose a health risk, the Department of Medical Sciences (DMS) has warned.

The department recently examined herbal medicines on sale that claimed to enhance sexual desire and it found they mostly contained three ingredients - sildenafil (sold as Viagra), tadanafil and vardenafil – which require a doctor's prescription.

However, some herbal sexual medicines contain aildenafil, a synthetic chemical compound that is a structural analog of sildenafil, DMS director-general Apichai Mongkhol said.

He warned this chemical could be dangerous because it not only enlarges penis arteries but also other arteries and could cause headache, dizziness, facial redness, digestion problems, breathing difficulties, hearing problems and vision problems, and dangerously low blood pressure, which may lead to death.

Dr Apichai said if herbal sexual products also contain this substance and other artery-enlarging ingredients, it increases the risk of side effects.
Patients with heart disease, diabetes or cerebrovacular risk factors, and the elderly, were taking a risk by consuming herbal sexual drugs containing aildenafil, he said.

After taking these sexual supplements, men could get erections that last longer than normal, lose energy and become exhausted, and that may lead to sudden heart failure, he said. A doctor's prescription is required for use of herbal sexual supplement products.

Food and Drug Administraton (FDA) deputy secretary-geneal Prapon Angtrakul on Thursday said aildenafil is not yet registered. Those found to produce herbal medicines containing this unregistered substance without permission were liable to a prison term of up to three years and/or a fine of up to 5,000 baht.

The FDA will seek information about aildenafil from the Department of Medical Sciences for use in legal procedures, he said.

❖ Accountability in Healthcare

Herald Goa, November 20, 2014

Any post-surgical death has to be viewed with extreme seriousness. Fifteen deaths immediately after a minor procedure, as in the case of the Bilaspur sterilization camp, are deplorable. Our hearts must go out to all those families struck by this tragedy. We are heartened to note that "A single-member probe commission has been constituted and Retired District and Session Judge Anita Jha has been entrusted with the responsibility of investigation and to

submit its report to State Government within three months. The Commission will investigate the case on following points of public importance: - 1) Was standard protocol followed in these camps? 2) What circumstances led to this incident? 3) Were the medicines used in these camps were of standard quality. 4) Who are the ones accountable for this incident? 5) What measures can be taken to avoid recurrence of such incidences? 6) Suggestions regarding Gender Equality in Family Welfare Programmes of the State. 7) This Commission for special probe of public importance is appointed by exercising its powers conferred under Section-3 of Judicial Commission Act (60 of 1952)".

Let us hope that the findings of this Commission and its recommendations are acted upon and not consigned to the dust bin of history as with so many Commissions before this; but is worth examining the incident in the light of the parameters mentioned above.

The issue of protocol has been settled by "Guidelines for Standards for Female and Male Sterilization Services" published by the "Research Studies & Standards Division" of the Govt. of India, MoHFW in 2006. This was a result of Supreme Court intervention in Ramakant Rai vs. GOI, 2005 and reinforced in Devika Biswas vs. GOI, 2012. However, were these guidelines followed? As per the guidelines, a maximum of 30 operations are permitted if two separate laparoscopes are used. One individual doctor may not conduct more than 10 sterilizations per day. One therefore wonders how 83 surgeries were performed with a single instrument, in a single day over five hours. This works out to less than four minutes per patient. Any surgeon will agree that merely transferring a patient on and off the operating table will take at least 15 minutes with super-efficient staff. Chemical sterilization of the equipment (with cidex) should take at least 20 minutes as per standard guidelines. Autoclaving (using steam) takes a little longer. 83 cases are possible only if, as reportedly stated by the surgeon, the equipment was wiped with spirit after each procedure, and the scalpel reused. In these days and age this is reprehensible and must be condemned. The excuse of pressures to meet targets makes it even more disgusting.

Some of the women belonged to the Baiga tribe, which is an endangered and protected tribe in whom the government has specifically banned any sterilization procedures. Thumb prints of dead women were taken on consent forms, who in life were able to sign their own names. The procedures were carried out in an abandoned charitable hospital, which had been non-functional for more than a year. According to police reports, there were cobwebs hanging from the walls, cracked floors and rusted furniture lying around, and the patients were operated lying on the floor.

Interestingly, male sterilization accounts for less than 2% of the total procedures under this programme, in spite of the fact that it is safer, quicker, cheaper and requires less infrastructure than female sterilization. The family planning authorities have never gone down this road due to the obvious convenience of gender bias.

Death in the immediate post-operative period can only be due to a surgical accident (a vital structure or blood vessel being damaged) severe infection or drug induced. Initial reports indicate that there was no evidence of damage to vital organs or infection. It has now emerged that there was multi-organ failure due to Zinc Phosphide, a chemical used in rat poison, found as a contaminant in the antibiotic (Ciprofloxacin) used. This is criminal. The drugs were supplied by a firm (Mahawar Pharma Private Limited) which had been blacklisted for two years for similar offenses. The firm has since been raided and sealed.
The problem of spurious drugs is not new. It has been highlighted by a BBC sting operation more than a year ago. The definition of "adulterated" drugs in the Drugs and Cosmetics Act was amended in 2008.The penalty was also increased so that in the event of adulteration causing grievous hurt, the punishment is now 7 years to life imprisonment, with provisions for compensation to the victim. At one point even the death penalty was suggested for anyone causing death by adulterating drugs. As a principle, I am not a proponent of the death penalty; but I am a strong advocate of life imprisonment, for the life of the perpetrator, without any chance of parole and tagged with intensive community service.

"Partnership for Safe Medicines" has produced alarming statistics. 25% of medicines in developing countries are counterfeit. 60% have no active ingredients; 17% have inaccurate doses of correct ingredients; and 16% have incorrect ingredients. Our Union Health Ministry concedes 5% of drugs in India, worth about Rs.5000 crores are substandard. The BBC sting documentary revealed that there is a thriving counterfeit industry in India where orders are priced according to percentage adulteration. When the interviewer asked how much a consignment of spurious antibiotics would cost, the answer was "it depends on the percentage of the active ingredient". The higher the percentage of the active ingredient, (which could be 50%, 25% or whatever you wish) the higher the cost. And the rest? Chalk, sugar or whatever. This on its own should have provoked suo-moto action by the authorities.

