Benefits of good practices in pharmacy- Setting standards for delivery of safe medicines to patients in WHO-SEA Region

SEARPharm Forum
South East Asian FIP-WHO Forum of Pharmaceutical Associations

South East Asian FIP-WHO Forum of Pharmaceutical Associations
Promoting Pharmacists Role in WHO's Health Agenda
South East Asia Region of WHO

27th April, 2012, Radisson Blu, Dwarka, New Delhi

COMPILATION OF PROCEEDINGS

PREFACE AND ACKNOWLEDGEMENT

We are pleased to present the proceedings of the SEARPharm Forum Seminar on benefits of good practices in pharmacy - Setting standards for delivery of safe medicines to patients in WHO-SEA Region at New Delhi. The seminar deliberated on implementation of GPP in hospital and community setting as well as promotion of safe use of medicines. The proceedings contain useful information and could serve as an important reference for member organizations interested in GPP development in their countries.

I would like to thank the ExCo members of the SEARPharm Forum, WHO-SEARO and speakers for the lively deliberations. I would also like to thank Indian Pharmaceutical Association for their support.

Pradeep Mishra

Assistant Professional Secretary

1

INTRODUCTION

FIP and WHO

Founded in 1912, the International Pharmaceutical Federation (FIP) is the global federation of national associations of pharmacists and pharmaceutical scientists and is in official relations with the World Health Organization (WHO).Through its 126 Member Organisations FIP represents and serves more than two million practitioners and scientists around the world.

Throughout its almost 100 year history, FIP's priorities have expanded both literally and figuratively to meet the needs and expectations of the profession in expanding healthcare services and integrating emerging scientific developments. Changes in pharmacy and the emergence of Pharmacy Practice as a cornerstone of the profession have lead FIP to become globally visible for its advocacy on behalf of the role of the pharmacist in the provision of healthcare, while still maintaining its grounding in the pharmaceutical sciences.

SEARPharm Forum

SEARPharm Forum is a Forum of International Pharmaceutical Federation (FIP), WHO SEARO and National Pharmaceutical Associations of South East Asia Region, established in 2001. Its secretariat is based in Delhi. The objective of SEARPharm Forum is to encourage and support a dialogue and collaboration among the National Pharmaceutical Associations of South East Asian Region, WHO-SEARO and International Pharmaceutical Federation (FIP).

SEARPharm Forum manages its annual meeting and such activities and projects from sources such as membership fees of National Pharmaceutical Associations, and contributions from WHO SEARO and FIP, and external sources including e.g. government and other member organizations.

2

SUMMARY AND CONCLUSIONS

PARTICIPATING ORGANISATIONS

- India
- Indonesia
- Nepal
- Sri Lanka
- Thailand

SUPPORTING ORGANISATIONS

- WHO-SEARO
- FIP
- Indian Pharmaceutical Association

FACILITATOR

- SEARPharm Forum

OBJECTIVE IN FOCUS

SEARPharm Forum's goal in practice is 'Improving health in the South- East Asia region by development and enhancement of pharmacy practice (Good Pharmacy Practice).'

ACTIVITY

In order to promote the standards for good practices in pharmacy settings in the region seminar on " Benefits of good practices in pharmacy- Setting standards for delivery of safe medicines to patients in WHO-SEA Region" was convened at New Delhi on 27th April, 2012.

Speakers from India, Indonesia, Nepal, Sri Lanka and Thailand deliberated on the theme of the seminar which was followed by a discussion cum review.

3

SIGNING OF MEMORANDUM OF UNDERSTANDING

For engaging retail pharmacies in RNTCP, The Central TB Division, Directorate General of Health Services signed an MoU with Indian Pharmaceutical Association (IPA), All India Organisation of Chemists & Druggists (AIOCD), Pharmacy Council of India (PCI) and SEARPharm Forum.

CONCLUSION

The conference was informative, productive, provided good opportunity for discussion on benefits of good practices in pharmacy settings and networking among participants from different countries of the region.

4

OPENING REMARKS- PD Sheth

Mr. P.D. Sheth, FIP Vice President made opening remarks and briefed participants on improving health through responsible medicine use. He drew attention of delegates to the Minister Summit and stakeholders round tables which will take place during the FIP Centennial Congress at Amsterdam from 3-8 October, 2012.

He highlighted that each year millions of dollars are allocated in countries' national budgets out of which substantial sum of money is spent on medicines to treat patients.

However, there are major concerns, about effective delivery, access and cost.

He quoted FIP President that pharmacists and pharmaceutical scientists should make difference. He further mentioned that FIP President cautioned to "Keep doors open because change was coming."

FORUM

For the last five years, the forum has been engaged in implementation of GPP in the region. The starting was with the FIP outreach project in Thailand and the adoption of the Bangkok Declaration. This was followed by the Jog Jakarta meeting. The role of FIP has been as an enabler.

The local bodies implement and produce results.

The process of sharing of country experiences has encouraged transparency and flexibility of approach. Throughout emphasis has been on measuring quality through periodic audits. A regional team has facilitated the process.

Two way communication and feedback mechanism has provided a platform for teamwork, cooperation and support.

It is in this context that the theme: benefits of good practices in pharmacy - setting standards for delivery of safe medicines to patients in WHO-SEA Region was decided.

SEARPharm Forum Seminar
Benefits of good practices in pharmacy- Setting standards for delivery of safe medicines to patients in WHO-SEA Region

09:00 am to 06:00 pm, 27th April, 2012, Radisson Blu, Dwarka, New Delhi

09:00 - 09:30 Registration

09:30 - 10:30 Session 1: Opening of SEARPharm Forum Seminar

Welcome and opening remarks

- Teera Chakajnarodom, President, SEARPharm Forum
- Prafull D. Sheth, Vice-President, FIP
- Nigorsulton Muzafarova, WHO-SEARO
- J. A. S. Giri, President, IPA

Keynote address: Gyanendra Nath Singh, Drugs Controller General (India), MoH.

Photo Session: All participants

TEA BREAK

10: 30 - 12:30 Sessions 2: Guidelines on Good Pharmacy Practice Implementation in SEAR

Chair: Teera Chakajnarodom, Thailand; Co-Chair: M. Dani Pratomo, Indonesia

This session will highlight:

- *Infrastructure for setting up accredited pharmacy*
- *Regulatory support for implementing GPP*
- *Understanding good trade practice in pharmacy*
- *Experience sharing on GPP Implementation*

Lecture 1: Setting up accredited pharmacy in India, Raj Vaidya, India

Lecture 2: Regulatory support for implementation of GPP in Thailand, Songsak Vimolkittipong,Thai FDA

Lecture 3: Good Trade Practice Sri Lanka, Chamila Samarsinghe, Sri Lanka

Lecture 4: Implementation of GPP in Indonesia**,** Wahyudi, Indonesia

12:30 LUNCH BREAK

13:30 - 15:00 Sessions 3: Framework for Hospital Pharmacy Practice in South East Asia

Chair: Chinta Abhayawardana, Sri Lanka; Co-Chair: Nasser Zahedee, Bangladesh

This session will highlight:

- *Education and continuing education for Hospital Pharmacy Practice (HPP)*
- *Status of hospital pharmacy in South East Asia*

Lecture 5: Status of implementation of Basel Statement in SEAR, Eurek Ranjit, Nepal

Lecture 6: Perspective of education and continuing education for HPP in India, G. Parthasarthy, India

Lecture 7: Setting up a model Hospital Pharmacy in Thailand, Kamonsak, Thailand

15:00 - 15:30 SIGNING OF MEMORANDUM OF UNDERSTANDING BETWEEN RNTCP AND IPA, AIOCD PCI, SEARPHARM FORUM

TEA BREAK

15:30 - 17:45 Sessions 4: Promoting Safe Use of Medicines in South East Asia

Chair: Nigorsulton Muzafarova, WHO-SEARO; Co-Chair: C. G. K. Murty, India

This session will highlight:

- *Good practices for safe and rational use of medicines*
- *Patient information and counseling for DOTS delivery*
- *Use of affordable technology for information dissemination*

Lecture 8: Good Practices for safe and rational use of medicines, Bejon Misra, India

Lecture 9: Patient information and counseling for DOTS delivery, Manjiri Gharat, India

Lecture 10: Challenges in gate keeping role for rational dispensing of antibiotics, Anit Kotwani, India

Lecture 11: M-health as a tool for promoting quality medicines, Pradeep Mishra, India

17:45 - 18:00 Summary and Way forward: Prafull D. Sheth, India

DINNER HOSTED BY DR. J. A. S. GIRI, PRESIDENT, IPA(19:00 hours)

PRESENTATIONS

Regulatory Support for Implementation of GPP in Thailand

Mr.Songsak Vimolkittipong

Bureau of Drug Control
Thai Food and Drug Administration
April 27, 2012

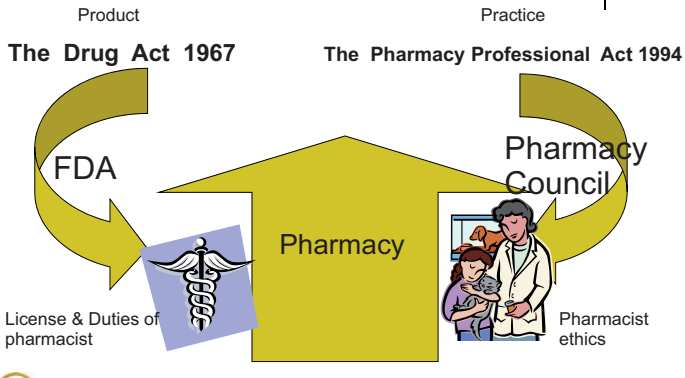
Topic

- Overview of drugstore and law regulation
- Regulatory support for GPP
- Plan for the future of GPP in Thailand

- **Population : 67,000,000**
- **Pharmacist : 29,000**
- **Drugstore : 16,000**

- **The Drug Act 1967**
- **The Pharmacy Professional Act 1994**

Law regulation to drugstore



Modern drug classification

1. Household medicine (OTC Drug)
2. Ready-packed drug which are not dangerous or specially-controlled drug
3. Dangerous drug
4. Specially-controlled drug
5. Narcotic & Psychotropic substance drug

The Drug Act 1967

4 type of Drugstores

1. A license to sell modern drugs (Type 1)
2. A license to sell only ready-packed modern drugs which are not dangerous or specially-controlled drugs (Type 2)
3. A license to sell only ready-packed modern drugs for veterinary use (Type 3)
4. A license to sell traditional drugs

A license to sell modern drugs (Type 1)

13,482 Pharmacy

A license to sell only ready-packed modern drugs which are not dangerous or specially-controlled drugs (Type 2)

2,431 drugstores

A license to sell only ready-packed modern drugs for veterinary use (Type 3)

423 drugstores

สถานที่ขายยาแผนปัจจุบัน เฉพาะยาบรรจุเสร็จสำหรับสัตว์

A license to sell traditional drugs

1,485 drugstores

Collaboration between FDA and Pharmacy council to Implement GPP

Type 1 Drugstore

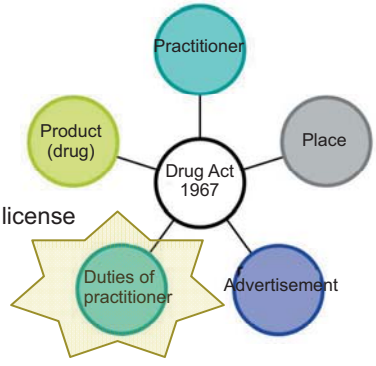
FDA encourage pharmacy to development (Promoter)

Pharmacy council (Accreditator)

ร้านยาคุณภาพ PHARMACY ACCREDITATION

Drug Act B.E.2510 (1967)

Criminal law,
- Imprisonment
- A fine
- Suspend or revoke license



Duties of Pharmacist

- On duties at the place of sale of modern drugs during the duration of business hours
- Control the separation of drug
- Control over labeling in accordance
- Etc.

Drug act 1967 section 39

New law as "mini GPP"

(New "Ministerial regulation" under Drug Act 1967)

- Pharmacist identification
  - Picture of pharmacist on duty
  - Role and responsibility
- Add the criteria for renewal of license
  - Needed to pass "Mini GPP"
  - Did not have history of punishment more than 3 times (in case of Pharmacist duties (Drug Act 1967 sec.39))

✓ To know "Who is Pharmacist"

-Uniform

-Photograph

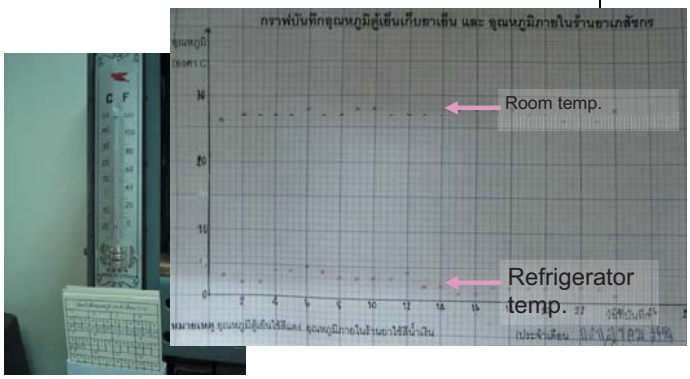
✓ Pharmacist Assistance and SOP

Difference from Pharmacist

Standard Operating Procedure

✓ Have area for “Counseling”

✓ Monitor suitable temperature for storage



Thai Food and Drug Administration

✓ Monitor for expiration date

-color code -note book -computer

And other methods that can to prove/ to make sure

Thai Food and Drug Administration

✓ Separate area for “Pharmacist only”

Thai Food and Drug Administration

✓ Pharmacist dispense all Dangerous drugs and Special controlled drugs

Thai Food and Drug Administration

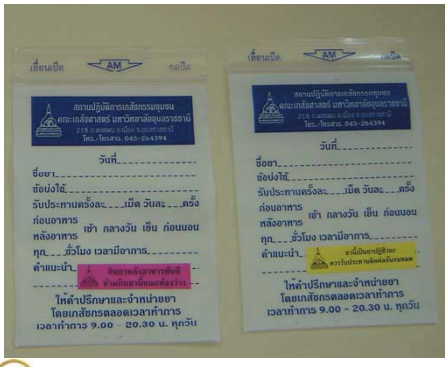
✓ Pharmacist have good in dispensing

Ask before dispense

-Who use…
-What medication use before
-How long
-Allergy
-Underlying disease
- etc…

Thai Food and Drug Administration

✓ Labeling for traceability and patient rights



-Name and Tel. of drugstore
-Dispense date
-Drug name
-How to use
-Caution (if necessary)

Thai Food and Drug Administration

✓ Don't dispense drug in Pharmacist area when Pharmacist not available

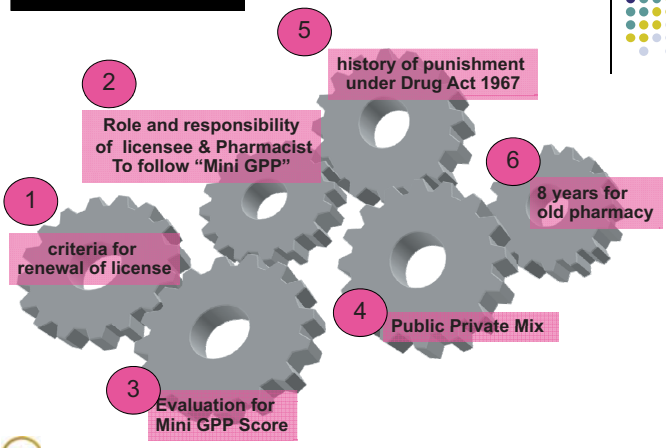
✓ Aware of “Drug allergy”

