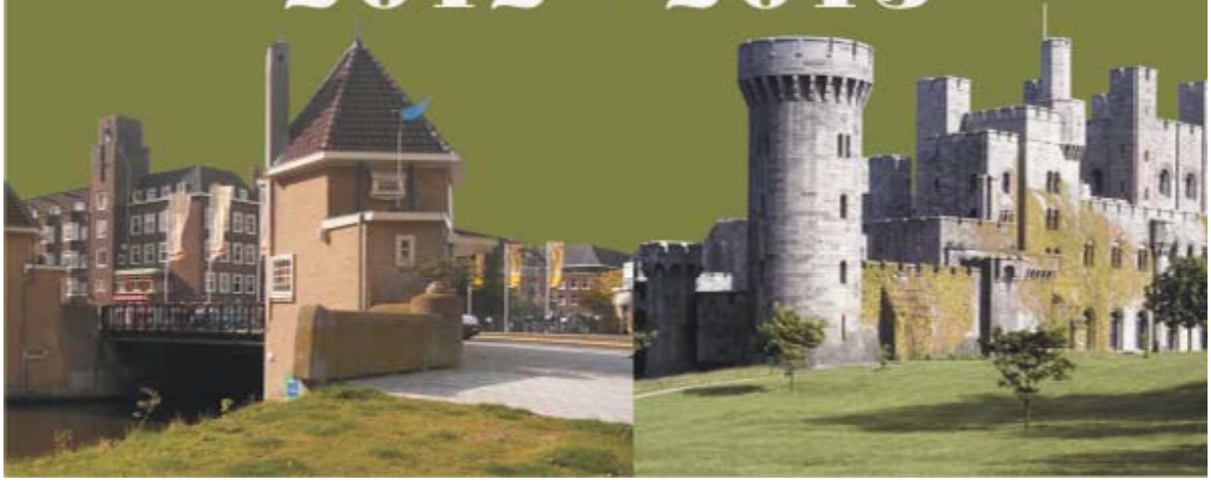
SEARPharm Forum

South East Asian FIP-WHO Forum of Pharmaceutical Associations

SEARPharm Forum

Annual Report

2012 - 2013



ANNUAL REPORT

SEARPharm Forum

2012-013

E-256, Greater Kailash -I, New Delhi-110048

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Member Countries

- Bangladesh
- India
- Indonesia
- Sri Lanka
- Thailand

Invited Members

- Bhutan
- DPR Korea
- Maldives
- Myanmar
- Nepal
- Timor Leste

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1. ADVOCACY OF FIP-WHO GUIDELINES ON GOOD PHARMACY PRACTICE (GPP) IN SEA REGION

Background

Since 2009, SEARPharm Forum has been reviewing the progress made by the member organizations in the GPP implementation through its regional management team consisting of ***Teera Chakajnarodom (Thailand), Dani Pratomo (Indonesia), Raj Vaidya (India).***

1) GPP implementation could be boosted by strong political will nationally and international pressure which would transform into stronger regulations and implementation.
2) Upgrade/rationalize the pharmacy work force to skilled workers by starting tailor made certificate programs which could harness GPP needs. Better remunerations of the pharmacists would inspire them to put themselves in GPP promotion practices.
3) Position pharmacists in the Primary health care programs and public health issues which will eventually build pharmacists' role as practitioners not mere dispensers.
4) Make National Alliance with other health care professionals associations on the lines of World Health Progressive Alliance (WHPA). This would collectively influence policies and bring an end in conflict of interest between the health care professionals.

In 2011, at the FIP Congress at Hyderabad Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services was released.

For the implementation of 2011 Joint FIP/WHO Guidelines on Good Pharmacy Practice, following four issues were addressed during the SEARPharm Forum Seminar on "Benefits of good practices in pharmacy- Setting standards for delivery of safe medicines" to patients in WHO-SEA Region, held on 27th April, 2012 at New Delhi:

- Setting up accredited pharmacy in India by ***Raj Vaidya, India***
- Regulatory support for implementation of GPP in Thailand by ***Songsak Vimol-kittipong,Thai FDA***
- Good Trade Practice in Sri Lanka by ***Chamila Samarsinghe, Sri Lanka***
- Implementation of GPP in Indonesia by ***M. Wahyudi, Indonesia***

Discussion highlighted the following issues:

- Infrastructure for setting up accredited pharmacy
- Mechanism for regulatory support for implementing GPP
- Experience on GPP Implementation
- Good Trade Practices in pharmacy

Based on the outcome, a Working group led by forum president, ***Dani Pratomo*** and members from Thailand, India, Indonesia and Sri Lanka was formed to assess the progress of GPP implementation in the region.

SEARPharm Forum has already received update report on the status of GPP implementation from Sri Lanka, India and Indonesia **(Annexure-1).** The reports from Bangladesh, Thailand and Nepal are awaited. Based on these updates, a report on the status of GPP implementation will be finalized during the SEARPharm Forum ExCO meeting in Colombo, Sri Lanka on 30th June, 2013.

2. EXAMINATION OF THE DATA ON NATIONAL MEDICINE POLICIES (NMP) AND DRUG USE IN SOUTH EAST ASIA

The forum through its national associations will be examining the existence and Implementation of National Policies, EML as a basis for public procurement, National Formularies, availability & affordability of EM in public & private facilities and prices, quality assurance in retail and distribution chains, data on sub-standard & fake products in the distribution chain.

Specifically in the domain of pharmacy, the national associations will examine the top 20 selling medicines for the following indicators and quantify them: distribution and retailing practices in community and hospital settings, prescribing and dispensing practices, availability of brand vs. generic, average no. of drugs prescribed per patient, direction on drug use from pharmacists and Continuing Professional Development for pharmacists.

The SEARPharm Forum is forming a working group as follows:

COUNTRY	EXPERT	NOMINATED BY
1) Bangladesh	Nasser Zahede	Nasser Zahede
2) India	Anita Kotwani	Prafull D. Sheth
3) Indonesia	TBD	Dani Pratomo
4) Nepal	Baburam Humagain	Uttam Budhathoki
5) Sri Lanka	Chamila Samarsinghe	Chinta Abhayawardana
6) Thailand	TBD	Teera Chakajnarodom

Based on initial discussion with Dr. Anita Kotwani the draft terms of reference **(Annexure-2)** have been prepared and identified preliminary list of core medicines based on for WHO/HAI medicine price survey for SEAR **(Annexure-3).** Further a Questionnaire has been prepared **(Annexure-4)** to carry out the survey in member countries and collected data will be examined by the working group. A report will be prepared on National Medicine Policies (NMP) and Drug Use in South East Asia. The report will be presented at One and a half day Seminar on "National Medicine Policies and Drug Use in South East Asia" to be held on 29-30th June, 2013 at Colombo, Sri Lanka **(Annexure-5)**. The meeting is being sponsored by Pharmaceutical Society of Sri Lanka (PSSL).

3. FIP CHALLENGE ON TB ROUND 1

India suffers more Tuberculosis (TB) cases than any other country in the world. The 1.9 million incident cases in 2009 represented one fifth of the global burden. In India, 50-80% of TB patients seek care in the private sector. It has been internationally recognized that public-private partnerships (PPP) are now necessary for TB control in several high prevalence countries.

The private sector comprises of all providers who operate outside the public sector and whose aim is to treat illness or prevent disease. The retail pharmacies fall in private sector. Although in recent years some innovative initiatives have been emerging, the concept of involving Pharmacists is relatively new and the enormous potential of this resource remains largely untapped in India. Therefore, it is necessary to look for such initiatives taken by Pharmacists in the vast nook and corners of India and document these. There are more than 700,000 registered Pharmacists practicing in the country. These Pharmacists can be made stakeholders in TB control.

The International Pharmaceutical Federation (FIP) established a Joint Statement with the World Health Organization (WHO) on the role of pharmacist in TB Care and Control at the World Congress at Hyderabad in 2011. This joint document has drawn up a set of Guiding Principles for National Tuberculosis Programs (NTPs) and National Pharmacy Associations (NPAs) on the approaches in the fight against TB and MDR-TB. At the same World Congress, the FIP round table was conducted for engaging the pharmaceutical sector in TB control in India. The Round Table made recommendations on each of the seven collaborative actions mentioned in the Joint Statement..

The FIP Challenge on TB Round 1 project was set up to find *inter alia* prevailing practices and prepare a Reference Document on Pharmacists' innovative approaches to target early Detection, delivery of DOTS, rational use, Public Education in TB Care and Control in India. The scope of the Reference Document was to establish an evidence base for pharmacist's interventions and specific roles in delivering safe, quality and cost-effective care for TB patients. The Reference Document collected case studies on outcomes and processes on TB Care and Control activities in community & Hospital pharmacy, and industry & other practice settings, so as to promote harmonization, alignment and effective collaboration of Pharmacists' involvement in TB care at state and national levels. The FIP Challenge on TB Round 1 project showed that Pharmacists involvement in India in prevention and care is still at a nascent stage. However, it very clearly brought out that there is an immense potential for Pharmacists in India to participate in the Revised National Tuberculosis Program and contribute to the different areas of the intervention.