Adverse incidents due to fake medication jumped 11 times in 8 years with the Asian subcontinent accounting for the vast majority of cases. The more important question; has any action been taken, and how many instances are there of prosecutions resulting in convictions and penalties? The Mashelkar Committee's report and recommendations, as indeed many before that, have largely been ignored. The procedure for drug testing remains outdated, slow, expensive, and grossly inadequate. "Out of the information received from 31 States/UTs, only 17 drug-testing laboratories were found to be functioning. Of these, only 7 were reasonably equipped and staffed. Some did not even have the bare minimum equipment" – Mashelkar Report. Other factors are shortage of drug inspectors, unduly prolonged judicial process, weak penal action, and undervaluation of human life.

It appears that there has been a colossal failure of administration as a result of which the patients were given spurious and contaminated antibiotics. This was the immediate cause of death. There has also been gross transgression of standard guidelines and surgical protocols by the surgeon; though this was

not the immediate cause of death. Responsibility must be assigned and heads must roll if confidence is to be restored in Indian healthcare so that it achieves its true potential. Otherwise this nation will remain mired in total insensitivity to our less well-off countrymen.

❖ Chhattisgarh used poor quality drugs

Asian Age, November 21, 2014

The state-owned Chhattisgarh Medical Services Corporation (CGMSC) is in the eye of a storm over alleged procurement of drugs that failed quality tests in different laboratories in India. The role of CGMSC, the central drug procurement agency of the state government, has come under the scanner after the tragic deaths of 14 poor young women following tubectomies performed in free health camps in Chhattisgarh's Bilaspur district, allegedly due to spurious drugs.

Enquiries revealed that three samples of a drug used for sanitisation of surgical equipment and the operation theatre had failed quality tests in seven different private laboratories. But the officials concerned continued to procure the drug, ignoring the adverse reports of the laboratories.

Incidentally, the drug has been purchased from private manufacturing units. "CGMSC procured the sanitisation drug, worth around Rs 2 crore, in the current financial year. The drug has now been withdrawn from government hospitals in the state and dumped in warehouses of CGMSC following the exposure of irregularities in its procurement," a senior officer in the state government told this newspaper here on Thursday on condition of anonymity. Shockingly, multi-vitamin capsules procured from private agencies in a similar manner by CGMSC have quietly been withdrawn from government hospitals following complaints about their quality from some doctors.

Senior officers in the state health department were tight-lipped on the issue. Earlier, the exposure of alleged favour shown by the state government to controversial drug firm Mahawar Pharmaceuticals Pvt. Ltd, which allegedly supplied drugs to the tragedy-hit sterilisation camps, had rocked the state.

The licence of the firm was cancelled eight times earlier for manufacturing substandard drugs, but still the company managed to get a "good manufacturing practice award" in 2014 from the state government.

❖ Beware of Counterfeit Medicines Sold Online: FDA

Medical Observer, November 22, 2014

Buying gadgets and gizmos online is just fine: You can check if there's something wrong with them when the items are delivered to your door or when you go to the tech boutique to pick them up. Ordering drugs and other

health products is an entirely different story.

Thus, the Food and Drug Administration has warned that the proliferation of Internet or online pharmacies was complicating the fight against counterfeit medicines, posing greater danger to the health of Filipinos.

At a press briefing on Monday to mark National Consciousness Week against Counterfeit Medicines, FDA Officer in Charge Nicolas Lutero III admitted that the agency was having a hard time going after syndicates that use the Internet to sell fake drugs.

“We are facing a problem with Internet pharmacies,” Lutero said. “A lot of medicines are being sold through the Internet from different websites so we have difficulty monitoring them.”

While the FDA has managed to shut down local online pharmacies, he said the agency was powerless against those based abroad.

“We cannot run after them because they simply say they are not violating Philippine laws since they are operating overseas,” the FDA OIC said. He said online pharmacies continued to proliferate because many Filipinos patronized them. “A lot of people order medicines from them so that is really our dilemma,” he noted. Thus, he appealed to the public to stop buying medicines online so as not to fall prey to scams.

Pharmaceutical Security Institute-Asia Pacific data ranked the country eighth in terms of prevalence of fake drugs between 2011 and 2013.

“Fake drugs were reported mostly in Metro Manila, Cebu, and Laguna. Most of these fake drugs came from China and India.”

Fake drugs were reported mostly in Metro Manila, Cebu, and Laguna. Most of these fake drugs came from China and India.

China and Japan had the biggest number of incidents involving counterfeit medicines in the region with 712 and 237 cases, respectively. Ahead of the Philippines—which accounted for 50 cases—were Pakistan with 237 incidents; South Korea, 154; Indonesia, 141; India, 108; and Taiwan, 79.

PSI-Asia Pacific director Samson Chiu said the top three fake drugs being sold were cardiovascular, metabolism, and anti-infective medicines.

About 90 percent of the counterfeit medicines were to be taken orally, while 6 and 4 percent, respectively, were injectable and inhalable drugs, Chiu said.

“It comes from all over the place and in different forms. That is why no single government or agency can tackle this problem of counterfeit drugs,” he said.

❖ Is it safe to have that capsule?

Business Standard, November 22, 2014

http://www.business-standard.com/article/economy-policy/is-it-safe-to-have-that-capsule-114112200734_1.html

In April this year, the Chhattisgarh government received the report of an injection sample that had been sent to the Kolkata-based Central Drugs Laboratory for testing. It sent the department into a tizzy. The injection, lignocaine, a common local anaesthesia, had been used in the government-organised cataract camp in the Balod district in October 2011. Forty-four people had lost their eyesight after the surgery. "The sample of injection contained fibres and a few black particles," read the Central Drugs Laboratory report, a copy of which is with Business Standard.

The laboratory stated that "the sample (lignocaine injection) referred to is not of standard quality as defined in [the] drugs act 1940". Copies of the report were marked to the Drugs Controller General in New Delhi and Chhattisgarh's Controller for Food and Drugs.

This should have been a wakeup call for the Chhattisgarh government. It wasn't. Seven months after receiving this damning report, the state government again finds itself in a spot. Fourteen women lost their lives due to suspected contaminated drugs and botched-up surgeries conducted in three sterilisation camps in the Bilaspur district on November 8. The Ciprocin 500 tablets given to the women who underwent tubectomy are said to have been of substandard quality. Traces of zinc phosphide, a component of rat poison, were found in the premises of the drug's manufacturing unit, Mahawar Pharma, which was operating out of a bungalow in Raipur. Within days of the incident, drugs at the unit, owned by Ramesh Mahawar, were set on fire. Mahawar, who has since been arrested along with his son, Sumit, hasn't explained why. Before his arrest, Mahawar said that all the allegations levelled against him and his company were baseless. In a statement, he said that after a free and fair probe, he would be given a clean chit. The state government has, meanwhile, seized the entire stock and banned its use.