-Separate plates or spoons and labeling

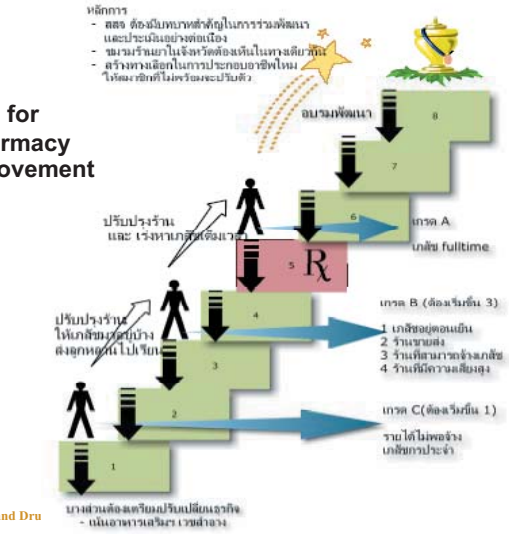
-Ask about allergy all patients

✓ Separate between knowledge and advertisement material

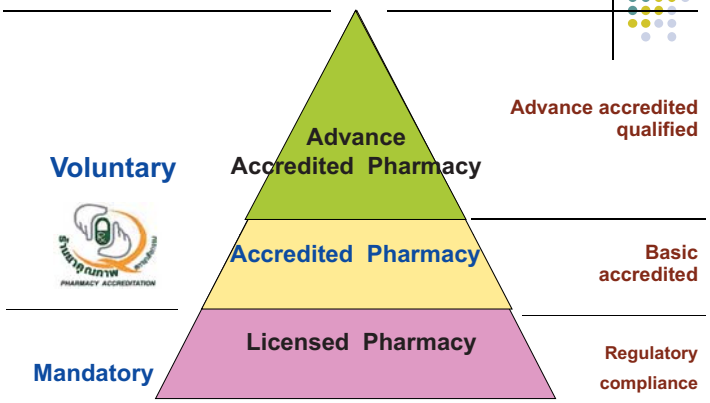
Mechanism



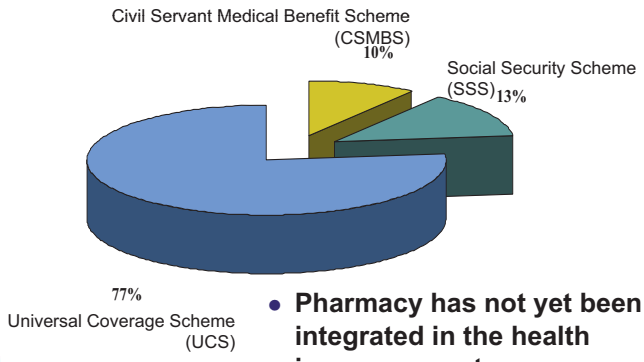
8 Steps for old pharmacy to improvement



Expected direction



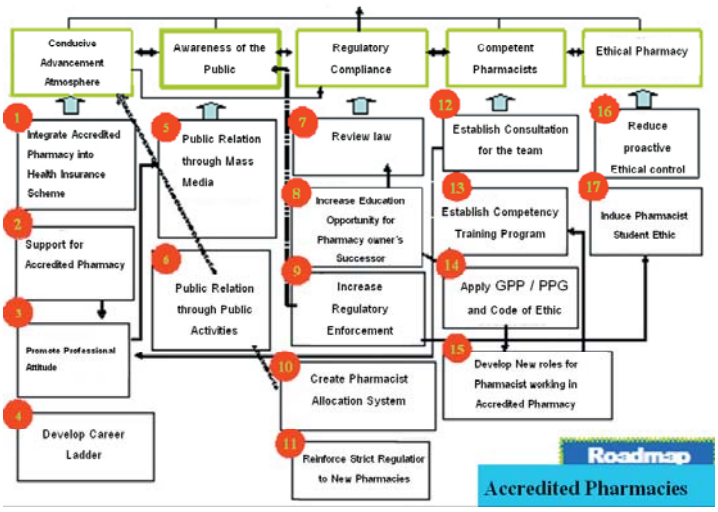
Health Benefit Scheme



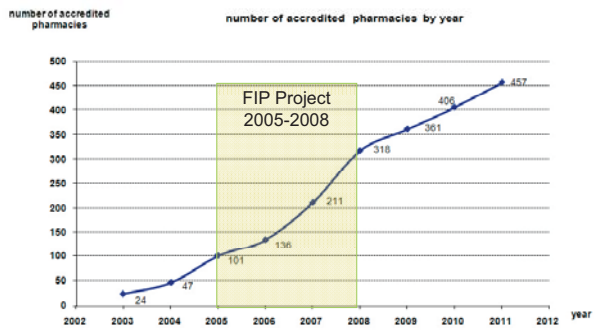
- **Pharmacy has not yet been integrated in the health insurance system**

The strategic plan

Holistic Approach :Accredited Pharmacy Across Thailand



Number of accredited pharmacy



Thank you for your kind attention

Good Trade Practice in Pharmacy

Chamila Samarasinghe
Council Member, PSSL
Promotions & Publicity Officer, SPC

Importance of Medicines

- Save lives and improve health
- Different from other consumer products
- Promote trust and participation in health services
- Substantive improvements in the supply and use are possible.

Medicines are costly.

Good Trade Practice (GTP)

A proper conduct and self-discipline in all aspects of Pharmaceutical supply, specially in marketing and trade.

A shared responsibility of everyone involved in the manufacture and supply chain.

- GTP should be applied to every step in the supply chain.

Why Good Trade Practice?

- To improve standards of ethical practice in the marketing of medicinal products
- To promote ethical practice
- Improper trading practice can cause significant risk to the quality of pharmaceuticals.

Structure of the health sector and the flow of funds

- Health care in Sri Lanka is provided by the government, private sector and to a limited extent by the non-profit sector.
- Tax funded free-health care system in the government sector.
- The government sector - financed from general revenue taxation
- Private sector financing is through out-of pocket spending, and contributions from non-profit organizations.
- Donor financing is largely channelled through the government sector, and in certain instances through nonprofit organizations.

Role of State Pharmaceuticals Corporation (SPC)

- The procurement arm of the government sector.
- Supply drugs to private sector through SPC distribution network.

Committed to serve the nation by supplying quality assured products at an affordable price.

Parties involved in GTP

- pharmaceutical manufacturers
- distributors
- other suppliers
- international organizations and donor agencies involved in procurement
- tenderers;
- relevant trade organizations;.
- governments;
- regulatory bodies;
- certifying bodies; and
- all parties involved in trade and distribution.

Basic Functions of Pharmaceutical Supply Management

- Selection
- Procurement
- Distribution
- Use

Selection

- Essential Medicines List
- Standard treatment guidelines
- DRA approved suppliers
- Quality assured products
- Supplier status/ supplier performance
- Recommendations of the technical experts

Selection

- As per National Medicines Policy (NMP) in Sri Lanka priority is given for:
  - Essential Medicines List (EML)

EML

- The medicines should be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, safety and efficacy and adequate information, and at a price the individual and the community can afford.
- List of most efficacious, safe and cost-effective medicines for priority conditions.

Procurement

Effective procurement

- A mechanism for managing the *BUYER-SELLER RELATIONSHIP* to ensure transparent and ethical transactions that result in the buyer receiving the correct goods and the seller receiving timely payment.

Procurement objectives

- Acquiring quality supplies at the best possible price
- Ensuring prompt and dependable delivery
- Following procedures that are transparent and not influenced by special interests
- Maintaining a procurement pattern that produces an even workload and a constant supply to clients
- Achieving efficiency through use of appropriate systems and procedures
- Limiting total procurement costs

Key procurement functions

- Selection of medicines
- Quantification of pharmaceutical requirements (based on the consumption, disease pattern, generic prescribing)
- Preparation of product specifications and quality standards
- Approval of suppliers
- Award of tender

These functions should be handled by separate individuals, units or committees. It helps professionalism and accountability.

Procurement cycle

- Mobilize procurement team and key players
- Review medicine selections
- Specify quality standards
- Determine quantities needed
- Reconcile quantities and funds
- Choose procurement methods
- Locate and select suppliers
- Specify contract terms
- Monitor order status
- Receive and check medicines
- Make payment
- Distribute medicines
- Collect consumption information

Good procurement practice

1. Reliable payment and good financial management
2. Procurement by generic name
3. Procurement in large volumes
4. Formal supplier qualification and monitoring
5. Competitive procurement
6. Transparency and written procedures
7. Order quantities based on reliable estimate of actual need
7. Separation of key functions
8. Product QA program
9. Annual financial audit with published results
10. Regular reporting on procurement performance

Requirements of the procurement office for effective procurement

- Trained staff
- Appropriate management systems
- Technical and policy committees to decide which medicines to buy, in what quantities and from which suppliers

Prequalification

- Essential procurement practice
- Essential key element in ensuring product quality

Prequalification

Advantages

- Ensuring product quality
- Avoid wasting time on suppliers that do not perform according to contract
- Helps minimize the possibility of introducing substandard product

Disadvantages

- May not be beneficial if it protects favoured suppliers from competition
- Ensuring new suppliers to the system is virtually impossible
- Initially can be extremely time consuming

Pre-qualification criteria of SPC

- Establishment of the company
- Qualifications of the management
- Financial capacity
- Experience
- Quality standards of raw materials / finished product
- DRA registration status
- WHO GMP status
- Registered countries
- Previous complaints
- Annual audited financial reports

A product will be eligible for pre-qualification in a tender, if the product has;

- WHO pre-qualification
- Suppliers' or products' approval by a stringent regulatory authority as an evidence

WHO prequalification program

- Facilitate access to quality medicines for HIV/AIDs, malaria and TB
- Manufacturers must present extensive information on their product on quality, safety and efficacy
- Manufacturing sites are inspected for the compliance of WHO GMP
- WHO carry out random quality control testing of prequalified medicines that have been supplied to countries

Procurement methods

- Open tender
- Restricted tender
- Competitive negotiation
- Direct procurement

Purchasing models

- Annual purchasing
- Scheduled purchasing / perpetual purchasing

Quality Management

Includes:

- A quality system, including the organizational structure, procedures, processes and resources
- QA; the systematic actions necessary to ensure adequate confidence that a material (or service) and the relevant documentation will satisfy given requirements for quality.
- GMP

Why GMP?

- To maintain the original quality
- Activities such as repackaging and re-labelling, in particular, can increase the risk of contamination, cross-contamination, mix-ups, degradation and changes in physical properties

Communication market information

- To succeed in the international market, procurement programs need;
  - Comparative price and availability data on products in the national and international market
  - Information about suppliers' capacity, reliability and quality

Distribution

- Goal: To maintain a steady supply of pharmaceuticals to facilitate where they are needed, while ensuring that resources are being used in the most effective way.

Characteristics of an effective distribution system

- Maintain constant supply of medicines
- Maintaining proper storage conditions
- Maintain accurate inventory records
- Good transportation mechanism to preserve the quality of medicines

Distribution Cycle

Dispatching goods

Medicine Consumption information sent back to the procurement unit

Distribution Cycle

- Port Clearing (For imported products)
- Receipt and inspection
- Inventory control
- Storage
- Requisition of supplies
- Delivery
- Dispensing to patients
- Feedback information

SPC Distribution Network

- Ministry of Health
- Open market
  - Rajya osu sala outlets
  - Wholesale Distributors
  - Franchise outlets's
  - Authorized retailers

Health Facilities

- Last step of the supply chain before delivery to the patient
- System should ensure;
  - Secure storage
  - Storage in correct environment conditions
  - Accurate record keeping
  - Effective reordering
  - Effective stock rotation and expiry monitoring
  - Effective fire and theft prevention

Pharmacists/ owners should;

- Provide quality medicines at an affordable price that is appropriate to local market needs
- Meet all premises standards required, including maintenance of adequate storage facilities
- Hire licenced, trained and skilled pharmacists
- Facilitate access to refresher training to upgrade pharmacists' skills

Standards of Promotion

- In general, the standards of promotion should subscribe to the good practice of ensuring that;
  - Data are substantiated.
  - False or misleading claims are not allowed.
  - Unapproved products and indications are not promoted.
  - Comparative statements must be used carefully.
  - Promotional ethics are adhered to.

Regulatory measures for GTP

Registration is compulsory for

- All medicines
- All manufacturers, importers, retailer & wholesalers
- All pharmacies
- All vehicles transporting medicines

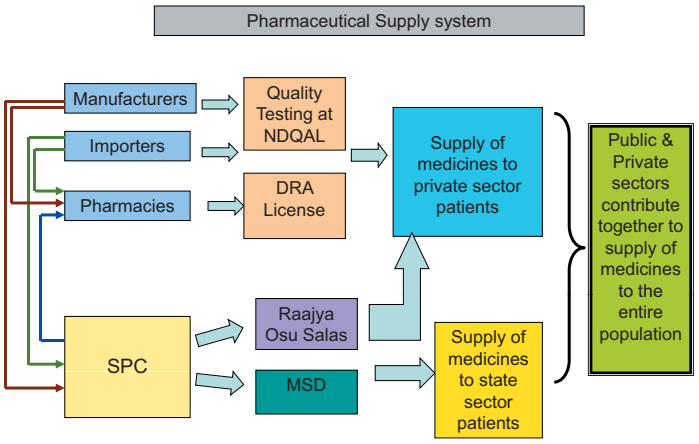
- Medicine advertisements
- Recall procedure

Challenges

- The availability of the drugs to the consumers during times of shortage issues
- Not receiving adequate cash advance at the correct time to settle bills.
- Frequent delays by suppliers as contracts are made annually.
- Frequently reported quality failures
- Weaknesses in the PMS
- Lack of pharmacists in appropriate positions

Challenges, Contd..

- Lack of expertise in Pharmaceutical Management
- Pre – qualification for pharmaceuticals to be strengthened.
- Lack of medicine utilization studies
- Pricing mechanism
- Adherence to code of trade practice



Commitment of the Pharmaceutical Industry

- ***The Pharmaceutical Industry, has a special position in the healthcare services, and has obligations in a fully responsible manner.***

References

- **http://www.sapi.org.sg/mktg.htm**
- Managing Drug Supplies
- http://whqlibdoc.who.int/trs/WHO_TRS_917_annex2.pdf

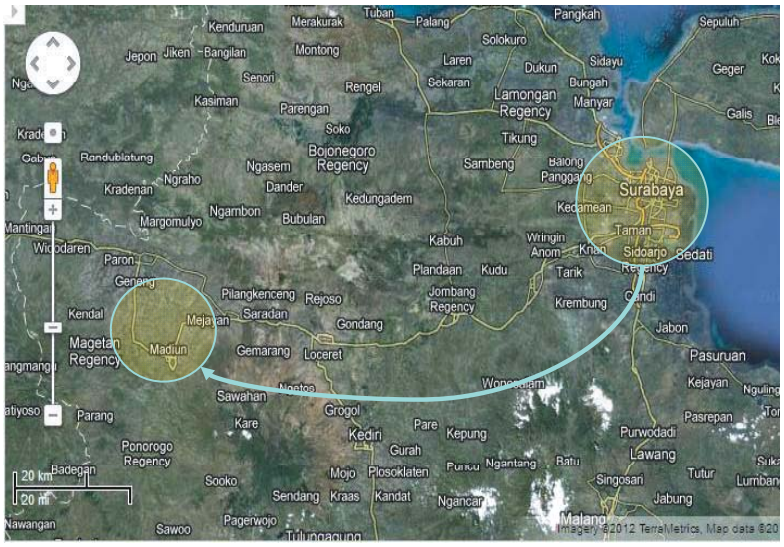
Note of Thanking…

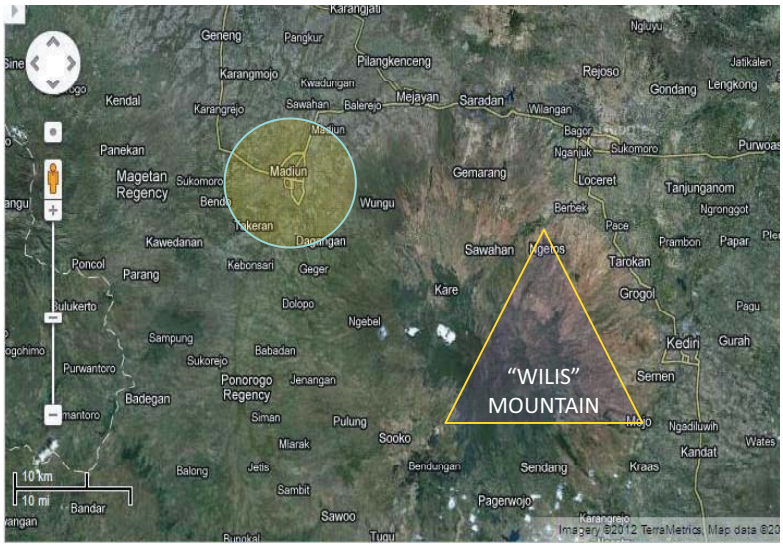
- Ms. Chinta Abeyawardena, President/ PSSL
- President, Professional Secretary and the members of the SEARPharm Forum Exco Committee
- Chairman & the General Manager / SPC
- Deputy General Manager (Marketing) /SPC
- Ms. Savini Senadeera / Lecturer, University of Sri Jayawardenapura