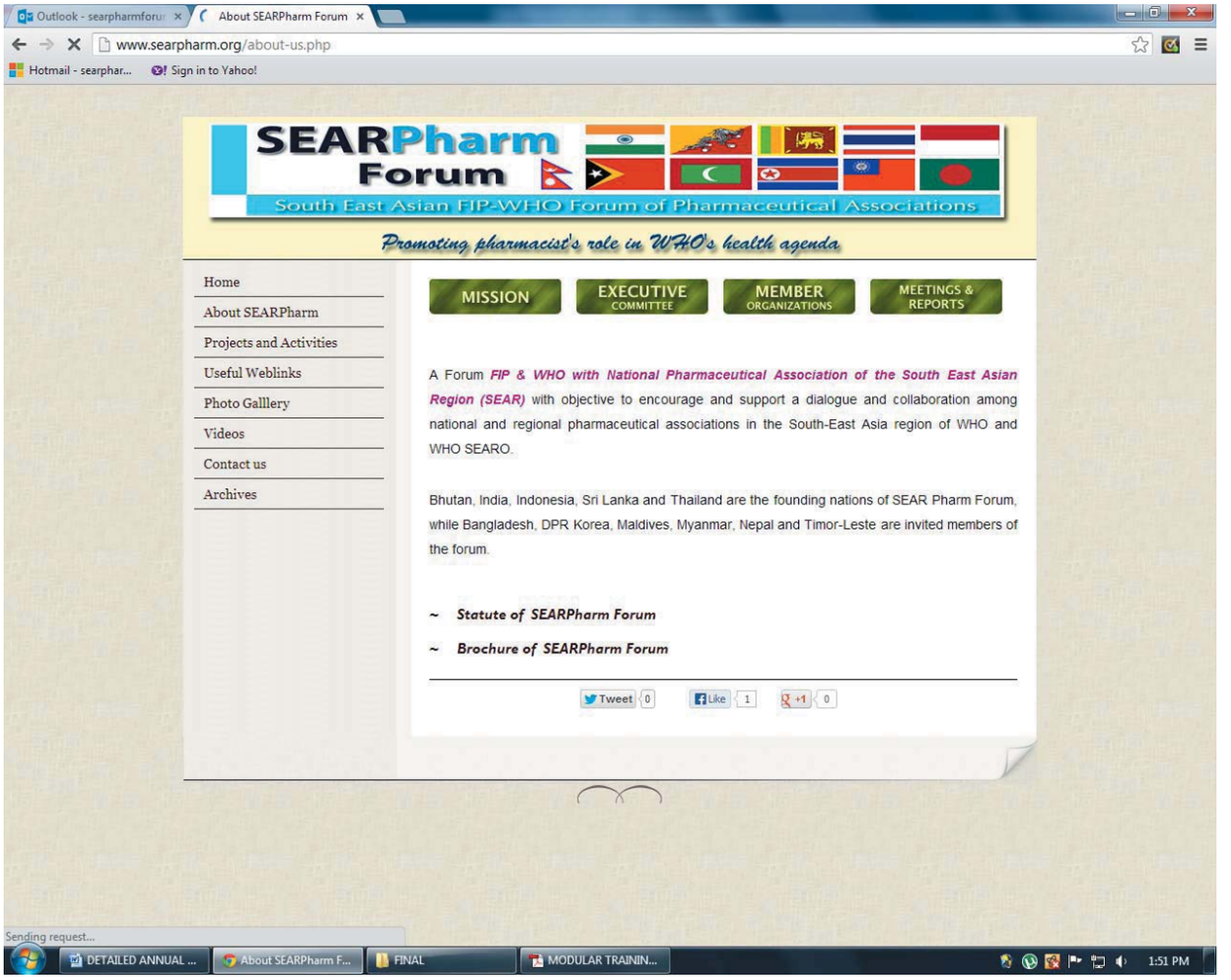
The major outcome of the project **(Annexure-6)** was realized when a Memorandum of Understanding (MoU) between the Revised National Tuberculosis Control Programme (RNTCP) and relevant stakeholders *viz.* IPA, All India Organization of Chemists and Druggists (AIOCD) , Pharmacy Council of India (PCI) and SEARPharm Forum on the role of Pharmacists in TB Care and Control in India. The memorandum of understanding has outlined Pharmacists role in national TB Care and Control thus paving the way for Pharmacists in India to be involved in the National Health Programme for the first time. Further to the MoU, IPA has developed training module for community pharmacists who will be involved in RNTCP project **(Annexure -7)**.

4. DATABASE ON INCIDENCE OF COUNTERFEIT MEDICINES

The Secretariat has been regularly updating such data since 2001. It has updated the database on SEARPharm forum website with the media reports on the incidents of counterfeit medicines for the year 2011-2012 (Annexure-8)

5. UPDATION OF SEARPHARM FORUM WEBSITE

The SEARPharm Forum Website has been updated and recent report have been uploaded on the website. Website is currently managed by Mr. Sohail Hassan.



Annexure -1

STATUS UPDATE ON GPP IMPLEMENTATION - INDIA

Background

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading “Good pharmacy practice in community and hospital pharmacy settings”.

This was further endorsed by WHO in 1997.

The Indian Pharmaceutical Association (IPA) developed GPP Guidelines for India in 2002, and followed it up with a GPP Training Manual in 2005.

At its conference, in 2007, the SEARPharm Forum prepared the Bangkok Declaration on GPP.

In 2008, Global Conference on the Future of Hospital Pharmacy was hosted by the FIP Hospital Pharmacy Section. Hospital pharmacists from around the world met and successfully developed 75 consensus statements reflecting the profession's preferred vision of practice in the hospital settings.

In 2009, SEARPharmForum prepared a GPP Training Manual for the SEARO Region.

In 2011, the FIP and WHO adopted an **updated version of Good Pharmacy Practice; “**Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services**".**

On going through the various aspects of GPP Guidelines of India, and relating them to legal requirements for the country, we could make the following observations :

FACILITIES :

1. Premises :
    - Identification & facade of Pharmacy

      Legal requirement : Yes. All the establishments involved in storage & sale of medicine should have proper name & address, with name displayed in front (façade) for proper identification of the Pharmacy.

      Ease of implementation : Yes. Most of the Pharmacies can meet these standard prescribed by GPP without any hurdle.

- Pharmacy products to be stocked separate from cosmetic, general items

  Legal requirement : No.

  Ease of implementation : No. It is not always possible to have a separate storage area for cosmetics & general items in Pharmacy because of space constrain. It might be possible in big pharmacies but in smaller pharmacies it is not always possible.

- Maintain pharmacy clean, dust free :

  Legal requirement : yes. Good storage area should be maintained to maintain integrity & stability of the drugs.

  Ease of implementation : No. Most of the pharmacies are located at the roadside without any A.C or automated doors, were dust can easily enter. Keeping Pharmacy clean & dust free in such condition is a cumbersome task & not always possible. It might be possible in smaller pharmacies with proper A.C. & door facility.

- Cleaning schedule to be maintained :

  Legal requirement : No.

  Ease of implementation : with few staffs working in pharmacy & heavy workload it is not easy to maintain cleaning records every time.

- Constant supply of electricity, especially for refrigerators :

  Legal requirement : Yes. This is specially required in case of medicines which require cold storage.

  Ease of implementation : although it is necessary to maintain proper storage temperature for medicines, most of times it is not possible due to frequent power cuts. Not all the Pharmacies have inverter installed or have provision of solar refrigerator (may not work during rainy season) to overcome problem of power shut down.

- Pharmacy environment to be comfortable, sufficient place for clients to stand/sit :

  Legal requirement : No

  Ease of implementation : No. Most of retail pharmacies are small, due to space constrain providing proper area for waiting/standing is not always possible & they might have to stand on pavement/road

- Space for patient information/display :

  Legal requirement : No

  Ease of implementation : this might not be possible in all the pharmacies due to space constrain. Space requirement for this purpose may not be huge, it can be made possible if pharmacist have will to provide additional services for patient benefit (patient information/display) as part of professional activity.

- Pharmacy should have a separate patient care/counselling area:

  Legal requirement : No

  Ease of implementing : with a small space available in pharmacy making provision for separate patient care/counselling area is very difficult. It might be possible in big pharmacies but in smaller pharmacies it is not always possible.

- Storage area to be protected from exposure to light, heat. Controlled temperature :

  Legal requirements : Yes

  Ease of implementation : with changing temperature/climatic condition as per seasons, frequent power cuts it not always possible to maintain proper storage condition.

2. Furniture & fixtures :

- Neat, well placed shelves with provision for storage of medicines, neatly placed :

  Legal requirement : Yes

  Ease of implementation : No. Most of retail pharmacies are small, due to space constrain providing proper shelve with provision for placing medicines neatly is not always possible. It can be made possible with proper organization & utilization of space.

3. Equipment's :

- Computers for management of inventory, warnings of expiry, etc :

  Legal requirements : No

Ease of implementation : Most of the retail Pharmacies (Almost 50%) are using computers today to ensure smooth working (easy & fast).

4. Personnel :

- Pharmacist to be directly and easily accessible to public.
  Legal requirement : Yes
  Ease of implementation : even though it is legal requirement to dispense medicines under supervision of pharmacist, still there are sum/many pharmacies which runs without any Pharmacist in it. Even if Pharmacist is present he might not be available every time.

- Staff recruitment policy, training, documentation
  Legal requirements : No
  Ease of implementation : Presently a little beyond comprehension of most.

- Allot clear job responsibilities to each staff
  Legal requirement : No
  Ease of implementation : Can be easily implemented.

- All staff should wear Apron. Pharmacists to additionally bear a badge stating "Pharmacist". Photo, Registration certificate, qualification certificate to be clearly displayed
  Legal requirements : No
  Ease of implementation : most of the time Pharmacist is not present in Pharmacy & medicines are dispensed by unqualified person in pharmacy. Therefore there is often hesitancy to wear Apron.

- Pharmacists to undergo regular training/CPD

  Legal requirement : No

  Ease of implementation : at present there are no professional Associations which provide formal training to the Pharmacist so arranging regular training/CPD for Pharmacist is very difficult.

- Pharmacists to be competent to assess prescriptions, recommend OTC medications , advise patients on appropriate use of medicines, etc.
  Legal requirement : No

Ease of implementation : Poor academic competencies / lack of CPD training / without updating knowledge, it is not possible to meet these GPP requirement.

5. Systems :

- Have a Quality Policy, Service Policy, Staff Training Policy, Complaints Policy, Drug Recall Policy, Audit Policy, Documentation Systems (Sops, etc) in place

  Legal requirement : No

  Ease of implementation : NO. At present there is no proper system to monitor/carry out all these activities. Currently it is not possible but can be developed later with proper system in place.

PROCESS GUIDELINES :

1. Procurement and Inventory Management :

Legal requirement : partly yes

Ease of implementation : some of the pharmacies have properly laid down system for inventory management. Although some of the aspects of inventory management are difficult, with system in place it is not very difficult to have procurement & Inventory management.

2. Storage :

Legal requirement :

Ease of implementation :

3. Storage management :

Legal requirement :

Ease of implementation :

- System in place :

Legal requirement : No
Ease of implementation : very few pharmacies have properly laid down SOPs for all the work activities carried out in Pharmacy. System is being followed partly.

- Temperature etc. maintenance
  Legal requirement : yes
  Ease of implementation : with changing climatic condition/temperature & no proper provision for A.C. it is difficult to maintain proper storage condition for medicines in Pharmacy.

- Expired drugs to be stored separately
  Legal requirement : Yes
  Ease of implementation : most of the Pharmacies have separate storage area for expired goods. It can be implemented easily.