Mahawar Pharma is not the only little-known company manufacturing drugs in the country. While the National Pharmaceutical Pricing Authority lists about 10,000 pharmaceutical units in India, J S Shinde, president of the All-India Organisation of Chemists and Druggists, says about 20,000 units are in operation. Monitoring these many companies is a regulatory nightmare. "There are several smaller ones that manufacture and sell their drugs in localised areas. They tie up with retailers and doctors and offer high profit margins on their medicine," says Shinde. Only about 300 companies, which are familiar names, account for 98 per cent of sales, adds D G Shah, secretary general of the Indian Pharmaceutical Alliance. "The smaller companies operate in states and districts and supply to the municipal corporations and local hospitals where political patronage matters a lot."

In Chhattisgarh, for example, the government's drug purchase policy is tilted heavily in favour of local manufacturers. Under the store purchase rules, the

company manufacturing products within Chhattisgarh gets a price preference of 20 per cent. The 'make-in-Chhattisgarh' policy could have led to unqualified people entering the medicine manufacturing business, resulting in the circulation of substandard medicine in the market.

Also questionable is the manner in which drug manufacturing units are inspected. Between 2011 and 2012, the Chhattisgarh drugs department had declared substandard 13 of the 17 samples it collected from Mahawar Pharma. Licences for another seven products were suspended for six to nine months. Despite this, the drugs department had issued 'good manufacturing practices' certificate to Mahawar Pharma for 2014. The drugs controller of Chhattisgarh is required to inspect manufacturing units once every three months. In Raipur, Deputy Drugs Controller Hemant Shrivastava was assigned the job. He has been suspended for the negligence.

"Inspection at both state and central level is poor and unscientifically done," says Chandra M Gulhati, editor, Monthly Index of Medical Specialties, a watchdog for human trials of drugs and vaccines in India. Sample collection, too, should be scientific, he adds. "Inspectors should pick enzyme samples and drugs that are nearing expiry, basically those things that go bad very soon," says Gulhati, adding that the Central Drugs Standard Control Organization's contention that only about 6-8 per cent of drugs are of substandard quality is on the lower side.

DRUG SAMPLES TESTED IN THE LAST THREE FINANCIAL YEARS*

YEAR	Samples tested	Samples declared as not of standard quality	Samples found to be spurious
2011-12	13,323	495	9
2012-13	14,311	491	2
2013-14	15,753	577	4
Total	43,387	1,563 (3.60%)	15 (0.03%)

* By all the seven drug testing laboratories in India

In the US, there is a follow-up inspection after one inspector has surveyed the unit, says Shah. "The second inspector reports what the first inspector might have missed, and that is reflected in the record of the first inspector. We don't have that system. The whole administration is lax." Inspectors are bribed and licences earned, he adds. Besides, the inspection system in America is of preventive nature and is done not just with the purpose of nailing and nabbing manufacturers of substandard or spurious drugs, adds Gulhati. For the record, Indian pharmaceutical companies have been under fire from the US Food and Drug Administration for violation of good manufacturing practices.

"In theory, every drug manufacturing unit should have a full-fledged, well-equipped and adequately-staffed quality control laboratory. In practice, very few possess such mandatory facilities that cost quite a bit of money not only

to install but [also] to run and maintain," writes Gulhati in his magazine.

To put the blame entirely on manufacturers would, however, amount to looking at half the picture. Responsibility needs to be fixed on distributors and retailers as well because how the drug is transported and stored and refrigerated in chemist shops also affects its quality. "In Siliguri, for example, I came across 15 chemists who chose to keep chocolate instead of penicillin injections in the refrigerator because chocolate would melt," says Gulhati. (Penicillin solutions have to be stored in a refrigerator at 2 degree Celsius to 8 degree Celsius). Many chemists, particularly in semi-urban areas, don't have functioning refrigerators, he says. Some turn them off on holidays, and then there is the problem of load shedding, all of which adversely affects temperature-sensitive drugs.

Shinde of the All India Organisation of Chemists and Druggists, which represents about 750,000 chemists, both retailers and wholesalers across India, counters, "Both consumers and sellers are more cautious these days. They will not take such chances." The greater challenge lies in monitoring manufacturers. There is nothing preventing small-time manufacturers from producing fake or spurious drugs named after bigger and credible brands, he says. "These manufacturers might fill a capsule with glycerine, glucose or even turmeric powder and package it so authentically that even a chemist or stockist would not be able to tell the difference," he says. "The factory of this manufacturer might be in Delhi but there is no stopping him from selling his products anywhere else in the country. The drug controllers of those other states will not even bother to inspect this medicine," Shinde adds. His advice to people is: "Buy medicine only from those chemists who know you. There is less chance of them deceiving you. Also, don't fall for heavy discounts." Shinde says his organisation advises retailers to buy drugs only from the authorised stockists of credible companies.

The tedious reward process

Five years ago, the Central Drugs Standard Control Organization had launched a 'reward scheme for whistleblowers' to check the menace of substandard and spurious drugs. The policy stipulates that the reward of a maximum of 20 per cent of the total cost of consignments seized or Rs 25 lakh (whichever is higher) would be paid to the informer. And if the informer is a government officer or an officer of the Central Drugs Standard Control Organization, the reward would not exceed Rs 5 lakh for one case and a maximum of Rs 30 lakh for the entire service. The reward would be given only when there would be confirmation of the seizure of spurious drugs, cosmetics and medical devices by the organisation's designated officers. In the last five years, not one person has been awarded under this scheme.

One of the flaws in the scheme is said to be the long-drawn process. The rule says, "In order to ensure the continued cooperation of informants, 25 per cent of the amount is to be awarded at the time of filing of the case in court, another 25 per cent upon a favourable disposition of the case at the first trial level, and the remaining 50 per cent upon final disposition in favour of the

government with no appeal pending."

It's a tedious process. "Besides, I wouldn't like to be a whistleblower in our country. There's no protection. Have you seen how many whistleblowers have been killed?" says Gulhati. As of now, a solution to the problem of substandard and spurious drugs appears far from sight.

Substandard versus spurious

A nationwide survey found that spurious drugs in India account for 0.046 per cent, while the extent of substandard medicines is around 6 per cent. There have been smaller inspections since (see table).

Though the terms are often confused, there is a distinction between substandard and spurious drugs. Spurious or fake are those that use someone else's popular brand name to pass off their own drugs. "Or, say a drug claims to be a paracetamol but has no paracetamol in it, then it is a fake," says Gulhati. Substandard drugs, meanwhile, are genuine medicines that do not meet the required quality specifications.