Implementation of GPP:
Prospective Reports of Community Pharmacist at Independent Pharmacy in East Java - Indonesia

M Y Wahyudi

- Society of Community Pharmacist, of Indonesian pharmacist Association, for East Java Province, Indonesia
- Practician in "INDICA PHARMACY" Madiun, East Java - Indonesia
- M.Pharm Student at "Airlangga University", Surabaya, East Java - Indonesia





"INDICA PHARMACY"
Independent Pharmacy (in there "a collaborative practice with GP")

"INDICA PHARMACY"
Independent Pharmacy before implementation GPP

"INDICA PHARMACY"
Independent Pharmacy before implementation GPP

Law : 2009 Act about Health

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(1) Pharmaceutical practice includes
- **the manufacture of pharmaceutical preparations including quality control,**
- **security, procurement, storage and distribution of drugs,**
- **the prescription drug services,**
- **drug information services**
- **as well as drug development, medicinal materials and traditional medicine**

should be carried out by health personnel with the expertise and authority in accordance with legislation

The State of Republic of Indonesia

2009 Act about Health

Indonesian Pharmacist Association
Standard of Profession:
- Standar of Competencies
- Code of Ethics

Government , Regulation :
- 2009, Regulation about Pharmaceutical Practices
- 2010, National Pharmaceutical Committe

- Pharmacy Practice System?
- Standard of Practice ?
- Good Pharmacy Practices

- Standar of Pharmaceutical Services in all Practice Institution

Indonesian Pharmacist Association

Society of "Apoteker"
- Pharmacist in Industry
- Pharmacist in Distribution
- Pharmacist in Hospital
- Pharmacist in Community

- Community Pharmacy
- Community Health Center
- Primary Clinic
- Collaborative Practice

Indonesian Pharmacist Association

- Standar of Competencies
- Code of Ethics
- Standar of Practice
- Good Pharmacy Practices

Pharmacist in Community (Society of Community Pharmacist)

- Model of Practice
- Standard of Community Pharmacy Practice
- Good Community Pharmacy Practice
- Policy of Organization
- Guidelines of Practice
- Statements of Practice
- Standard of Procedures

2009

PHARMACIST

- **Role 2: Provide effective medication therapy management**
- **Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products**
- **Role 3: Maintain and improve professional performance**
- **Role 4: Contribute to improve effectiveness of the health-care system and public health**

2011

PHARMACIST

- **Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products**
- **Role 2: Provide effective medication therapy management**
- **Role 3: Maintain and improve professional performance**
- **Role 4: Contribute to improve effectiveness of the health-care system and public health**

2011

PHARMACIST

Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products

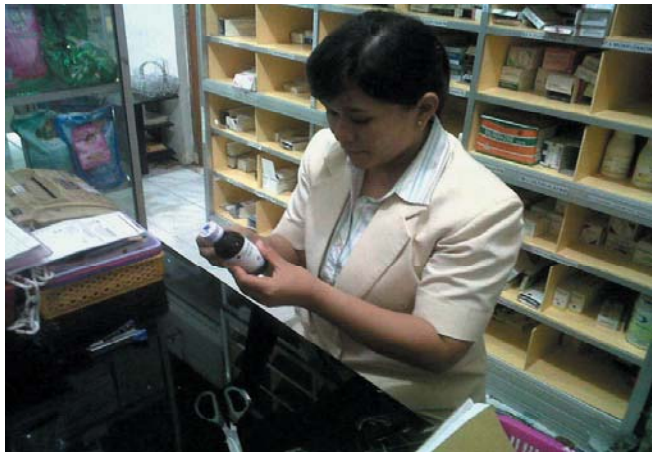
GPP FIP-WHO

Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products

- **Function A: Prepare** extemporaneous drug preparations and medical products
- **Function B: Obtain and store** drug preparations and medical products
- **Function C: Distribute** drug preparations and medical products
- **Function D: Administration** of medicines, vaccines and other injectable medications
- **Function E: Dispensing** of medical products
- **Function F: Dispose** of medicine preparations and medical products

Community

1. Good Distribution Practice
2. Good Dispensing Practice
3. Good Compounding Practice
4. Good Store & Dispose Practice




ICE CREAM
SOFT DRINK - SNACK
CAKE - TEA - COFFEE
BUKA


SELVIM
KAPLET
ASTATIN
K7.2 LO
CARDIO ASPIRIN
Aspilets


RAP TENANG

World Health Organization

fip

PHARMACIST

Role 2: Provide effective medication therapy management

GPP FIP-WHO

Role 2: Provide effective medication therapy management

- **Function A:** Assess patient health status and needs
- **Function B:** Manage patient medication therapy
- **Function C:** Monitor patient progress and outcomes
- **Function D:** Provide information about medicines and health-related issues

Community

1. Model of Practice
2. Standard of Community Pharmacy Practice
3. Guideline of Services Pathway
4. Good of Community Pharmacy Practice

GPP FIP-WHO

Role 2: Provide effective medication therapy management

- **Function A:** Assess patient health status and needs
- **Function B:** Manage patient medication therapy

PMR = Personal Medication Records/Review

I-R-C = (decision) Intervene, Refer , Collaborative

MTR = Medication Therapy Review

GPP FIP-WHO

Role 2: Provide effective medication therapy management

Function C:
Monitor patient progress and outcomes

Function D:
Provide information about medicines and health-related issues

Apoteker Care Plan

- Do-Fu-Plan : . Documentation
  . Follow Up
  . Monitor Care Plan
- MAP : Medication Action Plan
- PxIS : Patient Information Sheets

"INDICA PHARMACY"
"Point of Entry at Profession Counter"

"INDICA PHARMACY"
- "Point of Exit"
- Pharmacist Intervention:
  Counsel-Educate-Inform-Guide-Advice-Advocate

"INDICA PHARMACY"
"Point of Entry at Pharmacist Practice Room"

HOUSE HEALTH CARE CENTER

FORM REKAM FARMAKOTERAPI PELAYANAN RESEP

APOTEK INDICA
Jl. Setia Budi Timur No. 25
Telp. (0351) 497381,
Fax. (0351) 495498
MADIUN

NAMA KLINIK / RS :
PENJAMIN : Asuransi / Umum
NO :
NAMA PASIEN :
ALAMAT / TLP :
UMUR / BERAT BADAN :
ALERGI :
RIWAYAT PENYAKIT :
STATUS KEHAMILAN : Ya / Tidak
ALASAN TATAP MUKA :

NO REGISTER :

GOAL OF THERAPY

TGL.	KELUHAN (COLLECTING INFORMASI)				DATA LAB. (SIGN)	DIAGNOSA	MULAI SAKIT	OBAT YANG SUDAH DIKONSUMSI (MEDICATION HISTORY)	DOKTER	DU - DSM (DISEASE STATE MANAGEMENT) - GOT	KOMPLIKASI	RESEP (REVIEW) (DRP)	PCP		EGAA	MONITORING		STATUS		
	Sy	B	M	L									INTERVERENSI (DTP)	RUJUKAN		VIA SMS, TLP, YM, PIN BB	HOME CARE VISITE (CONTROL)	SUKSES	GAGAL	PROGRES

Menyetujui :
Paslen

(_____)

Apoteker

(Moch. Yeni Wahyudi M. Farm.,Apt)

dokter

(dr. Dwi Waluyo)

TERAPI DAN PENCEGAHAN

TERAPI

1. Terapi tanpa obat :
   - Pengaturan diet (karbohidrat, lemak, protein sesuai proporsi)
   - Olahraga : jalan/lari pagi, bersepeda, berenang, dll.
2. Terapi obat
   - Insulin
   - Antidiabetikal oral

Sulfonilurea : merangsang sekresi insulin pada pankreas. Contoh : Gliklazid, Glibenklamid, Glipizid, Glimepirid.

Biguanida : menghambat glukoneogenesis Contoh : Metformin

Tiazolidindion : meningkatkan sensitivitas insulin. Contoh : Pioglitazon, Rosiglitazon

Penghambat α - glukosidase Contoh : Akarbose, Miglitol

- Kombinasi keduanya

PENGATURAN DIET

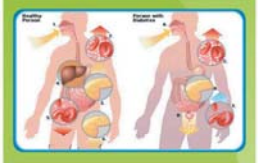
1. YANG BAIK DIMAKAN
   Sayur : brokoli, wortel, tomat, kubis, lobak, asparagus, mentimun, jamur, bawang.
   Buah-buahan : apel, pear, jeruk, anggur, nanas, cherry, strawbery.
   Sereal : sereal/biskuit dari kulit padi/ bekatul/oatmeal.
2. YANG TIDAK BOLEH DIMAKAN
   Gula pasir, gula batu, gula jawa, madu, sirup, selai, susu kental manis, kue manis, biskuit, kecap manis, petis, dan makanan lain yang mengandung gula.
3. YANG HARUS DIBATASI
   Nasi, kentang, singkong, jagung, mie, roti, makaroni, dan makanan lain yang terbuat dari tepung.

TIPS

1. Kendalikan tekanan darah (kurang dari 130/80 mg/dl) dengan pengaturan gaya hidup.
2. Upayakan berat badan ideal.
3. Makan dengan gizi seimbang.
4. Berolahraga secara teratur.
5. Tidak merokok.
6. Mengurangi stres.
7. Minum obat dengan TERATUR, TEPAT DOSIS dan TEPAT WAKTU.

DIABETES MELITUS

Pharmaceutical Care



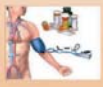
DIABETES MELITUS

Diabetes Melitus ("sakit gula/kencing manis") adalah gangguan metabolisme kronis yang ditandai dengan tingginya kadar gula darah disertai gangguan metabolisme karbohidrat, lipid, dan protein sebagai akibat insufiensi fungsi insulin.

APOTEK INDICA MADIUN
JL. SETIA BUDI TIMUR 25
MADIUN
Telp. (0351) 497381
www.farmasiku.com

TIPS

a. Periksa tekanan darah secara rutin
b. Memulai program olahraga untuk menurunkan berat badan
c. Mengurangi makanan berlemak dan asin
d. Stop merokok
e. Menghindari stress
f. Minum obat dengan teratur, tepat dosis, dan tepat waktu



Pengobatan Hipertensi

TERAPI TANPA OBAT

Penurunan berat badan (Menjaga berat badan normal/ideal)

Body mass index 18,5-24,9 kg/m²

Memperbaiki pola makan dengan mengkonsumsi buah, sayur dan makanan rendah lemak

Mengurangi asupan natrium (garam dapur) hingga < 2,4 mg/hari atau 1/3 sendok teh

Memperbanyak aktivitas fisik dengan berolahraga secara teratur seperti aerobik ringan atau jalan cepat selama 30-45 menit

Membatasi konsumsi alkohol dan rokok

TERAPI DENGAN OBAT-OBAT

Diuretik (HCT) Diminum pagi hari agar efek samping diuresisnya tidak menggangggu istirahat

Beta Bloker (Atenolol, Propanolol Metoprolol)

Antagonis Kalsium (Nifedepin, Verapamil, Diltiazem)

Penghambat reseptor angiotensin II (Valsartan, Losartan)

Penghambat enzim konversi agiotensin (Captopril, Enalapril) Sebaiknya diminum saat perut kosong yaitu 1 jam sebelum makan atau 2 jam sesudah makan

Informasi lebih lanjut hubungi : Apoteker kami

MAKANAN YANG DIBATASI :

1. Makanan yang mengandung tepung-tepungan (sumber karbohidrat) : nasi, kentang, roti tawar, mie, bihun, singkong, ubi, jagung, lontong, ketan, kue dari tepung-tepungan.
2. Bumbu : kecap asin, kecap manis, petis, magi, saus tomat

MAKANAN YANG DIBATASI :

Sayuran dan buah-buahan dalam jumlah tertentu (lihat daftar penukar makanan), yaitu : sayuran golongan rendah kalori.

HAL-HAL YANG PERLU DIPERHATIKAN :

- Olah raga teratur setiap hari dilakukan 1,5 jam - 2 jam setelah makan (jalan di tempat + lutut diangkat 90° dilakukan 30 menit) minimal 3 kali seminggu.
- Obat (OAD) diminum / disuntikkan antara 5 - 15 menit sebelum makan.

CONTOH MENU

PAGI
- Nasi
- Telur rebus
- Pecel kacang panjang + taoge
- Tempe bumbu bali

PUKUL 09.30
- Pisang rebus

SIANG
- Nasi
- Pepes Ikan
- Tempe bumbu bali
- Sayur Asem

PUKUL 15.30
- Kentang Rebus
- Pepaya

MALAM
- Nasi
- Daging Ungkep
- Perkedel tahu
- Sup Sayur

PUKUL 21.30
- Pepaya
- Kentang rebus

APOTEK INDICA MADIUN

Jl. Setia Budi Timur No.25
Telp. (0351) 497381
Madiun

DIET DIABETES MELITUS

NAMA :
UMUR : th
TINGGI BADAN : cm
BERAT BADAN : kg
ALAMAT :
TANGGAL :

Untuk mendapatkan keterangan lebih lanjut, hubungilah **AHLI GIZI.**

Kalau memeriksakan diri harap **LEAFLET** dibawa.