- Disposal of unused pharmaceuticals
  Legal requirement : No
  Ease of implementation : Unused pharmaceuticals are usually returned to the wholesaler. Good s which are not accepted by wholesaler is put into household waste. Nationally, there is no system in place for safe disposal of unused pharmaceuticals.

- Prescription handling :
  a. Review prescription, check for legality, completeness, etc
     Legal requirement : yes
     Ease of implementation : this is followed only by few of the pharmacies which carry out professional pharmacy practice. Cross prescribing, prescribing by quacks, dispensing of medicine by doctor, dispensing of medicines by unqualified person without pharmacists supervision is rampant. With such irrationalities it is difficult to keep check of each & every prescription.

  b. Check prescription for correctness, proper prescribing, drug interactions, etc.:
     Legal requirement : No
     Ease of implementation : due to lack of training & low standard of pharmacy education pharmacist in India are not sufficiently equipped to check authenticity & correctness of prescription.

4. Dispensing

- Filling of prescription

a. Removal of medicines from shelves as per prescription
Legal requirement :
Ease of implementation : YES

b. Pharmacist to give final check that correct medicines are dispensed. Legal responsibility lies on the pharmacist
legal requirement : YES
Ease of implementation : it is easy to implement. But some of the pharmacies run without any Pharmacist in it or he might not be present all the time. If law is made more stringent it is possible.

c. Packing of medicines
Legal requirement : Yes
Ease of implementation : Yes

d. Provide instructions/counselling to patient about medications – by pharmacist.
Legal requirement : NO
Ease of implementation : it is possible. Some of the pharmacies run without any Pharmacist in it or he might not be present all the time.

e. All dispensed medicines to be provided with a label bearing various details
Legal requirement : No
Ease of implementation : No legal sanctity yet. Apprehension whether this would be permitted. No such system in place. Without proper training for pharmacist, & in absence of Pharmacist in Pharmacy labelling of medicine during dispensing is often not possible.

f. Medication Records
Legal requirement : No
Ease of implementing : No, without proper system in place these is not possible at present.

g. Patient Follow-up
legal requirement : No

Ease of implementing : Not possible at present

e. Self Care health promotion, ill-health prevention – carry out health promotion activities in the pharmacy, guidance on self medication
Legal requirement : No
Ease of implementation : not possible in present situation

f. Pharmacovigilance
Legal Requirement : No
Ease of implementation : without proper system in place it is not possible.

g. Enhancement of professional role - pharmacists to keep updated, etc
Legal requirement : NO
Ease of implementation : with no Pharmacist present in Pharmacy, it is difficult to enhance professional role of Pharmacist.

Major hurdles therefore for GPP in India:

1. Pharmacist not present in the pharmacy. Medicines sold without his/her presence
2. Prescription medicines are easily available without a prescription
3. Pharmacists not equipped/trained for competent role
4. Salespersons also not trained, lack adequate knowledge

Annexure -1

STATUS REPORT ON GPP IMPLEMENTATION - SRI LANKA

Background

Sri Lanka is a country with 20 m population. It has been classified as a lower middle income country. (i.e. World Bank category "C"). Over ninety percent of Sri Lankans use Western Medicines regularly for their health concerns.

Pharmacy, as a profession, has not developed in Sri Lanka as in other countries. Non-graduate pharmacists are trained by the Sri Lanka Medical College Council for the community sector. After following a two year course under a "Master Pharmacist" the trainee has to sit for a qualifying examination conducted by the Sri Lanka Medical College Council. The successful candidates are registered as "Pharmacists" under the Sri Lanka Medical Council to practice as community pharmacists. This is a lifetime registration and at present there is no evaluation system to retain their registration. There are about 3000 community pharmacies operating throughout the country. The inadequate educational standards and lack of opportunities for continuous professional development has resulted in a poor service delivery by the community pharmacists. Their mindset is also mostly focussed towards business rather than service. The number of products in the market keeps on increasing with the advancement of pharmaceutical technology. The challenge is the rational use of these products and controlling their quality in an environment where pharmaceutical care is at a very minimal level. Hence there is a need for educating the community pharmacists in Good Pharmacy Practice in order to direct them towards patient care.

There are 4 main categories of community pharmacies operating in Sri Lanka:

1. Pharmacy owned by a pharmacist
2. Pharmacy owned by a non-pharmacist and employing a pharmacist
3. State sector managed chain pharmacies (State Pharmaceuticals Corporation outlets)
4. Private sector managed chain pharmacies

Annexure -1

Implementation of GPP

PSSL has decided to implement GPP in a phase manner

Phase 1 – Development of GPP Guidelines

As the initial step of educating community pharmacists, the Pharmaceutical Society of Sri Lanka has developed Good Pharmacy Practice (GPP) Guidelines based on FIP and WHO GPP guidelines. These guidelines were launched and introduced to the community pharmacists with the blessings of the Ministry of Health, supported by the Drug Regulatory Authority and the universities conducting pharmacy degree programmes. GPP was also included as a requirement in the National Medicinal Drug Policy of Sri Lanka.

Phase 2 – Training of community pharmacists

A Training of the Trainer's (TOT) programme was conducted with the assistance of the Community Pharmacy Section of the Indian Pharmaceutical Association. GPP has also been included in the curriculum of the trainee pharmacists. A series of training workshops were conducted for the community pharmacists using the GPP guidelines. It has been observed that the majority of the community pharmacists are now keen in following GPP and there is a considerable change towards a better service.

Phase 3 – Accreditation of GPP compliant community pharmacies

PSSL felt the need to have partnership with the Ministry of Health in order to have a successful accreditation programme. On a request made by the PSSL, the Ministry of Health has appointed a sub-committee to oversee the implementation of GPP and to have an accreditation programme in place. PSSL is now in the process of developing minimum national standards for all areas under GPP in order to initiate the accreditation process together with the Drug Regulatory Authority of the Ministry of Health.

Limitations:

There are some reasons behind this slow process in implementing GPP in Sri Lanka. The main reasons are:

- Absence of a separate directorate for the pharmaceutical sector in the Ministry of Health. It comes under the Laboratory Services. There are no pharmacists in the decision making positions in the Ministry of Health.

- Absence of graduate pharmacists in the permanent cadre of pharmacists in the state sector health institutions

  Non-pharmacists are functioning as Drug Inspectors. They are basically public health inspectors. After some years of service they are given a basic training in pharmaceutical legislation by the Ministry of Health and designate them as Food and Drug Inspectors.

Annexure -1

STATUS REPORT ON GPP IMPLEMENTATION - INDONESIA

Background

Indonesia is one of the five countries with largest population. There are more than 240 million people live in Indonesia. Economic situation in Indonesia is getting better in the last 3 years. The growth of middle class populations are very fast due to national economic growth. The gross domestic product (GDP) per capita more than USD 3500 last year.

Most of pharmaceutical products distributed in Indonesia produce locally. There are 204 pharmaceutical companies operated in Indonesia. Around 75% are local companies and the rest are multinational companies. Registered pharmaceutical products more than 19.000 item but only 65% of them exist in the market. There are 3 categories products in the market ie patented products, branded generic products and unbranded generic products. There are more than 21.000 pharmacies around the counties. Based on the ownership, pharmacies divided to pharmacy own by a pharmacist (less than 5%), pharmacy owned by non pharmacist (70%) and the rest are chain pharmacy. Last year, total pharma market reach USD 5 billion and growth rate approximately 10% each year. Aproximately 55% of the pharmaceutical products distributed through pharmacy.

Indonesian pharmacists have an organization named Ikatan Apoteker Indonesia/IAI (Indonesian Pharmacists Association). Right now there are more than 40.000 registered pharmacists and approximately 5.000 new pharmacist graduate from 70 school of pharmacy. All new graduates pharmacists are mandatory become a member of the association and automatically registered in the pharmacy council. Every 5 years pharmacists must renew their registration status.

Although pharmacist profession is already more than 60 years exist in Indonesia, the communities cannot feel the services from the pharmacist. Pharmacists are rarely serve the communities directly. The main reason is lack of competence and there is no role model. Most of pharmacy school in Indonesia still products oriented. The association trying hard to solve this this problem with so many programs and activities.

Implementation of GPP

After SEARPharm Forum annual meeting was held in Yogyakarta, Indonesia on 2008, Indonesian Pharmacists Association has decided to implement GPP. The first step of the implementation program was development of GPP Guidelines.

Indonesian Pharmacists Association together with DG of Pharmaceutical Service, Department of Health had developed Good Pharmacy Practice (GPP) Guidelines based on FIP and WHO GPP guidelines. These guidelines were launched and introduced to the community pharmacists since 2010.

Annexure -1

The implementation of GPP basically is voluntary for member. The great response comes from the pharmacy chain. They are trying hard to make GPP as the differentiation tools from others. But due to economic reason, they are still considering business rather than GPP as driver to run the pharmacies.

The response from independent pharmacy looks better especially from member who own pharmacy. They implement GPP with full awareness and use GPP as a lifestyle in the operational of pharmacies.

To accelerate the progress of GPP implementation, the association is trying to communicate intensively with the DG of Pharmacy Service as well as NAFDC (National Agency for Food and Drug Control) to make accreditation program for pharmacies who comply GPP. The involvement of government representatives believed by the association to be able to push the implementation of GPP.

Constrains

The main constrain of GPP implementation are coming from the member itself. Building member awareness about GPP is not easy, As far as there are no government involvement, the association will face the difficulties. Unfortunately the government officer who understand the principle of GPP are very limited and lack of political will .