❖ Some unscrupulous companies sell fake drugs: Nasim

VNews, November 03, 2014

Some unscrupulous companies sell spurious drugs in the market, using packets designed like famous branded ones, the Health Minister told Parliament on Sunday.

Replying to a scripted question of M Abdul Latif (Chittagong-11) if it is true that there is a big fraud in the name of life-saving drugs, Mohammad Nasim said: “Yes, it is true that some unscrupulous organisations are selling fake drugs in the market using packets designed like those of famous branded ones. “In some cases, spurious medicines adulterated with atta, flour and other materials are being marketed.”

He, however, said the mobile courts punished 465 offending drug producer/seller organisations in the first 10 months of the current year, imposing fines of more than Tk 68 lakh and sentencing 37 people to different jail terms.

“No Ebola virus infected patient has been detected in the country yet,” the Health Minister said, answering a starred question of Sukumar Ranjan Ghosh (Munshiganj-1),

He said Ebola virus scanning machines have been set up at every airport to detect the virus. “A total of 216 passengers, who came from Ebola virus affected countries, were selected for Ebola virus test from August 10, 2014 to November 15, 2014. Of them, 182 passengers have already completed 21 days under special observation.”

Answering a scripted question from Rustom Ali Faraji (Pirojpur-3), Nasim

informed the House that there were as many as 11,956 cervical cancer affected women and 14,836 breast cancer affected women in 2013.

The two figures are 19.30 percent and 23.90 percent of the total women cancer patients respectively in the country, he said.

Of the patients, 6582 women died of cervical cancer last year, while 7142 died of breast cancer.

❖ Drugs culprit: Doctor's arrest raises questions

The Times of India, November 26, 2014

With lab reports more or less putting the blame for 13 botched sterilization deaths in Chhattisgarh on Ciprocin 500 tablets laced with rat poison, questions are now being raised on the government's decision to book and arrest laparoscopy surgeon, Dr RK Gupta, under criminal charges of culpable homicide not amounting murder (Part II of 304 IPC).

While doctors' association in the state and elsewhere, including the Indian Medical Association (IMA), are protesting Dr Gupta' arrest dubbing it "unjustified", legal experts are also questioning government's decision. A bail petition for Dr Gupta has also been filed in the high court on Tuesday, following its rejection by the district and session's court last week.

Talking to TOI, senior advocate, Kanak Tiwari, said there is no justification in police slapping Part II of the Sec 304 of the IPC on Dr Gupta. He said there is huge difference in 304 (I) and 304 (II) of the IPC and the same has been clearly defined by the apex court in its various judgements.

Quoting a SC judgement, Tiwari said for punishment under Section 304 Part I, "the prosecution must prove: the death of the person in question; that such death was caused by the act of the accused and that the accused intended by such act to cause death or cause such bodily injury as was likely to cause death". And as regard Section 304 Part II, "the prosecution has to prove the death of the person in question; that such death was caused by the act of the accused and that he knew that such act of his was likely to cause death...."

He said the basic difference between the two is "intention and knowledge". He said moreover, the SC has clearly stated that Indiscriminate prosecution of medical professionals for criminal negligence is counter-productive and does no service or good to the society. He said as per SC's directive, Dr Gupta should not have been arrested without a report of the independent medical expert.

Tiwari said with lab reports confirming the presence of zinc phosphide (rat poison) in the medicines, the onus of the tragedy was on the drug manufacturing companies. "Dr Gupta was not knowing the drugs were spurious and he as surgeon had taken all care while conducting the

procedures", he added.

While there are many officials in the government who too feel the government "jumped the gun" in slapping criminal charges against Dr Gupta and instead should have waited for the inquiry report, some feel that the action was warranted as the surgeon had violated various protocols. "How can you professionally and safely conduct 83 surgeries in three and half hours", questioned a senior bureaucrat while requesting anonymity.

The police on their part are attempting to defend their action on grounds that they have reports that some of the deaths occurred due to "sepsis", a septic infection caused due to surgery procedures. "Besides the spurious drugs, botched surgeries too were responsible for the deaths of innocent women", claimed a senior official.

However, these claims are disputed by doctors who claim that sepsis usually occurs after 72 hours. "All the deaths happened within 72 hours of the surgery", they added while dubbing the police's claims as hollow.

A Bilaspur-based medico, Dr LC Madariya strongly blamed the government for its action and said, "If something is wrong with medicines then what is the fault of doctor. There is a problem in the system. They should check the medicine procurement system".

Police on their part are attempting to defend their action on grounds that they have reports that some of the deaths occurred due to "sepsis", a septic infection caused due to surgery procedures.

❖ Don't sell counterfeit medicines

The Daily Star, November 30, 2014

The platform of medicine retailers yesterday urged its members to stop selling counterfeit medicines and said it will not take responsibility if law enforcers crack down on them.

The leaders of Bangladesh Chemists and Druggists Samity also threatened a 48-hour countrywide strike from December 15 if physicians do not stop prescribing unregistered medicines, including supplements, in the next 15 days.

They said the retailers will now sell medicines at the "maximum retail price" without offering any discount, which gives some businesses an unfair advantage.

The retailers also demanded 25 percent commission, up from 12.33 percent now, from manufacturers.

Md Sadekur Rahman, president of the trade body, said they will start a

movement against the sale of unregistered medicines and food supplements. “We will not sell counterfeit medicines and unregistered supplements; we declare a war against those.” Rahman was speaking at a conference of the association at Bashundhara Convention Centre in the city.

Major General Md Jahangir Hossain Mollik, director general of the Directorate General of Drug Administration (DGDA), asked the retailers not to purchase medicines from unauthorised sources. “I have written to Bangladesh Medical Association, requesting doctors not to prescribe any illegal food supplement.”

The retailers are the ones who can rein in sales of such supplements, he said. “Why will you (the retailers) sell substandard or counterfeit medicines when Bangladeshi drug makers export their products to 91 countries?”

He requested the retailers to collect the list of companies that produce substandard medicines from the website of the drug administrator and stop selling their medicines.

The retailers should purchase drugs through receipts, and inform the association or the administrator if they find any unscrupulous medicine maker or seller, the Samity quoted its chief as saying in a statement.

The DGDA has a list of 62 illegal manufacturers whose production was once suspended, but still they are operating, said Rahman.

The Samity has 50,000 members, while there are 1.1 lakh licensed and more than 3 lakh unlicensed drug retailers in the country, said Abdul Hai, vice president of the platform.

Md Naser Shahriar Zahedi, president of Bangladesh Pharmaceuticals Society, suggested the retailers should write their registration numbers on the signboards of their shops.