DATA PASIEN HIPERTENSI

NO.	TGL.	NO. PERAWATAN HIPERTENSI	NAMA	UMUR	ALAMAT	TLP/HP	MONITORING		STATUS		
							VIA SMS, TLP, YM, PIN BB	HOME CARE VISITE	SEMBUH	SAKIT	PROGRESS
1		HTPC	Eddi Tn	57 th	Purwa Asri No. 6	081321396878					
2		HTPC	Sudarsih Ny	70 th	Mojoporno Rt. 8 / 2	0351-455646					
3	27-Des-11	HTPC 27122012	Karmi Ny	47 th	Mojoporno	081335716028					
4	28-Des-11	HTPC 281211-01 + HTPC 12012012-2	Suparti Ny	57 th	Ds. Bantengan Rt 01 Wungu	082141867171					
5	28-Des-11	HTPC 28122011-2	Murniati Ny	50 th	Jl. Arwana No. 11 A	085790496199					
6	29-Des-11	HPC 29122011-1	Slamet Tn	54 th	Jl. Budo Manis II A / 25	081335534296					
7	29-Des-11	HPC 29122011-1	Kusmiatun Ny	60 th	Jl. Kartika Manis	081231764647					
8	30-Des-11	HPC 30122011-2	Suhadi	68 th	Jl. Manggar Manis 13	081335960686					
9	31-Des-11	HTPC 31122011-1	Misinem Ny	73 th	Munggut	082143777525					
10	31-Des-11	HTPC 31122011-2	Sestuning Ny	74 th	Dungus Rt.27 / 2	081335692933					
11	03-Jan-12	HTPC 03012012-1	Sunoto Tn	70 th	Margahayu No. 03	0351-452849					
12	04-Jan-12	HTPC 04012012-1	Siti Aminah Ny	57 th	Jl. Sri Sedono No. 33	085265240861					
13	05-Jan-12	HTPC 05012012-1	Suminah Ny	60 th	Brumbun Wungu	085735103800					
14	06-Jan-12	PHC 612012-20	Suyati H. Ny	74 th	Jl. Kelapa Manis	0351-464289					
15	09-Des-12	HTPC 09012012-1	M. Mujiharto	56 th	Jl. Endra Manis 4 No. 18	081335231173					
16	30-Des-11	HTPC 30122011-01	Suroto Tn.	57 th	Jl. Raya Dungus No. 37 Mojopurno	0351-7811390					
17	09-Jan-12	HTPC 09012012-2	Suwarti Ny	60 th	Jl. Kiageng Pengging No.9 Selo	0351-481095					
18	10-Jan-12	HTPC 10012012-1	Sunarmi Ny	46 th	Perum Rejomulyo Blok 1 No. 16	0351-465068					
19	10-Jan-12	HTPC 10012012-2	Ahmad Tn	45 th	Mojopurno Rt.20 / 2	081234071295					
20	11-Jan-12	HTPC 11012012-01	Dami Ny	62 th	Jl. Kiageng Pamanahan No.38	082142411533					
21	11-Jan-12	HTPC 11012012-2	Sukatini Ny	79 th	Jl. Samapta Bakti 23 J	081233029190					
22	12-Des-12	HTPC 12122012-1	Kasifah Ny	56 th	Perumnas Mojopurno Munggut Peni IV / 8-11	081335823697					
23	12-Jan-12	HTPC 12012012-2	Suparti Ny	57 th	Bantengan Rt.1 / 1	082141867171					
24	12-Jan-12	HTPC 1212012-3	Sulistyorini	52 th	Kartika Manis 1	0351-471211					
25	12-Jan-12	HTPC 12012012-4	Sumaryo Tn	71 th	Jl. Setia Budi Timur No.18	0351-454454					
26	16-Jan-12	HTPC 16012012-1	Sigit Tn	30 th	Jl. Sri Dara No.1	0351-7811003					
27	17-Jan-12	HTPC 17012012-1	Lami Ny	84 th	Kwiran, Kare						
28	18-Jan-12	HTPC 18012012-01	Adib Tn	46 th	Jl.Munggut Peni Blok CO No. 4	0351-7723822					
29	18-Jan-12	HTPC 18012012-2	Suparno Tn	81 th	Brumbun	0351-461194					
30	19-Jan-12	HTPC 19012012-1	Suyatmi Ny	>60 th	Gorang Gareng	0351-439280					

DATA PASIEN DIABETES

NO.	TGL.	NO. PERAWATAN DIABETES	NAMA	UMUR	ALAMAT	TLP/HP	MONITORING		STATUS		
							VIA SMS, TLP, YM, PIN BB	HOME CARE VISITE	SEMBUH	SAKIT	PROGRESS
1			Suyitmo Ny	60 th	Jl. Tanjung Raya 47 Madiun						
2	28-Okt-11	DMPC 28102011-03	Kusmiati Ny	32 th	Mojopurno Rt/2 No.32						
3	13-Des-11		Katini	56 th	Jl. Kiageng Selo Gg Pingi II/3	0351-464833 7705531					
4	27-Des-11	DMPC 27122011-1	Siti Jumatyah Ny	46 th	Bantengan	085224457205					
5	27-Des-11	DPC 27122011-4	Umi Isticharoh Ny	43 th	Dagangan RT13 RW06	0351-7700042					
6	28-Des-11	DPC 2812201-2	Sugiyanto SH	73 th	Dolopo	0351-367001					
7	29-Des-11	DPC 291211-01	Sri Kartini Ny	60 th	Jl. Borobudur No.38	081259216665					
8	30-Des-11	DMC 30122011-1	Gandi Tn	50 th	Jl. Gegono Manis 6-2 NO.1	0351-455364					
9	30-Des-11	DMPC 30122011-2	Samadi Tn	41 th	Jl. Panorama Wilis No.10	0351-496691					
10	31-Des-11	DMPC 31122011-1	Sabekti Ny	61 th	Jl. Gubug Manis No.3	0351-456187					
11	01-Jan-12	DPC 112012-1	Agung Widya P. Dra.	46 th	Jl. Pondok manis III /29	0351-458919 081331290560 081335149371					
12	02-Jan-12	DMPC 02012012-1	Rina Ny	28 th	Dungus	085735957951					
13	03-Jan-12	DMPC 03012012-1	Titik Ny	58 th	Jl. Janur Sari IV No.15	0351-494642					
14	03-Jan-12	DPC 312012-6	Ishahudin Tn	58 th	Dungus Jln masjid Nurul Huda	085234106101					
15	04-Jan-12	DPC 412012-1	Salem Ny	70 th	Tanjung manis III/4						
16	05-Jan-12	DMPC 05012012-2	Saomi Ny	47 th	Sidorejo Rt 46/6	085785795087					
17	05-Jan-12	DPC 512012-3	Sujitmo Ny	62 th	Jl. Tanjung Raya 57						
18	05-Jan-12	DPC 05012012-04	Suprapti Ny	58 th	Jl.Tawangbakti No 7	0351-7800496					
19	05-Jan-12	DPC 512012-7	Imam Ny	52 th	Tanjung Raya No 3 kompleks PLN	081232026135					
20	09-Jan-12	DPC 09012012-01	Istikanah Ny	60 th	Dungus	0351-493705					
21	10-Jan-12	DPC 10012012-5	Sutrisno Tn	52 th	Raiya Yasa 29						
22	11-Jan-12	DMPC 11012012-1	Poni Ny	53 th	Jl. Janur Sari No. 25	0351-456008					
23	12-Jan-12	DPC 12012012-01	Sri Amini Ny	58 th	Jl. Argo manis Gg 3 No.5	0351-452608					
24	13-Jan-12	DPC 13012012-01	Sri Ny	53 th	Mojorejo RT 10/5 Kebonsari	082143377721					
25	20-Jan-12	DPC 20012012-01	Suwarti Ny	64 th	Mojorayung RT 15/4 Madiun						
26	23-Jan-13	DMPC 23012013-01	Panji Ny	48 th	Jl. Mayjen Sukowati No. 15 Magetan	085655774443					
27	23-Jan-12	DPC 2312012-1	Eko Tn	40 th	Jl. Banda 18	081335072423					
28	24-Jan-12	DMPC 24012012-1	Rakiyem Ny	77 th	Saradan	085649164241					
29	25-Jan-12	DMPC 25012012-1	Ismi Ny	63 th	Mojorayung	081217221496					

"INDICA PHARMACY"
- "Consultative – Monitoring Services"
  to Counsel-Educate-Inform-Guide-Advice-Advocate

"INDICA PHARMACY"
- "Consultative – Monitoring Services"
  to Counsel-Educate-Inform-Guide-Advice-Advocate

"INDICA PHARMACY"
Collaborative Practice with General Practician (in the same location):
Established MoU, MoA and some Protocols

"INDICA PHARMACY"
Collaborative Practice :
Pharmacist in the GPs Room of practice

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PHARMACIST

Role 3: Maintain and improve professional performance

Continuing

Professionalism

Development

GPP FIP-WHO
Role 3: Maintain and improve professional performance

Function A:
Plan and implement continuing professional development strategies to improve current and future performance

CPD

1) Pharmacists should **perceive** continuing education as being lifelong and be able to demonstrate evidence of continuing education or continuing professional development to improve clinical knowledge, skills and performance.
2) Pharmacists should **take steps** to update their knowledge and skills about complementary and alternative therapies such as traditional Chinese medicines, health supplements, acupuncture, homeopathy and naturopathy.

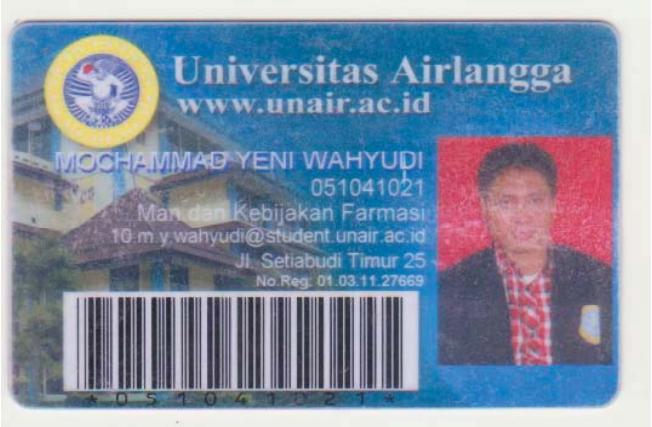
GPP FIP-WHO

Role 3: Maintain and improve professional performance

Function A:
Plan and implement continuing professional development strategies to improve current and future performance

CPD

3) Pharmacists should take steps to update their knowledge and be engaged in implementation of new technology and automation in pharmacy practice, where feasible.
4) Pharmacists should take steps to become informed and update their knowledge on changes to information on medical products.



World Health Organization

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PHARMACIST

Role 4: Contribute to improve effectiveness of the health-care system and public health

GPP FIP-WHO

Role 4: Contribute to improve effectiveness of the health-care system and public health

Function A : Disseminate evaluated information about medicines and various aspects of self care

Function B : Engage in preventive care activities and services

Function C : Comply with national professional obligations, guidelines and legislations

Function D : Advocate and support national policies that promote improved health outcomes

Community

1. Model of Community Pharmacist Public Health Practice
2. Good of Public Counseling and Education Practice

GPP FIP-WHO 2011, Conclusions

- There are four main roles where **pharmacists**' **involvement** or **supervision** is expected by **society** and the **individuals** they serve:
  (1) Prepare, obtain, store, secure, distribute, administer, dispense and dispose of **medical products.**
  (2) Provide effective **medication therapy management**.
  (3) Maintain and improve **professional performance**.
  (4) Contribute to improve effectiveness of the **health-care system and public health**.

1. These **roles** may vary for each individual pharmacist depending on their practice responsibilities.
2. **Specific standards** of GPP can be developed only within a national pharmac professional organization framework.
3. This **guidance** is recommended as a set of professional goals to be met in the interest of the patients and other key stakeholders in the pharmaceutical sector.
4. **Responsibility** for moving the project forward will rest with each national pharmacy professional association.
5. **Achieving** specific standards of GPP for each nation within thes recommendations may require considerable time and effort.
6. As health professionals, pharmacists have a **duty to begin the process** without delay.

Implementation GPP, a Prospective Reports, a notes of conclusions,

1. All Pharmacist Roles (as stated in the GPP FIP-WHO 2011) could be implement by each individual pharmacist who practicing in the community pharmacy, with the policiy framework of their society. The Society of Community Pharmacist, should establish all strategic documents, e.g.: “Model of Practice”, “Guideline of Services Pathway”, “Standard of Community Pharmacy Practice” and “Good (Guideline) Community Pharmacy Practice”. All document would be a legal protection (liability, accountability) to all pharmacist members.
2. Each Community Pharmacists may/could begin to implement all Pharmacist Activities (as stated in the GPP FIP-WHO 201) according to their professional capacity development scheme, simultaneously with the policy study research program of the society.
3. All strategic documents of practice (GPP etc) should be reviewed/agreed together with/by the other health professional organization, especially within the framework of “collaborative practices” development.

Implementation of Basel Statements in SEAR

Eurek Ranjit,

B. Pharm., M. Sc. (UK), M. Phil. (UK)

Vice-President, Hospital Pharmacy Section,

FIP (International Pharmaceutical Federation)

General overview of the presentation

- Basel Statement
- SEAR (South East Asia Region)
- Implementation of Basel statement in SEAR
- Positive Trends
- Recommendations

Basel Statements

Statements developed in Basel, Switzerland during Global Conference on the Future of Hospital Pharmacy .

Hosted by **FIP Hospital Pharmacy Section** as part of 68th Annual Congress (August 2008) of FIP

Hospital Pharmacists from around the world met & developed 75 consensus statements reflecting profession's **preferred vision of practice** in the hospital setting.

348 registrants representing 98 nations were present. (FIP, 2012)

BASEL STATEMENTS-2

Statements developed with years of planning preceded by a Survey conducted under supervision of Dr. Lee Vermeulen (Chair, Conference Steering Committee).

Statements unique & important (Ranjit, 2011):

- developed as consensus statements
- international representation & participation
- both developed and developing countries
- common vision for the future of hospital pharmacy.

BASEL STATEMENTS-3

Statements cover various areas of medicine use process and is divided as:

- Overarching Statements (16)
- Medicines Procurement (9)
- Influence of prescribing (7)
- Preparation and delivery (9)
- Administration of medicines (16)
- Monitoring of medicines (8)
- Human resources and training (10)

BASEL STATEMENTS-4: OVERARCHING STATEMENTS

1. The overarching goal of hospital pharmacists is to optimize patient outcomes through the judicious, safe, efficacious, appropriate, & cost effective use of medicines.
2. At a global level, 'Good Hospital Pharmacy Practice' guidelines based on evidence should be developed. These guidelines should assist national efforts to define standards across the levels, coverage, & scope of hospital pharmacy services & should include corresponding human resource & training requirements.
3. The "five rights" (the right patient, right medicine, right dose, right route, and right time) should be fulfilled in all medicines-related activities in the hospital.

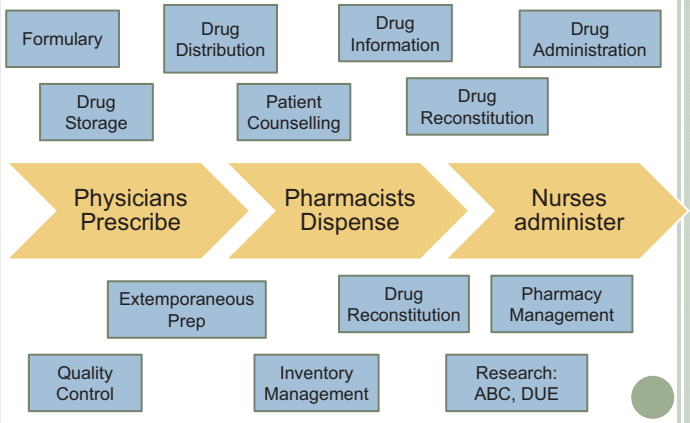
BASEL STATEMENTS-4: OVERARCHING STATEMENTS-2

4. Health authorities & hospital administrators should engage hospital pharmacists in all steps in the hospital **medicines-use process**.
5. Health authorities should ensure that each hospital pharmacy is supervised by pharmacists who have completed specialized training in hospital pharmacy.
9. Hospital pharmacists should serve as a resource regarding all aspects of medicines use & be accessible as a point of contact for health care providers.
10. All prescriptions should be reviewed, interpreted, & validated by a hospital pharmacist prior to the medicine being dispensed & administered.
14. Hospital pharmacists should provide orientation & education to nurses, physicians, and other hospital staff regarding best practices for medicines use.

Medicine use process:

Physicians Prescribe → Pharmacists Dispense → Nurses administer

Medicine use process:



PROCUREMENT:

Theme 1 - Procurement
17. The procurement process must be transparent, professional, and ethical to promote equity and access and to ensure accountability to relevant governing and legal entities.
18. Procurement should be guided by the principle of procuring for safety.
19. Procurement of pharmaceuticals is a complex process that requires pharmacist control and technically competent staff.
20. Operational principles for good procurement practice should be regularly reviewed and procurement models adapted to fit different settings and emerging needs in the most appropriate and cost effective way."
21. Procurement must be supported by strong quality assurance principles to ensure that poor quality medicines are not procured or allowed into the system. Proper storage to ensure maintenance of quality in the whole supply pipeline is mandatory.
22. Procurement should not occur in isolation, but rather be informed by the formulary selection process.
23. Good procurement must be supported by a reliable information system that provides accurate, timely, and accessible information.
24. A formal mechanism must be in place for pharmacists to request designated funds to procure medicines for their patients.
25. Each pharmacy should have contingency plans for medicines shortages and purchases in emergencies.

BASEL STATEMENT: THEME 2 - INFLUENCES ON PRESCRIBING

26. Hospitals should utilize a **medicine formulary system** (local, regional, and/or national) linked to standard treatment guidelines, protocols, and treatment pathways based on the best available evidence.