Terms of reference – APW on NMP

Identify top 20 medicines

Indicators and Quantification

- **Distribution and retailing practices in community and hospital pharmacy settings**
- **Prescribing and dispensing**
- **Availability of Brand Vs. Generics**
- **Average number of drugs prescribed in a prescription**
- **Continuous Professional Development**

Members participating in the project

Thailand, Indonesia, India, Sri Lanka, Bangladesh and Nepal

Outcomes

1. ***Existence and implementation of NMP***

   Basis:

   a. ***EML for public procurement***

   b. ***National Formulary***

   c. ***Availability and price of Essential Medicines***

   d. ***Quality assurance***

2. ***Data on substandard and fake products***

Survey Form

Part- 1: Demographic data of the country

Part -2: Data of Organisation

Part -3: Examination of specifics – Pharmacy Domain and outcome

List of core medicines based on for WHO/HAI medicine price survey for SEAR

Annexure-3

Medicine	Strength	Dosage Form	Enlisted in Essential Medicine List (Y/N)	Enlisted in National Formulary (Y/N)	Free availability in public sector	Reimbursed through insurance	Alternative therpeutic equivalent, if not available
Amitriptyline	25 mg	cap/tab					
Amlodipine	5mg	cap/tab					
Amoxicillin	500 mg	cap/tab					
Amoxicillin suspension	25 mg/ml	milliliter					
Atenolol	50 mg	cap/tab					
Atorvastatin	10 mg	cap/tab					
Beclomethasone inhaler	200 mcg/dose	dose					
Captopril	25 mg	cap/tab					
Ceftriaxone injection	1 g/vial	vial					
Ciprofloxacin	500 mg	cap/tab					
Clotrimazole topical cream	1%	gram					
Co-trimoxazole suspension	8+40 mg/ml	milliliter					
Diazepam	5 mg	cap/tab					
Diclofenac	50 mg	cap/tab					
Diethylcarbamazine citrate	50 mg	cap/tab					
Doxycycline	100 mg	cap/tab					
Enalapril	5mg	cap/tab					
Fluoxetine	20 mg	cap/tab					
Gentamicin eye drops	0.30%	milliliter					
Glibenclamide	5 mg	cap/tab					

List of core medicines based on for WHO/HAI medicine price survey for SEAR

Gliclazide	80 mg	cap/tab					
Ibuprofen	400 mg	cap/tab					
Metformin	500 mg	cap/tab					
Metronidazole	400 mg	cap/tab					
Omeprazole	20 mg	cap/tab					
Paracetamol suspension	24 mg/ml	milliliter					
Phenytoin	100 mg	cap/tab					
Ranitidine	150 mg	cap/tab					
Salbutamol inhaler	100 mcg/dose	dose					
Simvastatin	20mg	cap/tab					

National Medicine Policies (NMP) and drug use in South East Asia

(Information to be collected by Resource Persons of member countries)

Instructions for Completion of Questionnaire Electronically:

☐ **Text Boxes**- Click on text box and type your response. **Do not use [ENTER] at end of text entry-simply move your mouse to the next response or click outside the text box or use TAB key.**

☐ **Check Boxes**- Click on check box**.** Correct a wrong entry by checking the box again.

Note: Before completing the questionnaire save it on your computer and then complete. It can be re-saved after completion and E-mailed back to us on searpharmforum@hotmail.com as an attachment.

DETAILS OF RESPONDENTS

Name		
Are you a Pharmacist/pharmacologist/area of specialization/degrees		
Organisation/Association		
Title/Position		
Country		
Contact Details	**Postal Address**	
	Telephone	
	Fax	
	Email	

I. Demographics

1. Name of the country
2. What is the total population of the country (*In Millions*)
3. What is the total number of registered pharmacists in the country
4. What is the population per pharmacist in following areas of the country as per country definition of areas
   a) Rural/backward
   b) Urban/major cities
5. How much is the total healthcare spending (%GDP) of the country as follows:
   a) Public
   b) Private/ out of pocket
6. What is the total value of domestic pharmaceutical Market in USD
7. What is the domestic spending on medicines (USD)
   a) Public:
   b) Private:
8. Share of medicines in total public healthcare spending (% of total)
9. Does your country has a centralized drug regulatory authority?
   if yes, Name _____

II. National Medicine Policy

1. Does your country have National Medicine Policy?
   YES NO
2. Mention the year of last update of National Medicine Policy?
3. Mention the years for last three revisions of National Medicine Policy?
4. Is Pharmacist part of multidisciplinary team formulating/updating National Medicine Policy?
   YES NO

III. Selection of Drugs

National Essential Medicine List

1. Does your country have National Essential Medicine List?

   YES ☐ NO ☐

2. Mention the year of Last update of national essential medicine list: ☐

3. Mention the years for last three revisions of national essential medicine list:

4. Is Pharmacist part of multidisciplinary team formulating national essential medicine list? ☐

5. At which level of care essential medicine list is statutory requirement:

   a) Primary care YES ☐ NO ☐

   b) Secondary/district care YES ☐ NO ☐

   c) Tertiary care YES ☐ NO ☐

   d) Private hospitals YES ☐ NO ☐

   e) General physicians YES ☐ NO ☐

6. At which level of care is Pharmacist part of multidisciplinary team formulating essential medicine list:

   a) Primary care YES ☐ NO ☐

   b) Secondary/district care YES ☐ NO ☐

   c) Tertiary care YES ☐ NO ☐

   d) Private hospitals YES ☐ NO ☐

IV. National Formulary

1. Does your country have National Formulary?

   YES ☐ NO ☐

2. Mention the year of Last update of National Formulary ☐

3. Mention the years for last three revisions of National Formulary: ☐

4. What is the basis of Public sector procurement in your country?
   a) National essential medicine list ☐
   b) National Formulary ☐
   c) Other, Please Specify_____

5. What is the tool for information sharing among stakeholders on drug use:
   a) Essential medicine list ☐
   b) National formulary ☐
   c) Other, _____

V. Supply (Including Procurement and Production issues)

Inventory control/Re-order level

1. What is the percentage of stock outs in the inventory at following levels of care:
   a) Primary care ☐
   b) Secondary/district care ☐
   c) Tertiary care ☐
   d) Central medical stores ☐

2. What is the percentage of date expired goods including breakage in the inventory at following levels of care:
   a) Primary care ☐
   b) Secondary/district care ☐
   c) Tertiary care ☐
   d) Central medical stores ☐

3. What is the extent of substandard/spurious/ falsely labeled/falsified/counterfeit medicinal products (SSFFC) in your country?

   a) <5% ☐
   b) 5 -10% ☐
   c) 10-20% ☐
   d) >20% ☐

---

4. Is there a return good policy?

   YES ☐ NO ☐

5. What is the level of implementation of return good policy?

   a) Primary care ☐
   b) Secondary/district care ☐
   c) Tertiary care ☐
   d) Central medical stores ☐

6. What is the main reason for return good policy? (rate these from 1 to 4 where 1 means the most common reason)

   a) Change of prescription by the prescriber ☐
   b) Date expired products ☐
   c) SSFFC ☐
   d) Damaged stocks ☐

VI. Standard Treatment Guidelines (STGs)

1. Does your country have state endorsed Standard treatment guidelines (STGs)?

   YES ☐ NO ☐

If YES, specify the categories for which state endorsed STGs exist:

a) Tuberculosis ☐

b) HIV-AIDS ☐

c) Malaria ☐

d) Diabetes ☐

e) Hypertension ☐

f) Others ☐

_____

_____

_____

VII. Prescribing and Dispensing Habits

1. What is the common prescribing habit:
   a) Generic prescribing ☐
   b) Trade name prescribing ☐
   c) Prescribing based on essential medicine list ☐
2. Medicines are dispensed by?
   a) Private setting: Pharmacists ☐ Informal Dispensers ☐
   b) Public setting: Pharmacists ☐ Informal Dispensers ☐
3. Are prescription only medicines dispensed strictly against prescription?
   a) Yes ☐
   b) No ☐

VIII. Rational Drug Use

1. What is the extent (%) of compounding, loose dispensing versus prepackaged dispensing?
   a. Compounding ☐
   b. Loose dispensing ☐
   c. Prepackaged dispensing ☐
2. Does health department/ministry of the country has a Rational Use of Medicine (RUM) unit?
   YES ☐ NO ☐
3. Number of pharmacists in the RUM unit:
   _____
4. Is Pharmacist involved at national level in patient education on how to use medicines?
   YES ☐ NO ☐
5. Does your country have a nationally functional Pharmacovigilance program?
   YES ☐ NO ☐
6. Is Pharmacist involved in Pharmacovigilance program at national level?
   YES ☐ NO ☐
   If yes, at what level
   a) Reporting of ADR
   b) Managing Product recalls
7. Is there an Interdisciplinary to decide medicine use policy?
   YES ☐ NO ☐
8. If yes, does this group involves pharmacist
   YES ☐ NO ☐
9. Are the concepts of NMP and RUM taught as a part of pharmacy curriculum?
   YES ☐ NO ☐

Annexure-5

A SEARPharm Forum Regional Conference on "Assessment of Implementation of National Medicine Policies in South East Asia Region of WHO" in Partnership with Pharmaceutical Society of Sri Lanka

Colombo, Sri Lanka, 29th June, 2013

I. **June 28th, 2013**—Friday: Arrival of delegates
II. **June 29th, 2013**—Saturday : Conference
III. **June 30th, 2013**—Sunday:
Morning- Inauguration of PSSL Annual Meeting
Afternoon: SEARPharm Forum ExCo Meeting(14.00 - 16.00)
Evening: Dinner Hosted by PSSL

Annexure-5

CONFERENCE ON NATIONAL MEDICINE POLICY, 29TH JUNE, 2013 (09.00 TO 17.30)

This one day SEARPharm Forum Conference is on the development or update of National Medicine policy and legislation for pharmaceutical sector in South East Asia. It aims to share key information to enable Member Organisations to play an active role whenever National Pharmacy/Medicines Policy and Legislations are revised. The conference is held in the backdrop of FIP/WHO Workshop on Pharmaceutical Policies during FIP Centennial Congress, 2012 in Amsterdam.