- **Serious lapses at Bilaspur sterilisation drive exposed**
  Mail Today, December 02, 2014

Septicaemia, and not just spurious drugs which caused the death of 16 women who underwent sterilisation at a camp in Bilaspur in Chhattisgarh last month.

This has been established by a fact-finding team from four public health organisations. The team from Population Foundation of India, Family Planning Association of India, Parivar Seva Sansthan and Common Health made its report-Robbed of Choice and Dignity: Indian Women Dead after Mass Sterilisation-public on Monday, exposing serious lapses at the sterilisation drive that went horribly wrong.

The team surveyed the camp sites, interviewed doctors and support staff

involved in the service delivery and the women who had been sterilised, and the family members of those who had died. The team found that some of the critical cases admitted at the Apollo Hospital showed raised levels of procalcitonin that suggests septicaemia.

"Postmortem examinations of the first seven deaths at the Chhattisgarh Institute of Medical Sciences and the District Hospital had evidence of peritonitis and septic foci in the lungs and kidneys, also suggesting septicaemia. These indicate deaths by infection during or after the operation, and not just from spurious medicines as is being made out to be the case," said Poonam Muttreja, executive director of Population Foundation of India (PFI).

"According to forensic medicine and toxicology experts, to become lethal for women amount of zinc phosphide required is 4.5 gms, which is much higher than what could possibly have been consumed by the women in 500 mg of Ciprofloxacin. This also strengthens the argument that it was not the medicines alone that caused these deaths," she said. It was earlier said that the women died due to spurious drugs.

The fact-finding panel has also urged the state government to immediately make public the reports of postmortem, laboratory results of drug analysis and of the state committee set up to probe the tragedy.

"We found that that the families of the deceased had not been given the hospital records, nor told about the possible cause of death," said Dr. Kalpana Apte, assistant secretary general of Family Planning Association of India. The reports state that hygienic measures were compromised during the surgeries. "We found that one of the staff changed their hand gloves in between the procedures. The same injection needle and syringe, and the suture needle were used for all the cases. They were not sterilised and new needles were not used for each of the cases. The laparoscope after the procedure on each woman was cleaned by dipping into a big tray containing warm water and betadine, and by cleaning with a dry gauze piece before using in the next case. Only one laparoscope was used, while the Ministry of Health and Family Welfare guidelines prescribe three for a maximum of 30 patients," said panel member Sona Sharma.

The camp was organised at a non-functional health facility, compromising the basic standard of cleanliness and care during and after the procedure. All the women were kept in the hospital for 30 minutes to one hour after the procedure and were sent home with their motivators or relatives after a payment of Rs.600 as compensation money, as per the MoHFW compensation scheme. The post-procedure check-up was not done by any doctor or nurse, the report found.

The panel has said that the practice of convincing women for sterilisation against monetary compensation is also a violation of human rights. "None of the women were told about the procedure, what was to be done, what the potential sideeffects could be, and what to do after the procedure. "A woman

said, Bataya nahi gaya lekin jaise school ke dakhile ke liye form jama karte hein... uspar dastakhat karte hein... vaise hi hoga kuch... (We were not told anything, But it seemed like forms that one signs for admission in schools...)," said Sona Sharma.

❖ NGOs say infection killed women, not spurious drugs

Indian Express, December 02, 2014

A fact-finding team from four NGOs has debunked the spurious drugs theory on the Chhattisgarh sterilisation deaths and alleged that patients recovering after the surgeries in Apollo hospital, and postmortem of at least seven victims have found evidence of septicaemia, indicating infection.

Alleging a “cover up that began from the second or third day”, the team has called for an independent probe. The report has been prepared by a team from Population Foundation of India, Family Planning Association of India, Parivar Seva Sansthan and Common Health.

According to Poonam Muttreja, executive director of PFI, “We found that some of the critical cases showed raised levels of procalcitonin that suggests septicaemia or infection in the blood. Postmortem of the first seven deaths at the Chhattisgarh Institute of Medical Sciences and the District Hospital had evidence of peritonitis, or an inflation of the inner wall of the abdomen.”

In the report, Robbed of Choice and Dignity: Indian Women Dead after Mass Sterilisation, postmortem details were not included. Countering the theory of zinc phosphide mixed in the antibiotics administered to the patients, Dr. Alok Banerjee, from Parivar Seva Sansthan, said.

“According to forensic and toxicology experts, the amount of zinc phosphide required to be lethal for women is 4.5 gms, which is much higher than what could possibly have been consumed by the women.”

❖ Enforcing punishment for fake or counterfeit products

The Financial Express, December 04, 2014

Ordinary Bangladeshis are likely to be flabbergasted to learn from the media that the High Court has ordered the concerned authorities to procure gadgets or equipment to detect addition or spraying of preservatives detrimental to human health to many food items including fruits, fishes, milk, meat etc. It is unfortunate to observe that there are many unscrupulous manufacturing units across the country, which produce fake and counterfeit medicines, cosmetics, milk and other food products using harmful materials. Fake medicines do not contain medicinal ingredients, milk products or milk do not contain milk, cosmetics contain many a harmful ingredient etc. Unfortunately, the

packaging materials or containers are almost the same as they are produced in the local industries, printing presses, container manufacturers etc. It is time to bring these culprits to book so that they cannot escape punishment for their crimes. We are tired of hearing or reading in the media about harsh punishment being awarded to them, but in practice nothing happens.

The recent High Court directives should be implemented strictly so as to curb corruption related to adulteration of all kinds. There is no denying the fact that appropriate punishment as per laws of the land should be awarded to these criminals without fear or favour.

❖ Over the counter: A dicey doppelganger

Mumbai Mirror, December 09, 2014

Global surveys suggest 10 per cent of all prescription medication is counterfeit. Counterfeit medicines, sold online and across outlets, are the latest medical menace. They not only delay recovery, but may also prove potentially dangerous. Here's how to stay one step ahead.

The biggest disservice to mankind has to be the circulation of counterfeit medication. Sadly, there is no way for the doctor to know that the medicine is counterfeit, except when alerted by the patient's failure to respond. The catch here is that a patient's lack of response to a certain medication can have multiple reasons behind it - an erroneous diagnosis, for instance. The fact that the prescribed medicine, although appropriate for the situation, might be ineffective, is the last thing to cross a doctor's mind. At its worst, the effect of a non-responding treatment might be severe, especially in life threatening situations. This is why many doctors insist on branded medication from well-known pharmaceutical companies that can be relied on.