27. Hospital pharmacists should be members of **P&TC** to oversee all medicines management policies and procedures, including those related to off-label use and investigational medicines.

29. Hospital pharmacists should be involved in all patient care areas to prospectively influence collaborative **therapeutic decision-making**.

30. Hospital pharmacists should be an integral part of **all patient rounds** to assist with therapeutic decision-making and advise on clinical pharmacy and patient safety issues.

Basel Statement: Theme 3 - Preparation and Delivery

Hospital pharmacists should...

33. ..... ensure that proper storage conditions are provided for all medicines used in the hospital.

35. .... ensure that **compounded medicines** are consistently prepared to comply with quality standards.

36. ..provide pharmacy-managed injectable admixture services using aseptic technique.

37. Hazardous medicines including cytotoxics should be prepared under environmental conditions that minimize the risk of contaminating the product and exposing hospital personnel to harm.

Source: http://www.isotechdesign.com/docs/products/en/1.SpecMicrosphere_N&I-Eng-210108.pdf

Basel Statement: Theme 3 - Preparation and Delivery

34. Hospital pharmacists should assume responsibility for the appropriate labeling and control of medicines stored throughout the hospital.
35. Hospital pharmacists should ensure that compounded medicines are consistently prepared to comply with quality standards.
36. Hospital pharmacists should provide pharmacy-managed injectable admixture services using aseptic technique.
37. Hazardous medicines including cytotoxics should be prepared under environmental conditions that minimize the risk of contaminating the product and exposing hospital personnel to harm.
38. Hospital pharmacists should decrease the risk of medication errors by implementing evidence-based systems or technologies, such as automated prescription-filling, unit dose distribution, and bar coding systems.
39. Hospital pharmacists should support the development of policies regarding the use of medicines brought into the hospital by patients, including the evaluation of appropriateness of herbal and dietary supplements.
40. Hospital pharmacists should assume responsibility for storage, preparation, dispensing, and distribution of investigational medicines.
41. Hospital pharmacists should implement systems for tracing medicines dispensed by the pharmacy (to facilitate recalls, for example).

Basel Statement: Theme 4: Administration

Hospital pharmacists should ensure:

42. ... that the information resources needed for safe medicines preparation and administration are accessible at the point of care.

43. ..that allergies are accurately recorded in a standard location in patient records and evaluated prior to medicines administration.

44. ..that medicines are labelled to ensure identification and to maintain integrity until immediately prior to administration to the individual patient.

BASEL STATEMENT: THEME 4: ADMINISTRATION

45. Where medicines are labeled for individual patients, full details to ensure safe administration should be included, for example, name of medicine, route, and, where appropriate, dose in mass and volume.
46. Storage of concentrated electrolyte products (such as potassium chloride and sodium chloride) and other high-risk medicines on patient wards should be eliminated by dispensing ready-to-administer dilutions, or, if necessary, storing such products distinctly labeled in separate or secure areas.
47. Health care professionals responsible for administering injectable medicines and chemotherapy should be trained in their use, hazards, and necessary precautions.
48. Doses of chemotherapy and other designated medicines (based upon risk assessment) should be independently checked against the original prescription by two health care professionals at the point of care prior to administration.
49. Pharmacists should ensure that strategies and policies are implemented to prevent wrong route errors, including, for example, labeling of intravenous tubing near insertion site to prevent misconnections, and use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines.
50. Vinca alkaloids should be diluted, ideally in a minibag and/or large syringe (for pediatric patients), and dispensed with special labeling precautions in order to prevent inadvertent intrathecal administration.
51. Oral syringes that are distinctly different from hypodermic syringes should be used to prevent injection of enteral or oral medicines, especially in pediatric patients.

BASEL STATEMENT: THEME 5 - MONITORING OF MEDICATION PRACTICE

58. A reporting system for defective medicines should be established and maintained to monitor and take the necessary action to minimize identified risks. Reports of defective or substandard medicines should be sent to regional or national pharmacovigilance reporting programs where these are available.
59. A reporting system for adverse drug reactions should be established and maintained, and the necessary action should be taken to minimize identified risks. Reaction reports should be sent to regional or national pharmacovigilance reporting programs where these are available.
60. A reporting system for medication errors should be established and maintained, and the necessary action should be taken to minimize identified risks. Reports of medication errors should be sent to regional or national medication error reporting programs where these are available.
61. Hospital medication practice should be self assessed and data trended internally and compared with best practice in other institutions to improve safety, clinical effectiveness, and cost effectiveness.

BASEL STATEMENT: THEME 6 – HUMAN RESOURCE AND TRAINING

66. At a national level, health authorities should bring together stakeholders to collaboratively develop evidence-based hospital pharmacy human resource plans aligned to meet health needs and priorities across public and private sectors that optimize patient outcomes.
67. Key stakeholders should ensure that workforce education, training, competency, size, and capacity are appropriate to the levels, coverage, scope, and responsibilities of all cadres providing pharmacy services.
68. Hospital pharmacy human resource plans should cover all cadres and be linked to health targets. Such plans should describe strategies for human resource education and training, recruitment and retention, competency development, salary and career progression pathways, gender-sensitive policies, equitable deployment and distribution, management, and roles and responsibilities of stakeholders for implementation.

BASEL STATEMENT: THEME 6 – HUMAN RESOURCE AND TRAINING

69. Hospitals should maintain human resource information systems that contain basic data for planning, training, appraising, and supporting the workforce. Data should be collated at a national level to improve human resource strategy.
70. Health authorities, educators, professional associations, and employers should address pharmacy human resource shortages through sustainable strategies for workforce supply, recruitment, and retention, particularly in rural and remote areas.
71. The training programs of mid-level pharmacy human resources (technicians or the equivalent) should be nationally formalized, harmonized, and credentialed for the attainment of defined competencies within a defined scope of practice.
72. Hospital human resource policies should be founded in ethical principles, equal opportunity, and human rights and be compliant with labor regulations, guidelines, and hospital pharmacy practice standards.
73. Nationally, levels of practice and associated competency requirements should be defined and regularly assessed to form a competency framework for all cadres.
74. Hospitals should use a nationally accepted competency framework to assess individual human resource training needs and performance.
75. The hospital pharmacy human resource evidence gap should be explored and addressed through a strategic research agenda.

Guideline & Milestone for SEAR

The Basel Statements serve as a guideline and milestone for development of hospital pharmacy in SEAR.

They come as both opportunity and challenge for hospital pharmacists in SEAR.

South East Asia Region (SEAR)

Consists of 11 countries (WHO, 2011):

Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

SEAR

Home to one fourth (approx.) of world's population

Region consists some of world's poorest countries.

Highest GNI per capita is US$2,750 (Thailand) compared to US$59,590 (Norway) (WHO, 2007).

Many countries have low *adult literacy rate*.

Timor-Leste, Nepal, Bangladesh & India have adult literacy rates of 43%, 49%, 50% & 61% respectively (WHO, 2007).

Combination of low income & low literacy rate combined with less expenditure on health is having a negative impact in health care sector in general and hospital pharmacy in specific.

Implementation of Basel Statement in SEAR

In order for Basel Statements to have positive impact on health care of the patients in SEAR, the focus should be on its implementation part.

A gap analysis should be carried out to compare existing situation within a hospital, city, town or country with the potential situation presented by the Basel Statements.

Individual pharmacists, pharmacy associations, academic pharmacists, health ministries & all other stakeholders should try to implement the Basel Statements within their own capacity.

Implementation of basel statement in SEAR

It may not be possible to implement everything at once. An action plan can be developed based on:

- statements already implemented,
- in process of implementation and
- to be implemented in the future.

The implementation to improve patient care can be initiated from any point, however small it may be.

The mistake that hospital pharmacists make is to try to develop everything at once.

Implementation of basel statement in SEAR: positive trends

In Nepal, National Training Course on Drug and Therapeutics Committee was organized by MSH, WHO & MoHP of Nepal in 2001 with participants developing action plan to improve health care scenario in their respective hospitals.

This training & the awareness created by it, directly or indirectly led to introduction of DTC in major hospitals. Drug regulatory authority, DDA still organizes DTC training on a regular basis (Rajbhandari, 2011).

Such training which lead to initiation & implementation of new service seems to be of more importance in countries in SEAR.

Implementation of basel statement in SEAR: positive trends

SEARPharm Forum has formed **a working group** to assess situation in SEAR and help comply with Basel Statements in SEAR during its annual meeting held in Hyderabad on 6th September 2011.

An idea that countries in the same region would have similarities in terms of hospital pharmacy practice & it may be easier to share ideas from countries within the region rather than DIRECT implementation of ideas from the developed countries.

Limitations do exist

Implementation of basel statement in SEAR: Recommendations

Basel Statement to be used as a tool to assess practice

Have meeting with stakeholders, especially health ministers, policy makers, hospital board members, consumers, local leaders, politicians to familiarize with the Basel Statement

Conduct meeting with hospital pharmacy staff to assess the practice situation

Identify what hospital pharmacy practices are occurring and identify barriers to implementation of Basel Statement

Model Pharmacy Services

In the US, model pharmacy service used in past to demonstrate improved patient outcomes & maximize pharmacist's contribution to drug therapy.

Individual or a team of pharmacists within a country or multiple countries within SEAR could benefit by establishing a model pharmacy service to implement the Basel Statements.

The experience of such pharmacy service could then be extended to other hospitals in the region.

Quoting C. D. Hepler

In the developed world, pharmacy as a clinical profession made possible due to courageous & committed pharmacists who demonstrated that feasibility of pharmaceutical care & achieved acceptance by proving that pharmaceutical care can significantly improve the outcomes of drug therapy (Hepler, 2010).

Thus some self evaluation

Pharmacists from SEAR should ask some self evaluating question to themselves:

Have adequate effort been made to establish hospital pharmacy in SEAR?

Have work been done to achieve acceptance of hospital pharmacists from the patients and other health professionals?

Are hospital pharmacists recognized as integral part of hospital by hospital management?

Have they honestly tried to implement some or all of the Basel Statements?

Lets not do injustice to the patient:

The answers may vary from one to another.

Researches will shed more light regarding the Basel Statements.

However, self-evaluation at a personal level needed.

Unless we are honest with ourselves regarding our profession & what can be implemented, we, as healthcare professionals would be doing injustice to "the patient" for whom we exist by limiting the statements and guidelines to textbooks and research papers; and by not implementing the knowledge obtained to improve patient care..

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and
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Thank you
Any comments for improvement !!

Perspective of education and continuing education for HPP in India

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Mysore, India
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Presentation Outline

- Introduction
- Pharmacy Practice – Our Experience
- Hospital Pharmacist
  - WHO Recommendations
  - Basel Statements
- Continuing Professional Development
  - International Scenario
  - FIP recommendations
  - Indian Scenario

Introduction

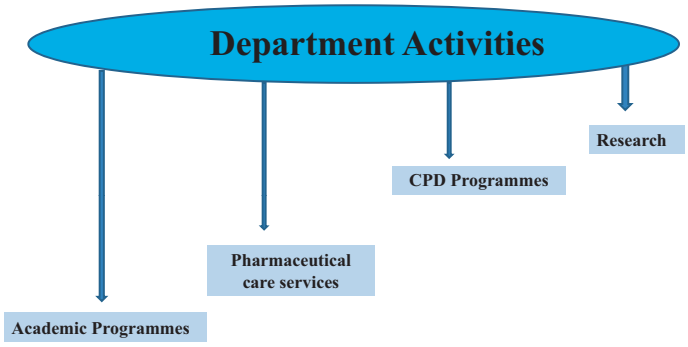
The role of pharmacist has evolved

- compounder → supplier of medicines
- provider of services and information
- provider of patient care

Introduction

- Globally for the past four decades pharmacy practice has moved more towards patient care from medicine supply
- The task is to ensure that
  - Patient's drug therapy is appropriately indicated
  - the most effective available
  - Safest possible
  - Convenient for the patient

DEPARTMENT OF CLINICAL PHARMACY



Pharmaceutical Care Services

- JSS Hospital, Mysore
- Swami Vivekananda Youth Movement Hospital, Sargur
- Ashakiran Hospital, Mysore
- Vikram Hospital (Cardiac care center)
- JSS Community Pharmacy, Mysore

Pharmaceutical Care Services . . .

- Drug Information service
- Poison information service
- Ward round participation
- Treatment chart review

Pharmaceutical Care Services . . .

- Medication History Interview
- Patient counseling
- Adverse Drug reaction detection, reporting & monitoring
- Patient referrals

Continuing Professional Development Programmes

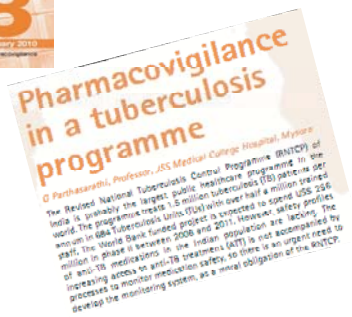
- Pharmacy Teachers
- Practitioners
  - Medical
  - Academic
  - Nursing
  - Pharmacy – Community Pharmacists

AREAS OF RESEARCH

- Pharmacovigilance
- Medication adherence
- Patients' knowledge, attitude and behavior
- Outcomes research– QoL studies
- Drug Utilization Evaluation Studies
- Medication Errors

Integrating pharmacovigilance in public healthcare programs

Pharmacovigilance in tuberculosis programme – SMART. Uppsala Report January 2010; 48:18 http://www.who-umc.org/graphics/22435.pdf


Pharmacovigilance in a tuberculosis programme

Integrating Pharmacovigilance in Public Healthcare Programs


PHARMACOEPIDEMIOLOGY AND DRUG SAFETY (2010)
Published online in Wiley InterScience (www.interscience.wiley.com) DOI: 10.1002/pds.1907

ORIGINAL REPORT

Adverse drug reactions to antiretroviral therapy (ART): an experience of spontaneous reporting and intensive monitoring from ART centre in India†

Retty Rajan Modayil MPharm[1], Anand Harugeri MPharm[1], Gurumurthy Parthasarathi MPharm, PhD, Grad Dip Clin Pharm, FICP[1]*, Madhan Ramesh MPharm, PhD, FICP[1], Rajendra Prasad MD[2], Vasudeva Naik MD[2] and Vamadeva Giriyapura MD[3]

Research

- Investigator initiated projects (Academic research)
- Funded projects:
  - ✓ICMR
  - ✓DST
  - ✓UGC
  - ✓DBT
- Sponsored research (Clinical Trials)
- Collaborations:
  National Pharmacovigilance Programme of India

The Hospital Pharmacist

- The hospital pharmacist is considered to be an expert on drugs who advises on prescribing, administering, and monitoring, as well as a supply manager who ensures that drugs are available through procurement, storage, distribution, inventory control and quality assurance

Hospital Pharmacy

- Purchase
- Manufacturing
- Storage
- Distribution
- Dispensing

Professional Responsibilities of Hospital Pharmacists WHO consultative committee report

- Hospital pharmacists play an important role in rational prescribing and rational use of drugs
- Offer Clinical pharmacy services such as treatment chart review, drug dosing adjustments, identification and resolving drug therapy related problems
- As a member of Pharmacy and Therapeutics Committee (PTC), can influence the drugs list selection, preparation of Hospital Formulary (HF) and maintaining the essential drugs in the pharmacy.

Professional Responsibilities of Hospital Pharmacists WHO consultative committee report

- Offer educational support to health care professionals regarding rational drug use practices
- Manufactures drugs through good manufacturing practices and procures high quality drugs
- Provides services in therapeutic drug monitoring using suitable analytical techniques.
- Monitors and reports adverse drug reactions in both ambulatory and inpatients

Basel Statements - Hospital Pharmacy Practice

- The Basel consensus statements are the reflections of vision of Hospital Pharmacy Practice.
- Six preferred areas of hospital Pharmacy Practice was assessed by the experts and opined on 75 statements using the 4 point Likert scale.
- Any statement scored > 50% is considered as Agree or Strongly Agree.
- Majority statements were Strongly Agreed by the representative members of the participating countries

Basel Statements that Scored 100%

- Goal of the Hospital Pharmacy is to optimize positive patient outcomes through judicious, safe, efficacious, appropriate and cost effective medicines use.
- Need to have Global level Hospital Pharmacy Practice guidelines.
- Health authorities should engage the hospital pharmacists in medicines usage process.
- Hospital Pharmacists should be treated as resource persons for information on medicines by all health care professionals.
- Hospital Pharmacists should be given access to patients medical case records.