REGISTRATION: 08:00 - 09:00

SESSION I : Welcome and Opening Remarks	**09:00 - 10:00**
1. *Welcome Address by Shalutha Athauda, President, PSSL*	*5 min*
2. *Address by Dani Pratomo, President SEARPharm Forum*	*5 min*
3. *Address by Kathleen Holloway, Regional Advisor, EDM, WHO-SEARP*	*10 min*
4. *Address by FIP Nominee (TBD)*	*10 min*
5. *Inaugural Address by High Official, Sri Lanka*	*10 min*
6. *Vote of Thanks, Chinta Abhayawardana, Vice-President, SEARPharm Forum*	*5 min*
Photo Session: All Participants	*5 min*
TEA	**10:00-10:30**
SESSION II: Development, Monitoring and Implementation of National Medicine Policy	**10:30 -13:00**
Co-Chairs: Kathleen Holloway; Shalutha Athauda	
7. *Current status of National Medicine Policies in South East Asia: Presentation of a survey report, Anita Kotwani & Pradeep Mishra, Professional Secretary, SEARPharm Forum*	*45 min*
Role of Pharmacists in National Medicine Policy in relation to following key components: a) Legislation, Regulation and Guidelines and Monitoring & Evaluation (Nasser Zahedee, Bangladesh) b) Selection of Drugs: National Essential Medicine List and National Formulary (Baburam Humagain, Nepal) c) Supply (Including Procurement and Production issues) and Quality Assurance (Chamila Samarsinghe, Sri Lanka) d) Prescribing and Dispensing Habits and Rational Drug Use (Anita Kotwani, India) e) Human Resource Development and Technical Cooperation among countries (J. A. S. Giri, India)	*20 min each*

Annexure-5

LUNCH	**13:00-14:00**
SESSION III: *Group Exercise: Participants will be divided into five groups. Each group will deliberate and propose recommendations on the Role of Pharmacists in National Medicine Policy in relation to the key components listed above. The group leaders will be the rapporteurs.*	**14:00-15:30**
TEA	**15:30-16:00**
SESSION IV: Finalization and Way Forward	**16:00-17:30**
Co-Chairs: Teera Chakajnarodom; Dani Pratomo	
8. Group work output presented by rapporteurs	*10 min each*
9. Conclusion and Way Forward by Chairs	*30 min*

Annexure-6

FINAL REPORT

AUGUST, 2012

FIP CHALLENGE ON TB ROUND 1

Compilation of a reference document of Pharmacists' innovative approaches to target early detection, delivery of DOTS, rational use, public education in TB care and control in India

SEARPharm Forum

Group Photograph after signing of MoU between stakeholders at SEARPharm Forum Seminar at New Delhi, April 2012

FINAL REPORT

AUGUST, 2012

FIP CHALLENGE ON TB ROUND 1

Compilation of a reference document of Pharmacists' innovative approaches to target early detection, delivery of DOTS, rational use, public education in TB care and control in India

SEARPharm Forum

TABLE OF CONTENTS

ABBREVIATIONS

AIIMS	All Indian Institute of Medical Sciences
AIOCD	All Indian Organisation of Chemists and Druggists
CDDEP	Center for Disease Dynamics, Economics & Policy
CPA	Commonwealth Pharmaceutical Association
CPD	Continuing Professional Development
CSR	Corporate Social Responsibility
DMC	Designated Microscopy Center
DOTS	Directly Observed Treatment, Short-Course
DSPRUD	Delhi Society for Promotion of Rational Use of Drugs
DTO	District TB Officers
FDC	Fixed Dose Combinations
FIP	International Pharmaceutical Federation
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
IIHMR	Indian Institute of Health Management Research
IMA	Indian Medical Association
IPA	Indian Pharmaceutical Association
IPA-SF	Indian Pharmaceutical Association-Students Forum
IPSF	International Pharmaceutical Students' Federation
ISTC	International Standards for TB Care
MDG	Millennium Development Goals
MDR-TB	Multi-Drug-Resistant Tuberculosis
MoHFW	Ministry of Health and Family Welfare
MoU	Memorandum Of Understanding
MSCDA	Maharashtra State Chemist and Druggist Association
NGO	Non-Governmental Organisation
NIPER	National Institute for Pharmaceutical Education and Research
NPAs	National Pharmacy Associations
NRHM	National Rural Health Mission
NSP CDR	New Smear Positive Case Detection Rate
NSS	National Sample Survey
NTP	National Tuberculosis Program
OTC	Over The Counter
PCI	Pharmacy Council of India
PERD	B. V. Patel Pharmaceutical Education and Research Development Centre
PPM	Public-Private Mix
PPP	Public Private Partnership
RNTCP	Revised National Tuberculosis Program
SOP	Standard Operating Procedures
SPF	SEARPharm Forum
TB	Tuberculosis
TPSA	Tracing Pharmaceutical in South Asia Project
WHO	World Health Organization
WHO-CO	World Health Organization- Country Office
WHO-SEARO	World Health Organization- Regional Office for South East Asia
XDR-TB	Extensively Drug-Resistant Tuberculosis

1. EXECUTIVE SUMMARY

India suffers more Tuberculosis (TB) cases than any other country in the world. The 1.9 million incident cases in 2009 represented one fifth of the global burden. In India, 50-80% of TB patients seek care in the private sector. It has been internationally recognized that public-private partnerships (PPP) are now necessary for TB control in several high prevalence countries.

The private sector comprises of all providers who operate outside the public sector and whose aim is to treat illness or prevent disease. The retail pharmacies fall in private sector. Although in recent years some innovative initiatives have been emerging, the concept of involving **Pharmacists** is relatively new and the enormous potential of this resource remains largely untapped in India. Therefore, it is necessary to look for such initiatives taken by **Pharmacists** in the vast nook and corners of India and document these. There are more than 700,000 registered **Pharmacists** practicing in the country. These **Pharmacists** can be made stakeholders in TB control.

The International Pharmaceutical Federation (FIP) established a Joint Statement with the World Health Organization (WHO) on the role of pharmacist in **TB Care and Control** at the World Congress at Hyderabad in 2011. This joint document has drawn up a set of Guiding Principles for National Tuberculosis Programs (NTPs) and National Pharmacy Associations (NPAs) on the approaches in the fight against TB and MDR-TB. At the same World Congress, the FIP round table was conducted for engaging the pharmaceutical sector in TB control in India. The Round Table made recommendations on each of the seven collaborative actions mentioned in the Joint Statement..

The FIP Challenge on TB Round 1 project was set up to find *inter alia* prevailing practices and prepare a **Reference Document** on **Pharmacists**' innovative approaches to target early **Detection**, delivery of **DOTS**, rational use, **Public Education** in **TB Care and Control** in India. The scope of the **Reference Document** was to establish an evidence base for pharmacist's interventions and specific roles in delivering safe, quality and cost-effective care for TB patients. The **Reference Document** collected case studies on outcomes and processes on **TB Care and Control** activities in community & **Hospital** pharmacy, and industry & other practice settings, so as to promote harmonization, alignment and effective collaboration of **Pharmacists**' involvement in TB care at state and national levels. The FIP Challenge on TB Round 1 project showed that **Pharmacists** involvement in India in prevention and care is still at a nascent stage. However, it very clearly brought out that there is an immense potential for **Pharmacists** in India to participate in the Revised National Tuberculosis Program and contribute to the different areas of the intervention.

The major outcome of the project was realized when a Memorandum of Understanding (**MoU**) between the Revised National Tuberculosis Control Programme (RNTCP) and relevant stakeholders *viz.* IPA, All India Organization of Chemists and Druggists (AIOCD) , Pharmacy Council of India (PCI) and SEARPharm Forum on the role of **Pharmacists** in **TB Care and Control** in India. The memorandum of understanding has outlined **Pharmacists** role in national **TB Care and Control** thus paving the way for **Pharmacists** in India to be involved in the National Health Programme for the first time.

Keywords*: *Pharmacists, Reference Document, DOTS, Detection, Public Education, Working Group, TB Care and Control, Hospital, Public Education, Adherence, PPM, MoU, Stepwise Approach

"In SEARPharm Forum we have to keep in mind both Opportunities as well as Barriers. Population is increasing faster in the South East Asia region. If curriculum reform is implemented today the human resource will be utilized especially for elderly population in the next decade."

Teera Chakajnarodom, President, SEARPharm Forum

"The IPA has worked towards pharmacist becoming DOTS providers. Still there is lot of work to do to get more pharmacist to become DOTS providers in the entire country. The Pharmacist have to take an active part by their knowledge information to provide value added services in providing necessary assistance from the diagnostic and treatment services. A suggestion that sputum collection provision can be made at pharmacist level is quite laudable and help sending the same for further examination and thus help RNTCP. "

Dr. C. G. K. Murty, President, Indian Pharmaceutical Association

"It was necessary to define the role of pharmacists in different public health programs including TB. In defining the competencies that are required pharmacists have to be made more aware about the disease profile so that they can play an effective role in public health. The prescribers and the dispensers should work in team to be able to bring this change. A large number of changes are envisaged in the pharmacy education regulation 2011 which will also include knowledge on the public health. Pharmacists are also shy to carry up patient counseling due to lack of knowledge and physicians do not have time for counseling. PCI is working so that the image of community pharmacists can be transformed from mere dispensers of medicines to an effective patient counselor."

Prof. B. Suresh, President, Pharmacy Council of India

"The partnership will be new beginning in terms of involving pharmacists as DOTS provider and sputum collector as well as for monitoring of treatment. RNTCP will provide small incentive to the pharmacists after successful completion of DOTS therapy for each patient."

Dr. Ashok Kumar, DDG, RNTCP, Central TB Division (MoHFW)

2. ACKNOWLEDGEMENT

This **Reference Document** was developed in 2012 by **India Working Group** on **Pharmacists**' innovative approaches to target early **Detection**, delivery of **DOTS**, rational use, **Public Education** in **TB Care and Control** in India.

The **Working Group** members were

1. Prafull D. Sheth (FIP)
2. Teera Chakajnarodom (SEARPharm Forum)
3. C. G. K. Murty (IPA)
4. Raj Vaidya (IPA)
5. Manjiri Gharat (IPA)
6. Pradeep Mishra (SEARPharm Forum)
7. Mohammad Ahmed Khan (SEARPharm Forum)
8. Alok Ghosh (Lupin Labs)
9. Kapil M. Khambolja (Novartis)
10. M. Mitra (Former Deputy Drug Controller, India)
11. N. K. Gurbani (IIHMR)
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13. R. N. Gupta (IPA)
14. Satish Kaipilyawar (PATH)
15. Subhash Mandal (IPA)
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This document benefitted from the review of the following members:

1. Nigorsulton Muzafarova (WHO-SEARO)
2. R. Parmeshwar (DSPRUD)
3. Sunita Prasad (Lilly-MDR)
4. Aditi Nigam (CDDEP)
5. Pramil Tiwari (NIPER)
6. C. J. Shishoo (PERD)
7. G. P. Mohanta (Annamalai University)

SEARPharm Forum thanks all the contributors for sharing their expertise and for helping to develop this **Reference Document**.

SEARPharm Forum profusely thanks Xuan Hao (FIP) and Ying Chan (FIP) for their guidance and encouragement to the national **Working Group**.

This work was made possible with the funding support of FIP.

3. INDIA'S NATIONAL SITUATION SITUATION

India suffers more TB cases than any other country in the world. The 1.9 million incident cases in 2009 represented one fifth of the global burden. In India, 50-80% of TB patients seek care in the private sector. It has been internationally recognized that public-private partnerships are now necessary for TB control in several high prevalence countries.