I can still recall the case of one of my outdoor patients -- and this was a man from a modest background -- who complained of persisting illness in spite of adequate treatment from my side. While I was flummoxed by his non-improvement, the man, in his unassuming Bombaiya tapori hindi, threw at me an unsettling question: 'Sahib, kahin yeh medicine duplicate toh nahi hain?' I promptly realised that the apparent layman had driven home a truth even I had failed to spot. Sure enough, on changing his medicines to those of a better brand, he started responding as he should have, and was there sitting at the outdoor one day, grinning from ear to ear - obviously doing better.

With the internet as a powerful new-age tool, access to medicines from across the world is easy. Commonly used drugs for treating erectile dysfunction, like Viagra, can be purchased on different websites for varying prices. Of course, there is no guarantee of its quality or effectiveness. An article by Berman in the Business Horizon refers to widespread efforts of identifying and capping the use of counterfeit medication. At the same time, the author points out the socio-economic effect of withdrawing counterfeit medication, including loss of employment and income, dip in revenue rates, etc. Global surveys suggest

that 10 per cent of all prescription medication is counterfeit. In 2012 the US FDA (Food Drug Administration) had cited 19 practices that had bought an anticancer drug, Avastin, made by Roche from overseas. All these were counterfeit versions of the drug.

Delepierre in his journal Med Mal Infect claims that not only are these harmful to individual patients but where antibiotics are concerned it might contribute to the bacteria becoming resistant to the antibiotic. Other UK researches like Jakson and his colleagues urge pharmacists to report such incident to regulating agencies and warn patients against buying such medication on the internet. Counterfeiting of medication is considered an organised crime involving networks of manufacture and distribution. The FDA has a CD-3 a small portable device used to detect counterfeit medication. It is battery powered and inexpensive and is like a torch which requires no training to use. It uses light of alternate wave lengths to rapidly discern differences between a product that is authentic and a potential fake. The Partnership of Safe Medication, University of Texas organisation, has been a constant crusader of combating counterfeit medication.

A little caution can go a along way to prevent the health hazard that is counterfeit medication -- it is imperative that the patient buys nothing but safe and regulated medicine.

❖ Barber turns surgeon, water life-saving drug

The Financial Express, December 10, 2014

A couple of days back the members of the Rapid Action Battalion (RAB)-3 detected the presence of an unauthorized orthopaedic 'clinic' in city's Agargaon area.

All the doctors and medical technicians of the said clinic, housed in a residential building, were fakes. The man who worked as an orthopaedic surgeon earlier had a job in a hair salon.

Last Monday, the members of the RAB-10 unearthed a 'pharmaceutical laboratory' at Kasaitully of old Dhaka, where, according to a report published in a Bangla national daily, 'life saving' drugs were being produced. In fact, the drugs that the RAB members recovered were 'life-threatening' ones.

The owner of the laboratory, reportedly, used to replace the content of low-cost injection vials with tap water, erase the original name of the injection and sell the same as anti-tetanus drug at high costs. He also used to follow the identical procedure to market fake versions of some widely used medicines.

The magistrate accompanying the RAB-10 team sentenced the producer of the spurious drugs to two years' imprisonment and sent him to Dhaka central jail.

The fake doctors and technicians of the unauthorized orthopaedic hospital were also fined and awarded very limited prison sentences.

The detection of a fake orthopaedic clinic and a drug manufacturing unit does again highlight the state of affairs in the country's health sector.

The RAB in particular has been conducting raids in a number of unauthorized hospitals, clinics and drug and cosmetic manufacturing units, particularly in Dhaka city. But that has not helped much.

The soft punishment usually meted out to the criminals concerned has not been able to deter others either from winding up similar operations or starting new ventures in a clandestine manner.

It is suspected that the problems emanating from fake doctors, unauthorized clinics and hospitals and units manufacturing spurious and counterfeit drugs are far more serious than how they are considered by the relevant official circles.

All these illegal operations pose a serious threat to public health. However, the affluent section and the educated middle class usually are not affected. It is the poor and low income people who are the targets of all sorts of deceitful activities, including those taking place in the health sector.

Some years back, a good number of children died due to the consumption of spurious paracetamol syrup, produced by a little known pharmaceutical company. The victims' families were low income ones.

The court has recently passed its verdict on the spurious paracetamol syrup case awarding long-term prison sentences to some of the directors and high officials of the drug manufacturing company concerned. It was a historic judgment in a case that was, in fact, instituted following strong pressure coming from the media in particular.

But there are ample reasons to believe that the mushrooming of unauthorized clinics and hospitals, particularly in areas where poor and low-income people live, and spurious drug manufacturing units in the crowded part of Dhaka city and in outside districts is linked to deliberate indulgence, given to by an unscrupulous section of officials in the health directorate and local law enforcing agencies.

Though the health directorate and the drug administration do often cite 'the shortage of manpower and logistics' as the main reason for not being able to stop irregular practices in the health sector, most experts are not ready to buy such a plea.

For instance, the unauthorized orthopaedic clinic unearthed by the RAB members was a legal entity until a few months back. It had a valid licence issued by the government agency concerned. For reasons best known to its owner/s, the licence was not renewed. The question is: How could the health

directorate grant licence to a health facility that, in fact, had no qualified doctors, medical equipment and other required facilities?

It does not require any elaboration how and why the licence was given. The same practice is being followed in the case of other health facilities that do not fulfil even the basic minimum requirement to be in business.

Policymakers do often project the achievements in the health sector. There are of course some remarkable achievements. Otherwise, the average life-expectancy of the population would not have crossed 70-year mark by now. But there are also failures and those need to be admitted frankly and addressed, with all seriousness. Stern actions against fake doctors, clinics and drug manufacturers should get the topmost priority.

❖ The sinister sway of fake medicines

The Independent, December 11, 2014

A mobile court on Monday raided a fake medicine manufacturing factory in old Dhaka, arrested the owner of the factory red-handed, convicted and sentenced him to two years imprisonment and sent him to the central jail. A report on this appeared in a vernacular daily on Tuesday. The report said Akbar Hossain Bhashani, the arrested person, had been producing fake medicines at his residence at Kosaituli in old Dhaka for a long time and selling the same. It may sound incredible but it is a fact that he had been making medicines for heart disease, tetanus and nasal drops. He used to erase the label of Atropine, a pain killer medicine, worth Tk 2 from the bottle, fill the bottle with water, put a label of anti-tetanus drug in it and would sell each bottle at Tk 1,000. Similarly, he was producing medicine of 'heart stroke' with gastric medicine Antac and nasal drops with the water of WASA and selling the same. Besides, he had been adulterating six life-saving medicines including analgesic Rolac and antibiotic Azythromycin and selling the same. In this way, he made fortunes at the cost of public health. The fake medicines that were being produced by Akbar Hossain found their way into the big wholesale market at Mitford in the capital and from there those were sent to different places of the country.