Basel Statements that Scored 100%

- Need for practice based curricula at UG and PG level in hospital pharmacy.
- Medicines procurement process should be ethical, transparent, according to the procurement principles and made under the supervision of hospital pharmacists.
- Hospital Pharmacists should be the members of Pharmacy and Therapeutics Committee (PTC) and should play key roles in medicines management policies.
- Hospital Pharmacists should ensure that the compounded medicines should comply the quality standards

Basel Statements that Scored 100%

- Using of dispensing labels on medicines while dispensing should be encouraged.
- Hospital reporting system for medication errors and ADRs should be established in hospitals
- Implementation and evaluation of clinical pharmacy services to assess therapeutic outcomes.
- Health authorities should bring the stakeholders together to promote the evidence based human resource development.
- Human resource policies should be framed considering ethical, non racial, equal opportunity, implementing hospital pharmacy practice standards.

Hospital Pharmacy Practice - Global Scenario

Survey Results

- 85 countries had participated in the survey representing 83% of world's population.
- In 41% of the countries, staff pharmacists partially control the medicines use process in the Hospitals.
- In 13% of the countries, there are no hospital pharmacists
- In 45% of the countries, hospital pharmacists can not be recruited because of non availability of qualified pharmacists.
- Essential medicines are not available in many less developed countries.

Hospital Pharmacy Practice in Indian Scenario

- In India amongst close to a million registered pharmacists, more than 50% work in community pharmacies and about 20% work in Hospital Pharmacies.
- Among the hospital pharmacists, majority pharmacists are with Diploma in Pharmacy (D. Pharm) qualification and are confined to prescription filling activity or medicines storage and distribution activity.
- Due to lack of clinical education and training, lower status and salaries , least importance towards CPD activities the hospital pharmacists are not showing any interests towards professional practices.

Strategies to improve the existing situation

- Creating Job responsibility awareness among the practicing hospital pharmacists.
- Creating an awareness among the practicing doctors about the Pharmaceutical care concept and complimenting role of pharmacists in better patients' care.
- Performance appraisal of the pharmacists functioning and creating support in key professional areas through Continuous Professional development programs.
- Creating performance linked appreciations in terms of increments on incentives or promotions.

Continuing education

- Continuing education is a strategy to improve and maintain the competencies in current duties and anticipated future services in any individual

Outcomes of CPD

- Structured CPDs will offer flexible career choices, enhances career satisfaction and ultimately helps the pharmacist to contribute in improved patient care

International scenario of continuing education for pharmacists

- In majority developed countries, CPD is mandatory for pharmacists and also an essential requirement for renewal of the practicing license
- Under CPD programs, the pharmacists are free to choose programs suiting to their professional requirements in order to improve their competencies and sharpen their skills

Pharmacy Practice Scenario in India

- Practice of Pharmacy at different levels of healthcare and at different settings
  - Hospital – Primary, Secondary, Tertiary Healthcare
  - Community
- Educational Background of Pharmacists
  - D Pharm, B Pharm, M Pharm, Ph.D. and Pharm D
- Pharmaceutical Sciences Vs. Pharmacy Practice

Indian Scenario

- In India, opportunities for CPD activities for hospital pharmacists are very limited
- Courses designed are redundant and doubtful in sharpening the professional competencies
- Lack of trainers and accredited programs

Need of the hour

- Considering the professional responsibilities of hospital pharmacists, need based CPD modules should be developed.
- These CPD modules should be piloted and tested for efficiency.
- A competent system for accreditation of these CPD modules.

FIP recommendations

National Pharmaceutical Associations in cooperation with pharmacy schools should work to

- Establish National Learning Needs
- Motivating the pharmacists towards CPD by demonstrating their usefulness
- Create opportunities for individual pharmacists choose best suitable CPD method through SMART (**S**pecific, **M**easurable, **A**chievable, **R**ealistic and **T**imed) plans

FIP recommendations

National Pharmaceutical Associations in cooperation with pharmacy schools should work to

- Establish mechanisms to evaluate the individual competencies and performances through suitable valid questionnaires, rating scales, self assessment tests
- Establish standards for CE providers and be part of any accrediting system
- Establish the quality assurance system for CPD activities against the learning objectives

Areas for continuing education

Areas of competencies required for hospital pharmacists

- Procurement of medicines through effective Inventory Control
- Safe stocking practices
- Drug dispensing and distribution skills
- Patient medication counseling skills
- Drugs and Poison information service – knowledge and skills
- ADR monitoring and reporting- knowledge and skills

Areas for continuing education

Areas of competencies required for hospital pharmacists

- Intravenous admixing and administration – safe practices
- Good Manufacturing practices in hospital pharmacy
- Total Parenteral Nutrition Program
- Rational use of Medicines
- Therapeutic Drug Monitoring
- Clinical Trial coordination

The Profession & the Professional

- An occupation possessing special attributes characterized with power, knowledge, and autonomy is called as profession
- An individual possessing knowledge and concerned with providing services to the client, patient or to the community is called as professional

SEVEN * * * * * * * Pharmacist

- Manager
- Life Long learner
- Teacher
- Leader

SEVEN * * * * * * * Pharmacist

- Care giver
- Decision maker
- Communicator
- Researcher (an added function)

To summarize.....

- Pharmacists are under utilized in the Indian healthcare system
- Opportunities to contribute are plenty
- New potential role for pharmacists in patient care has been realized but they are not trained

TAHNK YOU

The Partnership For
Safe Medicines India
Toll Free Helpline 1800-11-4424

"Good Practices for Safe and Rational Use of Medicines"

By

Bejon Misra, Founder, Partnership for Safe Medicines (PSM) India

www.safemedicinesindia.in and
www.consumerconexion.org

SEARPharm Forum Seminar on "Benefits of Good Practices in Pharmacy- Setting Standards for Delivery of Safe Medicines to Patients in WHO-SEA Region"

Friday: 27th April 2012 New Delhi, INDIA

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A Public Health Group Initiative: committed to the safety of prescription drugs and protecting consumers against Spurious, counterfeit, falsified, substandard or otherwise unsafe medicines

Just One unsafe Medicine Threatens Patient Safety… we all must work together to educate and to help protect patients around the globe

OBJECTIVES:

To integrate spurious with counterfeit, substandard, falsified and unsafe medicines as per the existing laws

To adopt modern technology from around the world to empower and enable consumers to access safe medicines

To ensure Consumer Safety prevails over profit by engaging all the stakeholders

2

PSM India Started Work on 6th September 2010 on Access to Safe Medicines as a Consumer Right

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- ✓**Standards**
- ✓**Choice**
- ✓**Accessibility**
- ✓**Non-discrimination**
- ✓**Transparency**
- ✓**Accountability**
- ✓**Information**
- ✓**Quality of service**

3

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Good Practices for Safe Medicines

Sample: Request a sample from your physician when you are first prescribed a medication to help you establish a "baseline" of a product's characteristics, including its appearance, taste, texture, reactions and packaging.

Appearance: Compare the prescription medicine with what it is supposed to look like by comparing pictures of the original manufacturer's drug and all associated packaging with the drug you are taking.

Feel: Take note of the prescription drug's taste and any associated feelings once you take it. Is there anything unusual in your body's reaction compared to previous experiences, such as a stomachache or headache?

Evaluate: Do you feel you are benefiting from the medication? Is your condition improving, stabilizing, or are you reverting back to ill health? Always ask your doctor or pharmacist what to do next. **NEVER SELF PRESCRIBE**

4

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Good Practices for Safe Medicines

Doctor: If your drugs do not seem to have the same taste or if you feel different than usual, immediately report your symptoms and contact your doctor and pharmacist

Report: If you have any concerns about the quality of your drugs, or have confirmed there is a difference in packaging, labeling, or pills, immediately contact the pharmacy where you purchased them. You may also contact the FDA and the manufacturer to report your concerns.

Unavailable: If you confirm that your medicine is spurious, immediately remove it from your medicine cabinet until you send it to the appropriate local law enforcement officials, or dispose of it safely

Gather: Gather all the information you can find on how, where, and when you obtained the spurious medication and how long you have been taking it. Do you still have the packaging? How long have you been taking the spurious drugs? If the medication must be taken routinely, contact your physician or pharmacist to arrange for a checkup and a new supply to resume

5

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Good Practices for Rational Use of Medicines Calls For:

- Consumer's Right to policies on medicine use and its impact;
- Right to evidence-based clinical guidelines on decision-making;
- Right to a lists of essential medicines and made mandatory;
- Right to monitor and implement interventions to improve use;
- Right to problem-based pharmacotherapy and prescribing;
- Right to continuing medical education;
- Right to publicly available independent and unbiased information;
- Right to public education about medicines;
- Right to elimination of financial incentives on prescribing;
- Right to regulations to ensure that promotional activities meet ethical criteria; and
- Right to adequate funding to ensure availability of medicines and health personnel.

6

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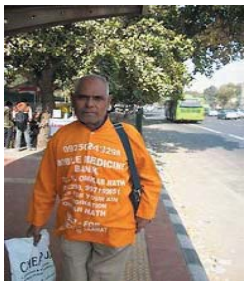
The 'Medicine Baba' Goes Door to Door



Mr. Omkar Nath Sharma receiving leftover medicine in the Green Park neighborhood of New Delhi on February 12, 2012.

7

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PSM India Recommendation of a technology for delivering fool-proof solution to counter spurious drugs should be:

- clone proof.
- Simple to use front end, with high technology on back end.
- Consistency and accuracy.
- Checks and verifications - at all points and all times.
- Empowering all stake holders, including the Enforcement Agencies, to do real time identification, authentication and Track-n-Trace.
- Capability of integration to existing processes.
- Discerning features.
- Ease of deployment.
- Commercially viable.
- Protection of PRIVACY.
- Capable for use / integration to meet imminent and implied needs (Patient compliance etc.).

8

WAY FORWARD

TASK/S: How To Connect and Empower:

More than 800 million consumers connected on mobile in India

More than 1 billion consumers connected on Television/Radio

What to Communicate and how to communicate?

DESIRED OUTCOME

- **How to Procure Safe Medicines from Secured Sources**
- **Educate Consumers to Report Adverse Reactions from Medicines**
- **Create Champions as Whistleblowers to Report Unethical Practices and Expose the Culprits**

9

Patient Information & Counseling for DOTS Delivery

Manjiri Gharat ,
Vice-President & Chairperson, Community Pharmacy Division ,IPA
Project Team Leader,DOTS TB Pharmacist Project

Pharmacies in RNTCP

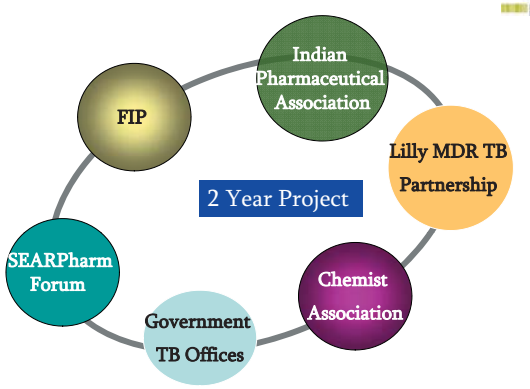
- **Expected benefits: Patient Perspective**
  - Longer opening hours
  - Convenient location
  - Easier access to free treatment
  - Pharmacist-medicine expert
  - Pharmacist -Patient friendly relations
  - Less stigmatic to get treated at Pharmacy

DOT Pharmacies : Acceptable & accessible DOT provider

Pharmacies in RNTCP

- **Benefits to RNTCP**
  - First Port of Call Health Professional: Opportunity for case detection
  - Increase outreach of DOTS services
  - Help reduce no. of patients outside DOTS…. eventually helps reduce MDR TB
- Pharmacists: new pool of pharmaceutical human resources available for RNTCP

DOTS TB Pharmacist Project : Public-Private Partnership Model ,Mumbai



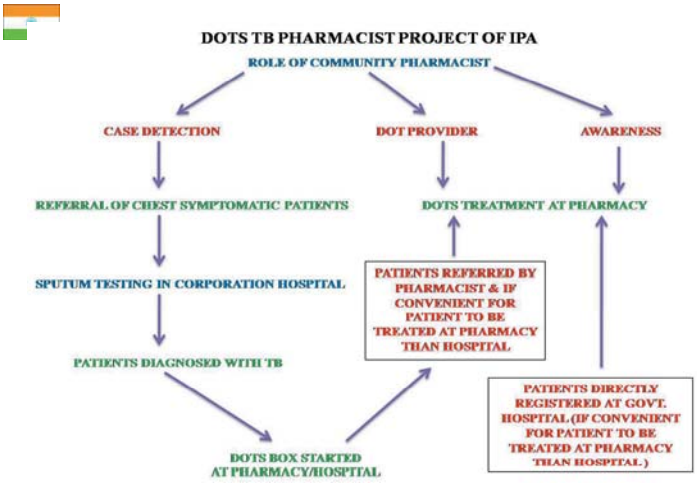
Task Mix for Pharmacists

1 Community Awareness about TB
2 Referral of Chest Symptomatic cases
4 Provision & monitoring of DOT treatment
5 Information to all TB patients about DOTS
6 Rational Use of anti-biotic

Pharmacists as health educator, counselor, case finder, DOT provider

Half Day Training Programme conducted by RNTCP ,IPA & Chemist Association

Special Training Module developed for the pharmacists



RNTCP Training, by City TB Officer: Kalyan Municipal Corporation

20 pharmacists trained

Project Areas

Mumbai & Thane District
No.of pharmacists trained 127

Navi Mumbai 41	Kalyan-Dombivli 49
Mumbai 24	Bhivandi 13

Approx. 3 % to 10 % of total pharmacies involved
Working with 4 City Corporations

Expansion Phase :Recent training

117 pharmacists trained
Total pharmacists trained :251

Nagpur 25	Ulhasnagar 20
Mulund 49	Badalapur-Ambernath 23

Now working with SEVEN City/District TB Societies

Pharmacist as DOT Providers

Felicitation by City Municipal Corporation on World TB Day ,2010

DOT Provider since 2008: Referral for several patients & DOT treatment for 14 patients

Patient Information

- Prominent Displays in the Pharmacy
- Leaflets/Fact Cards for patients
- Verbal Counseling

RNTCP Display Boards

About symptoms,free treatment & diagnosis

Standees for Pharmacies

Referral Form for Pharmacies

Revised National Tuberculosis Control Programme
Laboratory Form For Sputum Examination

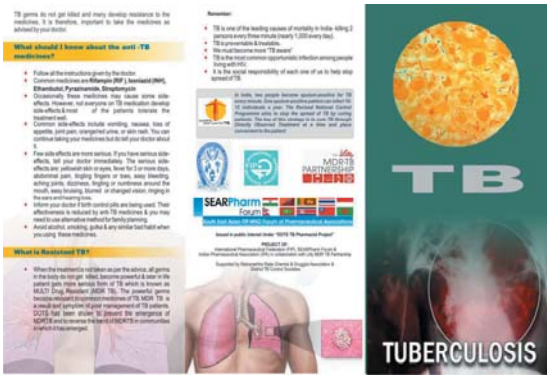
Name Of Referring Pharmacy / Health Facility..... Date.....
Name Of Patient:..... Age:.....Sex: M ☐ F ☐
Complete Address:.....