Over the years, India has made great strides in improving access to Tuberculosis **Detection** and treatment across the country. India's Revised National Tuberculosis Control Programme (RNTCP), based on **DOTS** strategy, has been implemented through general health system of the states under the umbrella of National Rural Health mission (NRHM) (*See Statewise data in Annexure-1*). The programme is implementing all components of WHO Stop TB Strategy 2006 and has made great strides in achieving global targets for new smear positive case **Detection** (NSP CDR) (70%) and treatment success (85%), as per the Millennium Development Goals (MDGs) and the related Stop TB Partnership's Global Plan (2006-2015).

The RNTCP has been one of the successful public health programmes in India with a highly successful **Detection** and cure rate. Recently, the programme has shifted focus to provide universal access for Total TB care. In such a scenario of universal access, the non programme service providers, both formal and informal become important stakeholders in the scheme of things. Effective involvement of these service providers would enable the programme to go through the last mile in universal access.

India still bears 21% of the global burden of incident TB cases and has the highest estimated incidence of Multi Drug Resistant-TB cases (MDR-TB) (131,000 out of global incidence of about 500,000 in 2007). Extensively Drug Resistant TB (XDR-TB) has also been reported from India. HIV prevalence among TB patients is reported to be 4.85%. With 70% of health care in India being provided by the private sector, it is of great importance that this sector is effectively engaged and included in the treatment of Tuberculosis. Private health care is rapidly expanding in India. Data from the National Sample Survey shows that the public health sector, to a large extent fails to provide the necessary outpatient services, even to the poorer sections of society. The private sector on the contrary is popular and accessible. **Pharmacists** and private physicians are seen in India as the first point of contact for a majority of illnesses.

With large scale migration in India from rural to urban settings for economic reasons, it is the urban poor who access and seek treatment for TB through private pharmacies and non–allopathic practitioners. With unregulated treatment practices, the MDR and XDR TB cases have emerged as a threat to successful TB treatment programmes. These coupled with the stigma to HIV-TB cases (which make these patients seek treatment in the comfort and anonymity of these private sector providers) has made it ever so necessary to effectively include the preferred providers of the urban for strengthening the TB programme in India and improving coverage and utilization of services. The unhealthy and cramped living conditions in urban slums leads to transmission of TB within the migrant communities much faster. It is these groups of communities which have resisted seeking treatment in formal government settings in spite of concerted efforts by various programmes for various reasons.

Public-private mix (PPM) has been suggested as the answer to improve case **Detection** and treatment. Studies have shown that lag time between first contact and referral to **DOTS** has impacted the outcome of successful treatment. Reasons for this delay are varied for different communities. Quite a few implementation projects have included training as one of their activities in the involvement of the private provider. However, past experience and evidence suggest that training without any tangible output and deliverables for the private service provider would remain an incomplete exercise and achieve nothing in the long run. Training may have to be tied up with a two pronged outcome –

i) Referral to national **DOTS** programme, or

ii) Delivery of quality services as per national guidelines.

In order to achieve both these outcomes the programmes and schemes would require attractive incentives (financial and professional) and a compliant monitoring mechanism.

Further inputs are necessary for guiding the national strategy on expansion of the existing **PPM** schemes. The reasons for low uptake require gathering of further information which might suggest the revision of the schemes. It is very necessary to differentiate the cadres of private service providers into formal (pharmacies, allopathic, non-allopathic) and the non-formal (other traditional healers and quacks).

The **Indian anti-TB market** is approximately 65 million dollars which is approximately 0.6% market share of the overall domestic drug market. This market is fragmented with 2 to 3 companies accounting for 50% of production volume and 38 companies accounting for remaining 50%. There are particular concerns regarding the bioavailability of rifampicin in Fixed Dose Combinations (FDCs) which is easily compromised if strict manufacturing procedures are not followed, or poor quality raw materials are used. If the bioavailability of rifampicin is inadequate, treatment failures and emergence of rifampicin resistant TB is possible. The role of industry is to ensure that bioavailability of rifampicin containing FDCs comply with prescribed quality assurance standards under WHOs Prequalification Programme. **(Report of the National Consultation on Developing Public Private Collaboration strategies, WHO)**

India's 700,000 retail Pharmacists offer a potential health resource. **Pharmacists** are charged by the drug regulatory authorities with the management and distribution of medicines to consumers and assuring their safety and quality. There is also an increasing recognition that providing consumers with medicines alone is not sufficient to achieve the treatment goals. To address these medication-related needs, **Pharmacists** must embrace responsibility for Good Pharmacy Practices for improving medicines-use outcomes and provide patients with value added medicines-use services. In the present scenario the entire pharma supply chain including distribution system has become very complex where so many players other than **Pharmacists** are involved. The distribution is also plagued with easy availability of prescription medicines and self medication by consumers.

Pharmacists are an important source of health advice preferred by many patients due to ease of access, , lack of waiting time, convenient opening hours, greater confidentiality in dealing with stigmatized

conditions (i.e. TB) and ability to purchase drugs in small quantities over a longer duration of the therapy.

4. FIP CHALLENGE ON TB ROUND 1

FIP's **Joint Statement** with WHO on the role of pharmacist in **TB Care and Control** has drawn up a set of collaborative actions for National Tuberculosis Programmes (NTPs) and National Pharmacy Associations (NPAs) on the approaches in the fight against TB and MDR-TB. (*See Annexur-3*) As per the Joint Statement, NPAs should co-ordinate with relevant stakeholders in setting up learning projects and supporting operational research on the role of **Pharmacists** in **TB Care and Control** within the framework of national TB control; document and share experiences and lessons learnt. This would help establish an evidence-base for developing practical guidance on strengthening the role of **Pharmacists** in **TB Care and Control**. Successful best practice models could be subsequently scaled up to national levels.

The **FIP Round Table** which was conducted during the 2011 World Congress at Hyderabad on Engaging the Pharmaceutical Sector in TB Control in India made the following **recommendations** on each of the seven collaborative actions mentioned in the Joint Statement:

Objective ONE: Provide joint stewardship in the development of policy guidance and resource.

mobilization to engage **Pharmacists** in **TB Care and Control**.

Recommendations:

- There needs to be a formal national plan or strategy to engage **Pharmacists** in the RNTCP. A Pan- India **Working Group**, led by the IPA and working in close collaboration with all stakeholders, especially AIOCD, Pharmacy Council of India and FIP South East Asia Pharmaceutical Forum, should be established as soon as possible and help develop this plan in line with the RNTCP programme objectives 2012 to 2017.
- IPA should request more clarity on the availability and applicability of NGO schemes in the RNTCP so as to apply for funding and support in scaling up projects. There is a need to discuss further how government schemes on engaging private health care providers should be used more effectively and reinforced.

Objective TWO: Undertake orientation and training of **Pharmacists** to enable them to contribute effectively to **TB Care and Control**, taking local context and needs into account.

Recommendations:

- The Pharmacy Council of India will lead the process for a review and update of the pharmacy curriculum in India, with a focus to strengthen education on the role of **Pharmacists** in **TB Care and Control**. This should also consider the wider role of **Pharmacists** in public health programmes.
- IPA and AIOCD will work together with RNTCP to ensuring continuing professional development (CPD) in training **Pharmacists** or other dispensers as **DOTS** providers under the **PPM** framework.

It is important to educate and train providers on how to detect early signs and symptoms for early referral to TB facilities.

Objective THREE: Facilitate effective contribution of **Pharmacists** to specific areas related to **TB Care and Control**

Recommendation:

- There is a need to conduct a research project on remuneration on fee-for-service models in TB care delivery. This may provide evidence and/or justification for scaling up of cost effective pharmacy-based TB services and explore effect of non-cash incentives and other key drivers for success.

Objective FOUR: Promote rational use of anti-TB medicines and ensuring that quality-assured medicines are procured and supplied and WHO recommended fixed-dose combinations are used.

Recommendations:

- RNTCP, IPA and AIOCD will help promote the nationally approved RNTCP guidelines on TB treatment and International Standards for TB Care (ISTC) in order to address irrational Prescribing of anti-TB medicines and regimens. This information should be made available on The websites of RNTCP, IPA and AIOCD. Hard copies of the guidelines should be printed and Widely distributed among all private physicians, **Pharmacists**, chemists and druggists. Translation should be made in local languages if necessary.
- IPA and RNTCP should develop a handbook on good prescribing practices for TB. Civil societies working in **TB Care and Control** can help to disseminate this resource among their health workers.
- All anti-TB medicines recommended in RNTCP regimens should be WHO pre-qualified.

Objective FIVE: Maintain a continuous dialogue with health care providers to rationalize and strengthen their TB management practices.

Recommendations:

- Professional associations such as IPA and IMA should send a strong message to their members that as health professionals, they should adhere to RNTCP guidelines when treating TB or refer patients to national TB facilities and never dispense anti-TB medicines without prescriptions.
- How to promote good prescribing practices in TB? How to do the right thing? Scaling up training of **Pharmacists** and chemists. Choose one or two models that work in India that promotes good prescribing practices consider support systems such as incentives. RNTCP does not have capacity to do it all but there is the potential to engage trade and professional associations to work on the same priorities of the RNTCP. How can we make this work? Provide better care that does not disrupt the business model that exists.

Objective SIX: Engage **Pharmacists** and their associations to be a part of the Stop TB Partnership's efforts at local, national and global levels.

Recommendation:

- In terms of resource mobilization, it is important to conduct a mapping of public funds for TB and this information needs to be then communicated to stakeholders, civil society and NGOs on how these funds may be tapped into.

Objective SEVEN: Develop and implement a system to monitor, evaluate and improve collaboration between national tuberculosis programmes and national pharmacy associations.

Recommendation:

- **The Pan-India Working Group** should begin documentation and sharing of experiences and lessons learnt in order to establish an evidence-base on the role of **Pharmacists** in **TB Care and Control** and also help identify and scale-up successful best practice models.

On **World TB Day** 2011, the International Pharmaceutical Federation (FIP) intensified its global commitment to stimulate national and local efforts aimed at full involvement of **Pharmacists** in **TB Care and Control** by announcing a series of new initiatives supported by the Lilly MDR-TB Partnership. This is a unique public-private collaborative network of range of partners including the World Health Organization (WHO), private and public healthcare professionals, academics, patient and community-advocacy groups, international organizations, and producers of medicines in developing regions.