Consumption of these bogus medicines are exposing the people to serious health hazards. A few years back, fake Paracetamol syrup produced by a dubious medicine company caused the deaths of many children. The persons responsible for the tragedy were brought to justice after a long time. It is worrying to note that cheating of this nature is going on unabated in our country under the very nose of the law enforcement agencies. There are scores of fake medicine produces like Akbar Hossain. They are making millions of taka jeopardising the lives of taxpayers.

It is the responsibility of the Drug Administration Department to keep a vigil so that adulterated and fake medicines cannot be produced and sold in the market. But what role it plays in this regard is not clear. There is no scope to

show leniency to producers of fake medicines who play with the lives of innocent people. Government must show zero tolerance to these abominable elements. Drive against this malpractice once in a blue moon will not do; constant vigilance is required. Deterrent punishment can stop this misdeed, much to the relief of the medicine consumers.

❖ Sale of lethal drugs

Daily Post, December 20, 2014

It's an irony that the government's attention is at the pricing of drugs which itself has been a matter of controversy in the wake of reports that there was manifold rise in rates essential drugs. Though the government denies this allegation, it's no denying a fact that medical care remains a distant dream for majority of the ailing population which has been suffering from deprivation and poverty over the years. What the Modi-led NDA government couldn't attend to was mushrooming growth of fake drug market in India on one hand and sale of medicines which have crossed expiry date across the counter in the pharmacies of many hospitals and several states. Though the successive governments have always denied existence of fake drugs, various reports released by native and foreign agencies reveal a different side of the shocking reality. The counterfeit drug industry is estimated to be worth $200 billion a year. It is defined as 'the crime of the 21st century' among almost every industry within Asia. At least 75 per cent of counterfeit drugs supplied world over have some origins in India, followed by 7 per cent from Egypt and 6 per cent from China responsible. There have been over 3,000 deaths across worldwide per year due to fake or counterfeit drugs, a report 'the Business of Counterfeit Drugs in India: A Critical Evaluation' by Saurabh Verma, Rajender Kumar and P J Philip, Research Scholars at the Department of Humanities and Social Sciences, NIT, Kurukshetra, Haryana, says.

This uncontested report refers to a study by the Pharmaceutical Security Institute (PSI, 2013) discovering 2,193 incidents of pharmaceutical crime during 2013. It says India's Pharma industry is 4thin the world in terms of production volumes and over 55 per cent exports are to highly regulated markets. India's drug exports totaled $14.6 billion (around Rs 82, 730 crore) in the financial year up to March 31, 2012. India is a classical example of developing country with a strong pharmaceutical industry and which also has effective drug regulatory system. A report by Rama Lakshmi also suggests that an estimated 12 to 25 per cent of all drugs sold within India are thought to be counterfeit. It claims India is not only one of the biggest producers of counterfeits drugs but it has also a huge market for spurious and counterfeit drugs. The health ministry, on the contrary, estimates that 5 per cent of drugs in India are counterfeit, while 0.3 per cent is spurious. Undoubtedly the health of pharmaceutical trade itself is doubtful, its ailing and requires emergency treatment. Unless fake drugs are eliminated, the health care to the poor people would remain in doldrums. At a time when government shells out huge sum for medical care to the poor and for rural and BPL families, there's need to put in place extraordinary measures to curb dubious import and sale of fake

drugs in its hospitals. It's needless to say that connivance of a section of medical professionals can't be ruled out.

❖ The 'Counterfeit' conundrum in pharma industry – Is it time for concerted action?

The Financial Express, December 22, 2014

The quality control measures at the customs with regard to the import and the export of medicines and APIs need to be strengthened to eliminate substandard, spurious, fraudulent and counterfeit medicines from international trade to or from India. An insight by Dr Gopakumar G Nair, Chief Executive Officer, Gopakumar Nair Associates

SSFFC — 'the latest World Health Organisation (WHO) initiative on Substandard/Spurious/Falsely-labelled/ Falsified/ Counterfeit medical products' has been making slow but steady progress through meetings in 2012, 2013 and the latest on October 29-31, 2014. A technically strong delegation comprising four seniormost drug regulators from (DCSO/DCGI) office represented India.

Countries like Brazil, Argentina, Ghana, Nigeria (NAFDAC-DG), the US, Europe and Korea were represented by strong delegations. However, not very surprisingly, China was represented only in token, by their officer in Geneva. India has been sending out 'mixed signals' to the global pharmaceutical community including WHO, primarily due to the genuine concerns expressed partially by the generic pharma industry and substantially by the civil society.

Consequent to the efforts of the MNCs and the western world countries to interpret 'counterfeit' as to include intellectual property violations and infringements also through International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of WHO and Anti Counterfeiting Trade Agreement (ACTA) having met with strong resistance, WHO has come up with SSFFC which has excluded the originally inclusive IP Issues such as patent infringement from the ambit of SSFFC. It is time for India to look at the core issues seriously and pursue permanent and futuristic solutions to the issues of quality, reliability, efficacy and good manufacturing practices.

A recent report by a US Organisation headed by Roger Bate had highlighted the lack of uniformity in quality of medicines supplied to Africa. The report had further emphasised on the substandard and spurious status purportedly of medicines from Indian origin. It is surprising that the American Enterprise Institute in Washington and their researchers could access unauthorised and unregistered medicines available in the African marketplace, while African and Indian healthcare regulatory authorities have failed to take a note. Stringent controls on pharma manufactures in India with regard to Good Manufacturing Practices (GMP) and quality excellence is called for. India needs to ensure that no unregistered medicines get exported to any country in the world. While, India is claiming to be 'Pharmacy of the World', any spurious or

counterfeit medicines labelled as of Indian Origin, could substantially damage India's reputation for quality. In this context, upgradation and strengthening of infrastructure at Central Drugs Standard Control Organization (CDSCO) and Drug Controller General (India) (DCGI's) office is of utmost priority.

Of late, there have been many instances of spurious, substandard and counterfeit medicines originating in China, but labelled as of Indian origin have been reported to have surfaced in African markets. These are clear instances of counterfeit medicines, the source and origin being different from what is on the label. These type of counterfeits where the product label claims to be originating from a manufacturer, while the product has fraudulently been manufactured by a third party amounts to criminal practice and need to be detected and punished severely. The quality control measures at the customs with regard to the import and the export of medicines and APIs need to be strengthened to eliminate substandard, spurious, fraudulent and counterfeit medicines from international trade to or from India.