Type of Suspect / Disease: ☐ Pulmonary ☐ Extra-pulmonary Site: .....
Reason for examination:
☐ Diagnosis ☐ Repeat Examination For Diagnosis
☐ Follow-up of anti- TB treatment Patient's TB No. .....
End Of I.P / Ext. I.P. /2month CP / End of Treatment

Stamp of Pharmacy (Name and Signature of referring pharmacist / official)

Pharmacists uses this form while referring case to Designated Microscopy Center

Development of Informative leaflets for Consumers (2)



Counseling contents: Case Referral

- Need to concentrate on Patients who are coughing & have been unwell
- Enquiry in detail about all symptoms, its duration (Specific symptoms like persistent cough, blood in cough, chest pain, fever, night sweats, weight loss, loss of appetite, *etc*.)
- Information about free diagnosis & free treatment under DOTS
- Referral form for sputum test

Counseling contents:Treatment

- Information about the disease, treatment duration & importance of **adherence**
- Explain to the patient ,the importance of direct observation of treatment
- Explain the entire DOTS treatment is free & can be made available even from the pharmacy
- Frequency and importance of sputum examinations, if sputum positive case
- Use of handkerchief/tissue while coughing .& Use of disposable cups with disinfectant like dettol/savlon to collect sputum

Counselling Contents: Treatment cont'd

- Infectiousness of TB to children and hence info. on the isolation of the patient
- Importance of contact examination and chemoprophylaxis of children below 6 yrs of age.
- Orange / red discoloration of the body fluids due to Rifampicin
- Effect of oral contraceptives (OCPs) may be reduced because of Rifampicin,use alternative method of contraception
- Referral to Medical Officer in case of serious side-effects
- Patients who smoke should be motivated to make an informed decision to stop smoking.

Counseling :rational use of anti-biotics

Inappropriate self medication of antibiotics & how it can lead to resistance

Several irrational prescriptions ….difficult situations ….

Challenges in Provision of Information & Counseling

Several Challenges are faced by pharmacist while providing information & counseling :

Patient Factors :

•Unwillingness of patients for several aspects : For check up, for public sector treatment, for continuation of treatment ,stigma,self medication practices …

Pharmacy Factors :

•Time constraints ,too many patients at the counter, space constraints

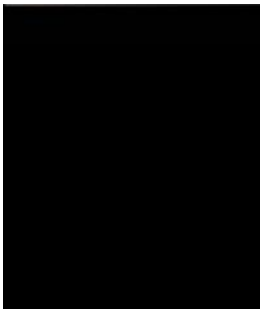
Other Factors :

•Irrational Rx, quack doctors,non-RMPs,

•resistance from doctors ..

Case Studies :One

- Young patient with recurrent fever was self medicating with some anti-pyretic etc. Pharmacist often told him to go for a check up. Patient was reluctant.
- Finally,Pharmacist insisted him to go for sputum test & gave referral slip .He followed up the patient & also informed TBHV regarding the same. After a week patient did his sputum test & the result was PTB.
- He was put on DOTS & after first 3 doses patient's box was kept at Pharmacy where pharmacists administered IP as well as CP
- Patient was cured after 8 months of treatment.
-



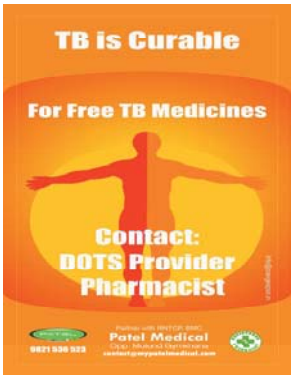
Pharmacist Mr Deeak Barai ,Shreeji Medical,Dombivli

Case Studies :Case Two

- A young girl 2 years old was not well,cranky,irritable,not gaining weight ,sometimes fever. Her parents took her to the doctor who offered expensive antibiotics Treatment was taken.but Girl was still kind of unwell .
- Pharmacist was observing this & then convinced parents to take her to nearby Corporation Hospital for a check up. She was diagnosed with TB & her entire treatment was done by the pharmacist.
- Parents had tears in the eyes when she was cured.

Pharmacist Mr Sagar Kulkarni, Yashashri Medical,Kalyan

Case Study :Effect of TB Standee



- Newly diagnosed TB patient from private sector came for enquiry after seeing the standee outside the pharmacy
- Pharmacist Mahadev Patel,Mulund explained about DOTS
- Patient was quite poor
- Went back to private physician & expressed wish to switch to DOTS
- Went to DMC ,got diagnosed
- Interaction between physician & pharmacist
- Patient's box started at Pharmacy
- Would have been possible case of default in private sector….

Community Awareness Programmes in Schools by pharmacists

- *The heap of boxes made me think that I must do something to make people aware about this disease-*
- Pharmacist Bharati Pathan .

- *Awareness Programmes in Schools* .

Appreciation of "good performers"

Well known social worker felicitating the DOTS Provider pharmacists

Mayor felicitating the DOTS Provider pharmacists

Media coverage

Retail chemists across city decide to provide free drugs to TB patients

LOKMAT

क्षयरोगावर काम करणाऱ्या औषध विक्रेत्यांचा सत्कार

Pharmacists in RNTCP Workshop: Historic Event 9th Feb,12

Central TB Division announces policy to engage pharmacists in TB programme

DOTS TB Pharmacist's Model: International Recognition: Replication in other high TB burden Countries

1st African TB Conference, Jo'burg,SA,July,2011

After learning from our work, Pharmacist model was one of the top recommendations from the Conference & will be tried in African countries, Establishing Indian leadership

•Vietnam Pharmacists will be visiting Mumbai in June ,12

•Tanzania Pharmacists later this year

Concluding Remarks:

- DOTS though community pharmacies :Great potential to strengthen national TB programmes. to achieve universal access & for improved case detection
- Pharmacists :Increased pharmaceutical human resources for TB control

ACKNOWELDGEMENTS

- International Pharmaceutical Federation
- Lilly MDR TB Partnership
- RNTCP Staff & RNTCP WHO Consultants
- AIOCD & Local Chemist Associations
- All participant pharmacists

Thank You

SEARPharm Forum

Promoting Safe Use of Medicines in South East Asia

CHALLENGES IN GATE KEEPING ROLE FOR RATIONAL DISPENSING OF ANTIBIOTICS

April 27, 2012

Anita Kotwani, Department of Pharmacology
V. P. Chest Institute, University of Delhi, Delhi, India

Presentation outline

- Setting the scene
- Appropriate use of antibiotic
- Inappropriate use of antibiotic
- How to evaluate and tackle inappropriate antibiotic prescribing & dispensing by pharmacists?
- Conclusion

Antimicrobials, Antimicrobial resistance, Post antibiotic era

3

- Discovery of antimicrobials/antibiotics revolutionized treatment of infectious diseases
- Soon  realized bacteria could develop antimicrobial resistance
- AMR, a serious public health problen
- Infections could again become serious health problem

Downward trend in development of new antibiotics

4

- After 1970 very few new classes of antibiotics launched*
- Gap between the burden of multidrug-resistant bacteria and the development of new Abs
- Burden of AMR is more for developing countries
- Need to tackle the problem at the earliest and by all stakeholders

*Butler & Cooper. Antibiotics in the ….J Antibiotics 211;64:413-425

Primary cause of AMR

5

- Resistance to antibiotic a natural phenomenon
- Indiscriminate and inappropriate use of antibiotics resulted in rapid increase and spread of AMR
- The reasons for drug pressure are multi-factorial and involve both human and animal use.

Appropriate use of medicine

- Patients receive the appropriate medicines, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost, both to them and the community (WHO)
- Definition true for antibiotic
- Inappropriate use of antibiotic when one or more of or more of these conditions are not met

Appropriate antibiotic prescribing & inappropriateness in antibiotic use

I. Prescriber

- Appropriate indication
- Appropriate antibiotic
- Appropriate patient
- Appropriate information

2. Pharmacists

- Prescribe and dispense antibiotics in developing countries

3. Patients

- Incomplete doses
- Self-medication

Inappropriate antibiotic use

8

- Antibiotics cure bacterial but not viral infection
- Globally 20-50% of antibiotic use is inappropriate
- Globally, antibiotics are prescribed for many viral, self-limiting conditions
- Netherlands with minimum DDD/1000 inhabitant consumption in Europe, also has overprescribing of antibiotics (ABs) by general practitioners
- Similar data of overuse of ABs from the USA for URTI, sinus, etc.
- Scanty data from developing countries

How to evaluate & tackle inappropriate use of antibiotics?

- Surveillance/measure antibiotic use (inappropriateness)
- Investigating the reasons and factors underlying
- Identify the barriers to behaviour change
- Suitable and sustainable interventions
- Implementing and evaluating interventions

Tracking antibiotic use and AMR

Developed country settings

10

- Extensive surveillance programs to track pattern of antibiotic use and AMR over time
- Antibiotic dispensing only on Prescription

- Swedish Program – STRAMA
- European Program – ESAC and EARSS
- Antimicrobial Stewardship Programs (Multidisciplinary teams)

Tracking antibiotic use and AMR

Developing country settings

- **Problem of AMR has little recognition**
- No quality database for antibiotic use
- Ability to undertake extensive surveillance is lacking
- Fragmented data available (high use of AB)
- A reproducible and sustainable surveillance methodology needed for quantifying antibiotic use and resistance in the community
- **Implementation of laws for dispensing of antibiotics is a challenge**

How far have we come?

Developing country settings

- WHO collaborated 5 pilot projects to develop validated reproducible and sustainable surveillance methodology for AB use (2002-05)
- Refined a methodology by conductin patient exit interviews at retail pharmacies, public sector, private clinics

- II phase of the study (2007- 2008), New Delhi expanded the established methodology to a detailed community surveillance of antibiotic use

Rising antibiotic use

13

- Between 2005 and 2009, the units of antibiotic sold increased by about 40% in India (IMS data)
- Increased sales of cephalosporins were particularly striking, the sales increased by 60%
- Survey conducted in part of Delhi in 2004* and 2008# showed increase in use of cephalosporins

*Kotwani A, Holloway K, Roy Chaudhury R. Methodology for surveillance of antimicrobials use among out-patients in Delhi. Indian Journal of Medical Research 2009; 129: 555-560

#Kotwani A, Holloway K. Trends in antibiotic use among outpatients in New Delhi, India. *BMC Infectious Diseases* 2011;**11.**

Findings from the survey…..

14

- The surveillance system successfully captured the pattern of antibiotic use (newer AB used)
- Repeat survey could catch the change in trend of AB use over a period of time
- Same methodology was used to study pattern of antibiotic (mis)use in URI and acute diarrhea
- 43 to 57 per cent patients with URI and acute diarrhea* receive an antibiotic, though not needed

*Kotwani A, Roy Chaudhury R, Holloway K. Antibiotic prescribing practices of primary care prescribers for acute diarrhoea in New Delhi, India. *Value in Health*, 2012; 15: S116-S119.

Why this overuse of antibiotics?

15

- Problem in effective health care delivery
- Factors that influence the use/dispense of antibiotics by health providers, dispensers and community members
- A proper understanding of these factors is a pre-requisite to develop more effective policies and programmes to address inappropriate antibiotic use and dispensing of antibiotics

Who all dispense antibiotics in developing countries?

16

- **Pharmacists – major stakeholder**

Others

- Doctors
- Non qualified doctors
- Community

Data on dispensing behavior of pharmacists

17

- Scanty data from developing countries
- Few studies by developed countries on antibiotic use and dispensing behavior of pharmacists of developing countries
- Legally pharmacists are not permitted to prescribe antibiotics but generally they do
- Each country has specific factor and challenges – access to ABs, socioeconomic reasons, demography reasons, cultural issues, etc.

Qualitative study with pharmacists in New Delhi, India

18

- FGDs were conducted with retail pharmacists, public sector pharmacists, and the office bearers of pharmacists' associations

#Kotwani A, et al. Irrational use of antibiotics and role of pharmacists:…..qualitative study New Delhi, India. *Journal of Clinical Pharmacy Therapeutics* 2011 Online published 23 AUG 2011

Insights from the qualitative study

19

- A. Prescribing & Dispensing behavior
  - Honoring old prescription
  - Irregularities in supply of Abs in public facilities
  - Self-medication by patients and demand
  - Pharmacists prescribing behavior
- B. Commercial interest
  - Honoring inappropriate prescriptions
  - Push factors of pharmaceutical companies

Insights from the study…

20

- C. Advisory role of pharmacist
- D. Suggestions for intervention strategies
  - Increasing awareness among consumers
  - Awareness and education of pharmacists
  - Changing prescription habits of doctors
  - Easy return policy for near expiry in public sector
  - Changing pharmacists' dispensing
  - Redefine the role of pharmacists

Lot to learn from the study

21

- This study adds to the growing body of knowledge for the need to devise interventions to improve prescribing and dispensing of antibiotics by pharmacists
- Community pharmacists are willing to participate, need to work with doctors and with multidisciplinary team under a big and reputed organization
- Need recognition…may be award and certificate

What are the challenges???

22

- Multidisciplinary team
- Political will
- Team work
- Respect for all stakeholders
- Recognition of all stakeholders
- Recognition of members with good work
- Implementation of laws for one and all

National policy for containment of antimicrobial resistance

23

- Front-page news of NDM-1in 2010
- Task force of MoH, GOI prepared the national policy for containment of antimicrobial resistance, 2011 with objective to monitor AMR, steps to decrease the AMR & misuse of ABs in the country
- National policy available on National Centre for Disease Control website which is an institute under MoH

➢ Cont…

Highlights of policy

24

- For monitoring use and misuse of antibiotics: A separate Schedule H1 to be introduced, exclusively for sale of antibiotics. Color coding system and restricting access for third generation antibiotics and all newer antibiotics to tertiary care hospitals
- Hospital based sentinel surveillance system for monitoring antibiotic resistance
- Documenting prescription patterns and establishing a monitoring system for antibiotic use
- Enforcement and enhancement of regulatory provisions for use of antibiotics in human, veterinary and industrial use
- Promoting rational use of drugs

Next steps……. SEARegion

- Inappropriate antibiotic use in the community? YES
- Variation in health systems and stakeholders

Each country needs to

- Measure, monitor antibiotic use
- Factors responsible at all stakeholders
- Committed program for intervention & monitor
- Required political commitment and multidisciplinary team

Conclusions

26

- Antibiotics are indeed wonder drugs
- Use antibiotics judiciously
- Save the newer generations of antibiotics for next generations and severely ill patients

mHealth

a Tool for Promoting Quality Medicines

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Quality Medicines +
Poor Information = Quality Healthcare ?

Quality Medicines +
Quality Healthcare Information = Quality Healthcare
(Rational use of Medicines)

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Lack of information delivery system missing /not reaching stakeholders for rational use of drugs?

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CURRENT SCENARIO
Challenges in Healthcare information Delivery

People: Physicians/Doctors, pharmacists, nurses other paramedics ANMs, ASHA & Anganwadi workers

Objects: Published references, Formularies (NFI, BNF)

Environment: Remote, no/limited internet access

Things: Patient awareness, Low level of implementation of Govt programs like NRHM

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POSSIBLE SOLUTIONS

Information: Non biased

Ease of distribution: Reach both the India- urban/rural

Ease of accessibility: English/ regional languages
PC/internet access

Continuity : Updation of this information

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mHealth

mHealth (**mobile health**) is a term used for the practice of medicine and public health, supported by mobile devices.

The term is most commonly used in reference to using mobile communication devices, such as mobile **phones**, **tablet** computers and personal data assistant (**PDA**s), for health services and information.

Ref. Vital Wave Consulting (February 2009). *mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World*. United Nations Foundation, Vodafone Foundation. p. 9.

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www.thinktwo.net

CURRENT APPLICATIONS

- Collecting community and clinical health data
- **Delivery of healthcare information** to stakeholders
- Real-time monitoring of patients
-
- Direct provision of care (via mobile telemedicine)

Source : Germanakos P., Mourlas C., & Samaras G. "A Mobile Agent Approach for Ubiquitous and Personalized eHealth Information Systems." Proceedings of the Workshop on 'Personalization for e-Health' of the 10th International Conference on User Modeling (UM'05). Edinburgh, July 29, 2005, pp. 67-70.