FIP recognizes that systematic efforts will be required to enable **Pharmacists** to achieve their full potential in contributing to **TB Care and Control**. This may include sensitizing both national TB programmes and national pharmaceutical associations on the benefits of working together. Country specific models of collaboration on the ground may then have to be developed, tried out, documented and scaled up. **Pharmacists** can contribute significantly to different tasks essential for quality **TB Care and Control**. To this effect, FIP launched the **first ever FIP TB Challenge Round-1** on innovative approaches to target the following interventions:

- Early identification of TB suspects and referral activities for diagnosis thereby reducing delays In diagnosis, saving costs of care and contributing to increasing case **Detection**.
- Support delivery of **DOTS** treatment focusing on training of **Pharmacists** and patient **Adherence**, so as to enhance treatment success, reducing defaults and contributing to cutting the disease transmission.
- improving rational use of anti-TB medicines and contributing to preventing emergence of drug resistance.
- **Public Education** and communication campaigns on TB and MDR-TB awareness

In September 2011 SPF and IPA entered into a **collaborative partnership with FIP** and undertook a project under FIP Challenge on TB round-1 to compile a **Reference Document** of **Pharmacists**' innovative approaches to target early **Detection**, delivery of **DOTS**, rational use, **Public Education** in **TB Care and Control** in India.

5. METHOD USED

a. NATIONAL WORKING GROUP

In line with the objective, a national **Working Group** of **Pharmacists** was constituted to create evidence of the work actually being done by the **Pharmacists** in each of the interventions defined. (*See Annexure-2*).

b. TERMS OF REFERENCE

This project proposes development of a **Reference Document** of **Pharmacists**' innovative approaches to target early **Detection**, delivery of **DOTS**, rational use, **Public Education** in **TB Care and Control** in India. The IPA will utilize the **Reference Document** and create a joint document between the NTP and IPA on the role of **Pharmacists** in **TB Care and Control** in India.

The scope of the **Reference Document** is to establish the evidence base for pharmacist's interventions and specific roles in delivering safe, quality and cost-effective care for TB patients. The **Reference Document** will collect state wise case studies on outcomes and processes on **TB Care and Control** activities in community, **Hospital** pharmacy and other practice settings, so as to promote harmonization, alignment and effective collaboration of **Pharmacists**' involvement in TB care at state and national levels.

When considering priority actions for **Pharmacists** in quality assurance of their services there is a need to establish definitions and recommendations on appropriate standards of care and the measurements of quality outcomes at country level, entry level practice skills, continuing education, and overall professional development of **Pharmacists** in TB, training and partnerships with other healthcare professions and collaboration, monitoring and supervision of other healthcare workers where appropriate.

The reference paper would serve to assist IPA in developing strategies to support organization's involvement in implementing FIP/WHO Joint Statement in particular to identify practical ways to engage IPA in planning through National Policy and decision making process in the implementation of RNTCP plans. These include initiatives to support advocacy, country level support, promotion of effective interventions and capacity building at country level. As accessible and cost effective source for pharmaceutical care, the reference paper would essentially make the case based on evidence that **Pharmacists** can make a difference in the TB initiative.

The reference paper would address specific competencies of **Pharmacists** who participate in the care of Indian population.

c. STEPWISE APPROACH

Objective	Activity	Quantitative and verifiable outcome	Timeline
1. Development of National **Working Group**	Identification and setting up of pan-India **Working Group**.	Terms of reference-scope and structure of the **Reference Document** Approaches to be used for this document	Dec, 2011
2. India's National Situation (state wise)	Demographic data	State wise breakup of prevailing situation	June, 2012
	Public Private Mix activities	Database	June, 2012
3. Early identification of TB suspects and referral activities for diagnosis thereby reducing delays in diagnosis, saving costs of care and contributing to increasing case **Detection**.	Prevailing methods for TB diagnosis	Guidelines for Early **Detection**	June, 2012
	Recent Trends and innovation in TB diagnosis	Guidelines for use of novel methods for early **Detection**	June, 2012
	Collection of references and case studies of **Pharmacists**' work.	Evidence of Pharmacist role in Early **Detection** of TB in community, **Hospital** and other practice settings.	March, 2012
4. Support effective medication therapy including **DOTS** treatment focusing on training of **Pharmacists** and patients on **Adherence**, so as to enhance treatment success, reducing defaults and contributing to cutting the disease transmission.	Collection of references and case studies of **Pharmacists**' work.	Evidence of Pharmacist role in effective medication therapy management in community, **Hospital** and other practice settings.	March, 2012
5. Improving rational use of anti-TB medicines and contributing to preventing emergence of drug resistance.	Collection of references and case studies of **Pharmacists**' work in promoting rational use of anti-TB medicines	Evidence of Pharmacist role in promoting rational use of anti-TB medicines in community, **Hospital** and other practice settings.	March, 2012
6. **Public Education** and communication campaigns on TB and MDR-TB awareness.	Collection of references and case studies of **Pharmacists**' work in **Public Education** and communication campaigns on TB and MDR-TB awareness	Evidence of Pharmacist role in patient education and improving **Pharmacists**' professional performance in community, **Hospital** and other practice settings. Role of professional organizations in patient education and contributing to improving effectiveness of healthcare system and Public health	March, 2012
7. Preparation of the final report and database		e-database	August, 2012

6. CASE STUDIES ON PHARMACISTS' WORK

Since 2001, the South East Asian FIP-WHO forum of pharmaceutical associations (SEARPharm Forum, SPF) has been emphasizing **Pharmacists**' role in WHO programmes in prevention of HIV-AIDS and Tuberculosis.

The Indian Pharmaceutical Association (IPA), a member of SPF and FIP is the premier professional association of **Pharmacists** in India. In 2005, a TB fact card project was launched by IPA in Mumbai. This pilot project was a collaborative project of IPA with Commonwealth Pharmaceutical Association (CPA) and International Pharmaceutical Students' Federation (IPSF). The project was supported by Maharashtra State Chemist and Druggist Association (MSCDA) and Mumbai District TB Control Society. The project activities involved creating awareness among TB patients by use of a TB Fact Card made in local languages. The project reached out over 5000 patients. Another major breakthrough was participation of **Pharmacists** as **DOTS** providers. This is an excellent example of Public Private Mix (**PPM**) effort for the improvement of community health.

In November, 2007, SPF and IPA with WHO India country office examined the role of **Pharmacists** in healthcare systems in India in different practice settings. This meeting was attended by managers of the Revised National Tuberculosis Control Programme (RNTCP) and advocated that the services of community **Pharmacists** should be utilized in early **Detection**, referring, counseling and in **DOTS** strategy implementation programme of RNTCP.

In January, 2010, the FIP, SPF and IPA entered into collaborative participation with Eli Lilly MDR-TB Partnership. The understanding between Eli Lilly and SPF was facilitated by FIP. It is unique public-private collaboration with the support of Lilly MDR TB in partnership with Government, All India Organization of Chemists and Druggists (AIOCD) and IPA in India.

Accordingly, a pilot project was launched to train **Pharmacists** for the **DOTS** protocol: case **Detection** & referral, medication management, counseling and overall monitoring of the treatment in selected hotspots of Mumbai and subsequently scaling up advocacy campaigns in other 4 to 5 major cities of India.

In February 2011, **WHO's National Consultation on developing public-private collaboration strategies for RNTCP** invited FIP, SPF and IPA along with manufacturers of TB medicines and regulators to examine the role of private pharmacies in rapid TB diagnosis and full completion of TB treatment.

1. DOTS TB Pharmacist Through TB Fact Card Project in Mumbai

Pharma Times *- Vol 42 - No. 06 - June 2010*

Community (Retail) **Pharmacists**, being first port of call health professional, are in unique position to fight against TB but their involvement for the said purpose had been rare. One of the first attempts of involving **Pharmacists** for community TB awareness was TB Fact Card project (Year 2005-06) in Mumbai, a collaborative project of Indian Pharmaceutical Association (IPA) with Commonwealth **Pharmacists** Association (CPA) and International Pharmaceutical Students' Federation (IPSF). After its successful completion, IPA developed an innovative public-private partnership by involving retail **Pharmacists** in **DOTS** services. Participation of retail **Pharmacists** in the national health program i.e. Revised National Tuberculosis Control Program (RNTCP) had been quite uncommon till then. This public-private mix (**PPM**) activity is now scaled up in Mumbai by the International Pharmaceutical Federation (FIP), SEARPharm Forum (SPF) along with IPA. This project is being funded by Lilly MDR TB partnership & is well supported by the Maharashtra State Chemists & Druggists Association & City/District TB Control Societies.

Total 120 **Pharmacists** in Mumbai, Navi Mumbai and Kalyan-Dombivli areas are trained with the help of City TB authorities. **Pharmacists** have been trained for **DOTS** protocols by the Corporation City TB officers. These trained **Pharmacists** will help in **Detection** and referral of chest symptomatic (lung TB) cases, will create awareness about TB and **DOTS** in the society, and will act as **DOTS** medicine providers. TB information leaflet for consumers have been made in English, Hindi and Marathi. These leaflets will be distributed by the participating **Pharmacists** to create awareness about causes of TB, its prevention, precautions, treatment, **DOTS** facility etc. The project is of 2 years duration.

The ultimate goal of the project partners is to advocate and scale up this pharmacist centric model for nationwide implementation which will help to strengthen the work of RNTCP. This will widen the **DOTS** network, increase access to the medicines and will contribute to reduce the chances of MDR TB cases.

2. Public-private partnership in tuberculosis control: experience in Hyderabad

Int J Tuberc Lung Dis. 2001 Apr;5(4):354-9.

The area selected is a poor section of Hyderabad city in the State of Andhra Pradesh, India. Most employed residents work as daily wage laborers or street hawkers. There are virtually no government health facilities in the area covered by this project. A microscopy centre was established at a non-profit **Hospital**. A **Hospital** physician visited all identified allopathic and non-allopathic private practitioners at their offices, encouraged them to refer patients, and gave specific, detailed feedback on each patient referred, including recommendations for management of non-tuberculous lung conditions. After diagnosis, patients received directly observed treatment free of charge at either the trust **Hospital** or at 30 conveniently located small **Hospital**s operated by local

private practitioners. Nursing and/or pharmacy staff at these small **Hospital**s provided treatment observation after hands-on training by staff from Mahavir **Hospital**. No incentives other than repeated contacts were used to encourage physicians or their staff to refer patients or to provide treatment observation. Diagnosis, treatment, recording, reporting and case and outcome definitions were done as per **DOTS** policies.