Tragedy struck a recent sterilisation camp in India where 15 women died after sterilisation, reportedly because of administration of contaminated and spurious antibiotic from a Raipur manufacturer. The said medicine has been found to be contaminated by zinc sulphide, a rat poison. The manufacturer appears to be a licensed manufacturer. Even though the drug manufacturing licence has been cancelled, the punitive action should include prevention by ensuring that the concerned persons are no more permitted to set up any other drug manufacturing facility anywhere in the world.

A blacklist need to be created to exclude persons with criminal record from getting back into the pharma manufacturing and trade. The Indian Drug Regulations under Drugs and Cosmetics Act and Rules thereunder need to be reviewed, strengthened and harmonized both in letter and spirit. India should join International Code of Harmonisation (ICH) as an observer with a view to become a regular member in five to ten years. This can only be done by strengthening the office of the DCGI.

In the emerging scenario, India needs to take confident strides towards quality assurance of global standards. The current apprehensions on interpretations of SSFFC medical products must be overcome by concrete propositions from India. The latest definition excludes patents and patent infringement disputes from the definition of counterfeit in countries and regions such as the US and the EU as well as ASEAN and RCEP. This negotiated compromise will lead to a better handling of quality issues across the board in pharma trade, globally.

❖ Counterfeiters fashion fake cosmetics as law enforcement agencies sit idle

The Financial Express, Dec 30, 2014

Adulterated cosmetics and toiletries under the false names of leading local and foreign brands are randomly sold in markets across the country, putting

public health at risk, industry people and pour enforcement officials say said.

Many of the users of these counterfeit beauty and sanitary items contract skin diseases-skin cancer being the most fatal one.

The substandard cosmetics sell from footpath to modern shopping malls as a number of syndicates are involved in making and selling these products, the sources said.

According to a study done by the Consumers Association of Bangladesh (CAB), 45 per cent of cosmetics have no certification by the Bangladesh Standards and Testing Institution (BSTI).

Bangladesh Cosmetics and Toiletries Manufacturers Association statistics show annual turnover of the sector is around Tk 150 billion. Local companies share 60 per cent of the market cake.

Among the major local companies are Square Toiletries Ltd, Kohinoor Chemicals Ltd, Keya Cosmetics Ltd, Mousumi Industries Ltd and Aromatic Cosmetics Ltd.

Beauty products of nearly all renowned international cosmetics brands are imported into Bangladesh-and those are largely high-priced.

The world majors in this sector include L'Oreal, Revlon, Estee Lauder, Max Factor, Avon, Maybelline, MAC Cosmetics, Garnier, Elizabeth Arden, Lalique, bareMinerals, BeBeautiful, Bioré, Biotherm, Bobbi Brown, Chanel, Clinique, CoverGirl, Crabtree and Evelyn, Dior, Essie, Frederic Fekkai, Fusion Beauty, Giorgio Armani, Guerlain, Nivea, Lakme, and Emami.

Most of foreign cosmetic products are imported from the USA, Germany, France, the Middle East, China, Thailand, India and so.

After visiting several markets in the city from December 25 to 28, the FE correspondent found many of the leading local-and global-brand cosmetics and toiletries adulterated.

The shoddy stuffs include body spray, soap, lotion, makeup boxes, shampoo, snow, cream, powder, face-wash, leap liner, mascara, lipstick, nail polish, nail- polish remover, liquid makeup, eye-shadow, and pain tick.

These are sold publicly as the customers cannot immediately differentiate between fake and real stuffs and the purchase price is less than that of the real brand products.

Sources in the law-enforcement department said a number of fake cosmetics factories have been set up on both sides of Buriganga River. The down-market manufacturers include Companyganj, Jinjira, Kalindi of Keraniganj area, Chawkbazar, Begumbazar, Rahmatganj, Islambagh, Borokatra, Chotokatra and Kamrangirchar.

The agencies also said a number of supermarkets in Chawkbazar Chawk supermarket, Chawkm-ogalatuli, Mansur Plaza, Mumtaz Market, Khan Market, Friendship Market, Johan Market, Shamim Market, Eastern Plaza, Plaza Muscat in Uttara have are selling fake cosmetics.

The syndicates are producing fake products of Square Toiletries, Kohinoor Chemical and Lalbagh Chemicals, Unilever, Hugo, Ferrari, Poison, Royal, Havoc and Cobra brands by using labels.

"Branded cosmetics and toiletries are being adulterated and sold across the country," Jahangir Alam, general secretary of Bangladesh Cosmetics and Toiletries Importers Association, told the FE.

He said the law-enforcement department knows but doesn't have any action against the fakers.

Every year, he added, the leading local manufactures and importers have been counting huge amounts of fake cosmetics frequently selling at shops to footpaths.

Munir Ahmad Khan, co-chairman of Bangladesh Cosmetics and Toiletries Manufacturers Association, said locally two types of fake cosmetics go for sale.

He said some of the fake cosmetics are produced locally while others are coming from different other counties.

A trader at Pallabi supermarket said the fake cosmetics is being made in Dhaka's Lalbagh and Hazaribagh areas, Kamrangir Char and Keraniganj.

He said the fake cosmetics look similar to brand products and sell at low prices to the detriment of customers.

AHM Anwar Pasha, Executive Magistrate with the Rapid Action Battalion (RAB), said a number of dishonest businesses have been manufacturing and selling fake version of local and foreign cosmetics.

"People are being cheated, this way," said the magistrate, who dispenses spot justice in mobile court on different drives conducted by the elite force.

He said in recent times a mobile court sentenced seven persons to jail terms ranging from two years to six months at Chawkbazar in the capital for such offences.

Skin specialist Dr Saiful Islam said, "We have tasted counterfeit cosmetics several times, which tested positive for a range of toxins."

Things such as arsenic, lead etc are mixed with counterfeit cosmetics which can seriously damage human skin. Even it can harm inner-side, too.

He said the skin on your face absorbs things differently than anywhere else on your body.

"Especially the skin around your eyes is the thinnest skin on our body," he said.

"It could cause acne on your face, dermatitis or eczema or scaling. Theoretically, you can absorb through your skin too. There could be bacteria because there is no quality control," said the physician.

Counterfeit cosmetics can even cause skin cancer, he said.

He said the number of skin patients is increasing nowadays due only to using counterfeit products.

He also suggested that the consumers, specially the women, should use natural products instead of chemical to avoid the use of counterfeit products.

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