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What is being done around the World in mHealth

Type of mHealth initiatives

The majority of Member States (83%) reported offering at least one type of mHealth service (n =112)

The four **most** frequently reported mHealth initiatives were:

- Health call centres - 59%
- Emergency toll-free telephone services - 55%
- Managing emergencies and disasters - 54%
- Mobile telemedicine - 49%

Source: mHealth- New horizons for health through mobile technologies,WHO, 2011

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What is being done around the World in mHealth

Type of m Health initiatives

The **least** frequently reported initiatives were

- Health surveys - 26%
- Surveillance - 26%
- Awareness raising - 23%
- Decision support systems - 19%

Source: mHealth- New horizons for health through mobile technologies,WHO, 2011

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WHAT IS HAPPENING GLOBALLY?

Based on information available on rational use

Mobile apps
- BNF
- Medical references

Web
- WHO model formulary
- Others

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Demographics -India

High population growth

High burden of disease prevalence

Low healthcare workforce

Large number of rural inhabitants

Limited financial resources to support healthcare infrastructure and health information systems

High transaction costs to deliver healthcare

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Mobiles- outreach

India
884 million subscribers (73 percent of population) in November 2011
up 154 million from November 2010. (TRAI, Jan 2012)
66 percent of mobile subscribers are **urban** dwellers

China
963 million subscribers (71 percent of population) in November 2011
118 million of these are 3G users.

USA
322.9 million subscribers (102.4 percent of population) in June 2011 (CTIA)

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Mobiles- outreach

Android is the top smartphone operating system in 2011. (February 2012)

48.8 percent of smartphones shipped in 2011, shipped with Google's free Android OS

Smartphones now outsell PCs

Operating System	Shipments 2011 (millions)	Market share 2011	Annual growth
Android	**237.7**	**48.8%**	**244%**
iOS	93.1	19.1%	96%
Symbian	80.1	16.4%	-29.1%
BlackBerry	51.4	10.5%	5.0%
Bada	13.2	2.7%	183.1%
Windows Phone	6.8	1.4%	-43.3%
Others	5.4	1.1%	14.4%
Total	487.7	100%	62.7%

Source: Canalys (Feb 2011)

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India - Mobile phones internet users

Second largest telecommunication network in the world after China. With over 771 million mobile lines in service [1]

Surge in Internet usage - over 50 million active monthly Internet users on both PCs and phones. [1]

Total number of mobile Internet users in
2010 - 12.1 million[2]
2011- 30 million (Expected) [2]
2015 – 237 million (Expected) [3]

40 percent consumers accessing internet daily through Smartphones
34 percent of these users log in for more than half an hour each day

1. [illegible]
2. IMRB International and the Internet and Mobile Association of India
3. Boston Consulting Group

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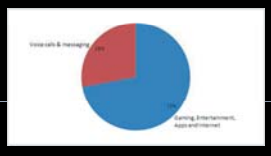
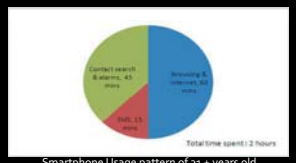
India - Mobile phones internet usage pattern

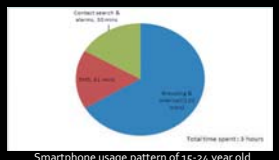
Indian smartphone users spend more time on the Internet than on traditional voice calls and SMS's



Smartphone usage by Indian users



Smartphone Usage pattern of 31 + years old



Smartphone usage pattern of 15-24 year old

Source :Nielsen and Informate

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National Formulary of India (NFI)

- 431 Drugs
- 32 categories/therapeutic segments
- 15 Appendices
- More than 800 Pages
- MoH document on Rational use of Drugs

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National Formulary of India (NFI)

a case study

m NFI
The First Formulary in world available as m App
In FREE TO DOWNLOAD

The 2nd Formulary in world available as m App
BNF Android Version ($39.75)

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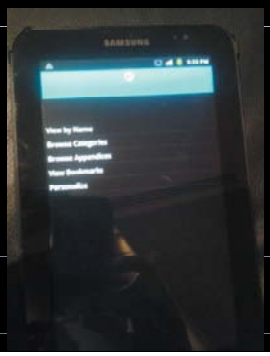

The User Interface (UI)

View By Name
Browse Categories
Browse Appendices
View Bookmarks
Personalise

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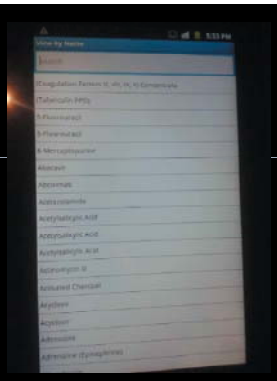

View By Name

Search Browser &
Drop down

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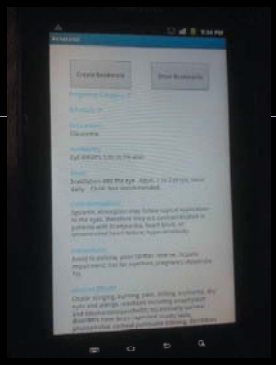

Product Description

Create Bookmarks

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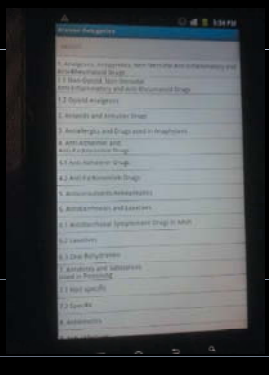

Browse Categories

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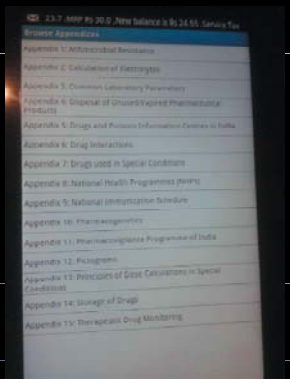

Browse Appendices

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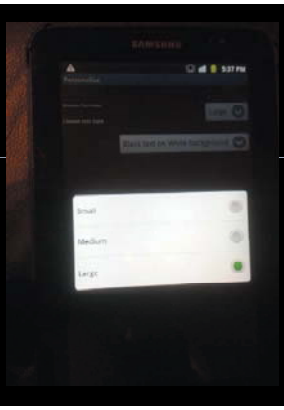

Personalise

Increase in font size
Background change

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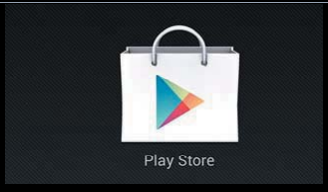
Distribution



Earlier Android Market

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Role in the diffusion of information

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Only adults
seem to marvel at
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For toddlers,
our romantic future is
their ordinary present

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Acknowledgement

Mr. Prafull D. Sheth, FIP Vice-President
Dr. G. N. Singh, DCG (I)
NFI Team, Indian Pharmacopoeia Commission

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SIGNING OF MOU

Memorandum of Understanding between The Central TB Division Directorate General of Health Services, and Indian Pharmaceutical Association (IPA) All India Organisation of Chemists & Druggists (AIOCD), Pharmacy Council of India (PCI) and SEARPharm Forum.

The Objective of the Collaboration is to strengthen the Revised National Tuberculosis Control Programme (RNTCP) by engaging pharmacists in RNTCP for TB Care & Control in India.

The focus of Pharmacists involvement will be for early identification and referral of TB suspect for diagnosis, Directly Observed Treatment (DOT) provision for TB patients, increasing community awareness about TB and MDR-TB, patient education and counseling, promoting rational use of Anti-TB drugs and contributing to preventing the emergence of drug resistance & any other activity mutually agreed by the parties as per the local need.

Thus, collaborating parties, nationwide will undertake systematic efforts to involve pharmacists in RNTCP for TB care and control as a part of strengthening health systems in general and health work-force in particular.

SEARPharm Forum has agreed to provide necessary external guidance and expertise to foster this partnership.

MEMORANDUM OF UNDERSTANDING

between

The Central TB Division

Directorate General of Health Services,

and

Indian Pharmaceutical Association (IPA)

All India Organisation of Chemists & Druggists (AIOCD), Pharmacy Council of India (PCI) and SEARPharm Forum

This MEMORANDUM OF UNDERSTANDING (herein after referred to as "MOU"), is entered into between the Central TB Division (CTD), Directorate General of Health Services,(herein after referred to as "CTD," or the first Party to the MoU"), and Indian Pharmaceutical Association (herein after referred to as "IPA"),a professional body of pharmacists in India , All India Organisation of Chemists & Druggists (herein after referred to as "AIOCD") representing trade body of chemists and druggists, Pharmacy Council of India ((herein after referred to as "PCI") representing statutory body for regulating pharmacy education and SEARPharm Forum (herein after referred to as "SPF") representing Forum of World Health Organization (WHO-SEARO) – International Pharmaceutical Federation (FIP) and National Associations in South East Asia.

This agreement is made by and between the Parties to set out the policy of engaging retail pharmacies (community pharmacies) in Revised National Tuberculosis Control Programme (RNTCP).

NOW THEREFORE, THE PARTIES AGREE AS FOLLOWS:

1. OBJECTIVES OF THE COLLABORATION

The main objective of this MOU is to strengthen the Revised National Tuberculosis Control Programme (RNTCP) by engaging pharmacists in RNTCP for TB Care & Control in India.

The focus of Pharmacists involvement will be for early identification and referral of TB suspect for diagnosis, Directly Observed Treatment (DOT) provision for TB patients, increasing community awareness about TB and MDR-TB, patient education and counseling, promoting rational use of Anti-TB drugs and contributing to preventing the emergence of drug resistance & any other activity mutually agreed by the parties as per the local need.

Thus, collaborating parties, nationwide will undertake systematic efforts to involve pharmacists in RNTCP for TB care and control as a part of strengthening health systems in

general and health work-force in particular.

2. RESPONSIBILITIES OF CTD, MINISTRY OF HEALTH AND FAMILY WELFARE

CTD hereby agrees to:

2.1) Policy Dissemination

a) Promote and propagate the need for these collaborative actions stated below to all states TB programmes .CTD will ensure that the State TB programme will further take it to district TB programme & thus the entire RNTCP will be well communicated about this policy decision& necessary directives will be issued by CTD.

b) Promote the need for engaging pharmacists in RNTCP to drug regulatory authorities .CTD will ensure that the State TB programmes take it to state drug regulatory authorities.

c) CTD in consultation with IPA will formalize a National Plan and strategies to engage pharmacists in RNTCP.

2.2) Information Education and Communication (IEC)

a) CTD will issue necessary directives to the State and District TB Officers for printing TB Information Education and Communication (IEC) material jointly developed by CTD and IPA for display & use in pharmacies.

b) CTD will create navigation button exclusively for sharing the training module, other documents and reports of Pharmacists and RNTCP on its website, www. tbcindia.nic.in.

2.3) Training

a) CTD will review the existing training modules and teaching tools for Pharmacist training and develop a final module.

b) State and District Health Societies through State TB officer and District TB officers, will impart training to pharmacists with the help of local chemist and druggist association.

2.4) Coordination

a) CTD will coordinate with IPA, AIOCD, PCI and SEARPharm Forum to form a National Core Committee of RNTCP – Pharmacy partnership.

b) The National Coordination Committee will meet at least once in a quarter to begin with or as and when it is required apart from the regular quarterly meetings to review the progress of the partnership

c) CTD will recommend to the States and Districts to form State as well as District level coordination committees.

d) CTD will recommend the States and Districts to review the engagement partnership every quarter in the quarterly review meeting. A representative from the local chemists and druggists association will be invited to the quarterly review meetings.

e) Representatives from IPA and AIOCD will be invited for the National Biannual RNTCP review.

2.5) Recording and Reporting

a) CTD will recommend to the States and District to acknowledge the referrals from pharmacies and properly document in the Laboratory register. Necessary skills for filling the referral forms and necessary formats will be imparted by RNTCP during training.

b) CTD will periodically report the contribution of pharmacists to referral and DOT

2.6) Monitoring and Supervision

a) Central TB Division will develop monitoring indicators.

b) Central TB Division, STOs, and DTOs will monitor & evaluate the status and progress of the engagement during regular field visits, regular review meetings and Central and State internal evaluations.

c) Technical Evaluation Missions involving participants from CTD, IPA, Civil Society partners, Health activists will be facilitated by CTD. Pharmacist contribution also will be appraised during External Evaluation Missions like Joint Monitoring Mission and Joint Donor Mission.

3. RESPONSIBILITIES OF IPA

IPA agrees:

3.1. To work in collaboration with RNTCP, AIOCD, PCI and SPF for facilitation of the process of engaging pharmacists at a national level.

3.2. Serve as a major technical support to RNTCP for pharmacists' engagement & will share the training & relevant material to CTD for adoption.

3.3. Will jointly develop TB IEC material with CTD for display in pharmacies.

3.4. To submit an annual report to CTD for publishing in the Annual TB reports.

3.5. To regularly attend Core Committee, meetings & review the pharmacists work & take necessary steps to solve problems, if any.

3.6. To provide maximum visibility to pharmacists work in conventions, bulletins, publications etc.

4. RESPONSIBILITIES OF AIOCD

AIOCD agrees to:

4.1) Promote the need for the above mentioned collaborative actions to all states association & will ensure that the State will further take it to district/local chemist and druggists association & thus all levels of chemist and druggists associations will be well communicated about this policy decision.

4.2) Identify State and District level nodal persons for coordinating with RNTCP at the respective levels.

4.3) Facilitate formation of State and District level coordination committees to support chemists and druggists engagement in RNTCP.

4.4) Share the list of pharmacists and pharmacy shop with local District/ Sub-district RNTCP functionaries.

4.5) Ensure help to RNTCP in nominations of pharmacists for training.

4.6) Ensure that the partnering pharmacists are functioning in accordance with the objective of the collaboration.

4.7) Ensure the nodal persons will regularly attend State/ District level Core Committee meetings and RNTCP quarterly review meetings and review the pharmacists work & take necessary steps to solve problems, if any.

4.8) Ensure reporting and recording as needed by RNTCP

5. RESPONSIBILITY OF PCI

5.1 Work on the relevant pre-service curriculum and training development for fulfilling the objectives of the collaboration in community and hospital settings.

5.2 Conduct continuing professional development program for in-service pharmacies fulfilling the objectives of the collaboration.

6. Responsibilities SEARPharm Forum-FIP-WHO forum of National Associations of Southeast Asia (SPF)

6.1 SPF will provide necessary external guidance and expertise to foster this partnership.

7. Expected Outcomes

7.1) Increase in TB suspects referrals from pharmacist.

7.2) Increase in number of Pharmacy shop DOT centers.

8. FINANCIAL ARRANGEMENTS

8.1) State and District Health Societies will bear the organizational costs for training.

8.2) Various possibilities for Non- financial incentives (apart from the regular excellence certificates) from RNTCP will be deliberated & recommended by National Core Committee to RNTCP.

8.3) Registered pharmacists associations can apply for relevant RNTCP schemes and are eligible for accepting funds available for the such schemes as per the RNTCP guideline. Approval of such schemes will remain with the local State/ District Health society.

8.4) The travel expenses for the IPA and AIOCD representatives for attending the coordination meetings and review meetings will be borne by respective associations.

8.5) The collaborators are free to seek financial assistance from outside RNTCP to facilitate the engagement of pharmacies in meeting the objectives of the collaboration.

9. Documentation and Reporting

9.1) Regular reporting about pharmacist's engagements will be compiled by IPA and share it with RNTCP for publishing it in the National Performance report. Annual report of the same will be submitted to CTD for publishing in the Annual TB reports.

10. Period of MoU

10.1) The MoU will be effective for one year from the date of signing.

10.2) Extension of MoU will be decided in consultation with the signatories and CTD.

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Accepted on behalf of the Directorate General of Health Services Central TB Division	Accepted on behalf of IPA AIOCD PCI SEARPharm Forum

LIST OF PARTICIPANTS

INDIA

ANITA KOTWANI

ARINDAM MISHRA

ARUN GARG

ASHOK KUMAR

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SRI LANKA

CHAMILA SAMARSINGHE

CHINTA ABHAYAWARDANA

SIGNING OF MEMORANDUM OF UNDERSTANDING

GROUP PHOTOGRAPH: SEARPHARM FORUM SEMINAR