Private practitioners' nursing and pharmacy staff were oriented in treatment observation policies, and provided treatment observation. To facilitate patient **Adherence** and reduce patient travel costs, centers for treatment observation were established at 30 small, conveniently located private **Hospital**s (known as nursing homes) and NGOs. The administrators of these small private **Hospital**s allowed their premises to be used for treatment observation and offered the services of a night nurse or pharmacist free of charge as a treatment observer. The treatment observer was taught how to maintain treatment cards and account for drugs.

3. Rifampicin in the Context of Treatment & Control of TB at AIIMS, Delhi

Dr. Sunil Kaul, Universal Access and Rational Therapy- A Dissemination Workshop on Tracing Pharmaceutical in South Asia (TPSA) Project, Centre for Health and Social Justice, Undated

A Cardiologist contracted TB soon after completing his DM at AIIMS, India's most prestigious college. When patient tried to start the short course chemotherapy, he just could not tolerate Rifampicin. The gastritis and vomiting made him panic. When the patient tried to return the drug to the pharmacist, the pharmacist advised him to start at a very small dose and to gradually increase the dose. The trick helped him while the advice of experts and academics at AIIMS and the experience were of no use.

4. Shopkeeper's Contribution to Stop TB, Gujarat

Success Stories, TB India, RNTCP at http://www.tbcindia.org/success.asp, 2008

Idrish Abdula Ravda is a DOT provider from Chhaya, a place in Porbandar, Gujarat. He is a shopkeeper and is well known in his area. He likes serving people and has been working as a DOT provider since 2003. He takes out time to provide medicine and has been working as a DOT provider to 98 patients till date. He has successfully cured 40 patients and 38 patients have completed the treatment. Many of the WHO consultants and other officials who have visited his DOT Centre are impressed with his work.

5. Public Sector Undertaking Collaborates to "Stop TB", Jharkhand

Success Stories, TB India, RNTCP at http://www.tbcindia.org/success.asp, 2008

Hindustan Copper Ltd. is one of the oldest copper mines in India and was established in 1924 as Indian Copper Corp Ltd (HCL). It was converted to HCL in 1972. It also runs a **Hospital** for its employees and ex-employees. The **Hospital** with 80 beds has a fully functional lab, an operation

theatre and an X-Ray unit. Fourteen doctors including four specialists, 21 nurses and 62 paramedical staff work here. The company is also involved in community outreach programs as part of its Corporate Social Responsibility (CSR) and conducts regular health camps in the surrounding villages every month. The **Hospital** is in remote area and caters to a large rural population. Keeping this in mind a DMC and **DOTS** centre has also been started in the **Hospital** since 29th October, 2007. Two doctors, four **Pharmacists** and three lab technicians have been trained in RNTCP at the DTC Jamshedpur. The whole program is running under the leadership of the Chief Medical Superintendent, Dr. D.K. Singh, whose enthusiastic response and initiative has made this program possible in HCL. He was responsible for encouraging his staff to take active part in getting trained and following RNTCP norms.

6. **Tuberculosis Awareness Campaign by Pharmacy Students, Mumbai**

Manjiri Gharat,http://www.fip.org/www/index.php?page=latest_news &news=newsitem & news item=44, 2012

Indian Pharmaceutical Association (IPA), the premier professional association of **Pharmacists** in India has been working in area of Tuberculosis which is a major health problem for the country. IPA has been innovative in involving retail **Pharmacists** in community awareness of TB & has successfully carried out TB Fact Card project in Mumbai. IPA is also leading the way to involve retail **Pharmacists** in national health program (RNTCP) of the Government and developing model of **DOTS** Provider **Pharmacists**. Now IPA, has come up with another model to create awareness in the community and it is by involving pharmacy students as Community Educators. Under the leadership of President Mr. Subodh Priolkar and Hon. Secretary Mr S. D. Joag, IPA has recently formed Students Forum (IPA-SF), a national level association of pharmacy students under IPA.

Tuberculosis awareness campaign by IPA-SF on World TB Day, 24th March, marks the beginning of IPA-SF's community health activities. Students are our real strength & IPA plans to increase its community outreach activities through this large pool of the enthusiastic budding **Pharmacists**, says Mrs. Manjiri Gharat Hon. Secretary of Community Pharmacy Division of IPA who has initiated this model. IPA–SF students reached out to the community in various parts of Mumbai, & Navi Mumbai & delivered the talk about the disease, its symptoms, its prevention, treatment, Governments **DOTS** program. The students also distributed informative material on TB. These students have been trained by Mumbai District TB Control Society officials Dr Rasalkar & Dr Naik.

Students reached out to factory and construction workers, Municipal Corporation school children and residential complexes. At each place they received excellent response and each place people curiously asked plenty of queries which were well satisfied by these "TB educators"

IPA SF coordinators Karvin Mehta, Manish Rathi and entire team of 50 students has worked hard to organize this activity on 24th March and are determined to carry it through the year as on-going activity. Thus this first attempt of IPA-SF to conduct public health campaign was highly successful & has encouraged students to work enthusiastically on consistent basis and carry it to a national level.

7. DOTS an effort towards TB free Delhi

*'New Paradigm in TB Control through Involvement of **Pharmacists** in Delhi', Advocacy Workshop by Govt. of Delhi, 2010*

Delhi **DOTS** program has started a new initiative to rope in the Pharmacist and Drug Shop owners to bring uncovered TB cases into the **DOTS** fold. In order to achieve this objective, a sensitization program for the involvement of the new stake holders was planned. An advocacy workshop was conducted at New Delhi TB Centre to garner the support of **Pharmacists** and drug shop owners in providing access to **DOTS** in the community. The objectives of the workshop was-

To set up a platform for partnership between Revised National TB Control Program, Drug Control Department -Government of Delhi and Retail Chemists/Wholesale Dealers for effective referral of TB suspects for diagnosis and treatment to the **DOTS** system.

To promote rational use of Anti-TB Drugs sale in Delhi- by sensitizing the Retail Chemists to refrain from selling Anti-TB drugs without the prescription of a Registered Medical Practitioner.

Increase access to RNTCP at community level- **Pharmacists** being accessible and acceptable to the community can help in ensuring treatment **Adherence** by acting as treatment providers

Promotion of IEC on TB and **DOTS** through private pharmacies- **Pharmacists** have a valuable public health role in promoting community awareness of tuberculosis, particularly in reducing the stigma and discrimination often associated with the disease. They can also counsel patients on proper use of their medication leading to greater patient involvement in treatment and compliance.

The participants included office of Drug Controller General of India, Drug Controller Delhi, Drug Inspectors, Retail Pharmacist of all five Zones in Delhi, All India Organization of Chemists and Druggists, Indian Pharmacy Graduates Association, Indian PharmaceuticalAssociation and Registrar Delhi Pharmacy Council. The **Pharmacists** were addressed by Hon'ble Minister of Health, Government of Delhi- Dr. Kiran Wallia, DDG(TB)- Dr. L. S. Chauhan, MO(WHO)- Dr. Puneet Dewan, Drug Controller Delhi - Mr. Manoj Kumar and STO Delhi -Dr. R. P. Vashist.

Hon'ble Minister in her address acknowledged the efforts of Central Government, WHO and State Government in the involvement of community pharmacist for effective referral of TB suspects to the **DOTS** system and to promote rational use of Anti-TB Drugs sale in Delhi.

8. Involving the Pharmacists in RNTCP, Andhra Pradesh

Success Stories from the States, RNTCP Annual Status Report, 2011

The State TB Control Society, Andhra Pradesh has taken the initiative to strengthen the involvement of **Pharmacists** in the TB control program and to develop a referral mechanism of TB symptomatic from these **Pharmacists**, to bring TB care services more accessible to all, with technical support of PATH and funding by USAID. Initially the program is piloted in Ongole TB unit in Prakasam District, Andhra Pradesh. On 24th March 2010, a **MoU** was signed between District TB Control Society, Prakasam in the presence of Chairman and Collector, Prakasam district and the Ongole Retail Chemists and Druggist Association, Ongole. The document was also signed by the Assistant Director, Drug Control Office, Prakasam district.

In the initial round all the **Pharmacists** of the Ongole were sensitized on the need for TB control. 79 **Pharmacists** have given their consent to voluntarily participate in the TB control efforts and to refer any symptomatic to the nearest DMC. Later in a phased manner, all the **Pharmacists** were trained on need for TB control, identification of symptomatic, filling up of the referral slips. Over the last two months 48 TB symptomatic were referred by these **Pharmacists** and 42 have under gone sputum diagnosis and two were found affected by TB.

9. Engaging Pharmacists through Lilly, Mumbai

Success Stories from the States, RNTCP Annual Status Report, 2011

International Pharmaceutical Federation (FIP), SEARPharm Forum (FIP-WHO Forum of National pharmaceutical Associations of South East Asia) (SPF) and Indian Pharmaceutical Association (IPA) with support of Lilly MDR TB partnership have launched a "**DOTS** TB Pharmacist Project" in Mumbai. The project involves private retail **Pharmacists** (at the chemist shops) to deliver DOT services and thus TB patients can have easier access to the treatment. The project is being implemented with the help of local Chemist Associations and City/District TB authorities. Around 130 **Pharmacists** in Mumbai and Thane district are trained with the help of City TB authorities. The key role of **Pharmacists** is case **Detection**, case referral for diagnosis (sputum test), awareness and counseling using TB information leaflets, developed in local languages and Provision of DOT medicines at the Pharmacy. The project will be spread to 4 more cites in India and plans to engage around 500 more **Pharmacists** by the end of 2011.

10. Drug Logistics Management, Pune

Success Stories from the States, RNTCP Annual Status Report, 2011

Drug requirements, consumption and stock positions, both at State and district levels are monitored at the Central TB Division through the Quarterly Reports submitted by the districts. The 1st Line Anti-TB Drugs procured are stored at the six Government Medical Store Depots (GMSDs) across the country and issued to the States based on the Quarterly District Program Management Reports and

the monthly State Drug Stores (SDS) Reports. The States are required to maintain defined buffer stocks at each levels i.e., at the PHIs, TUs, DTCs & the SDS. The District Quarterly Reports are analyzed in detail at CTD and any discrepancies arising are notified to the concerned districts & States for necessary corrections. For long-term sustainability of the program, decentralization of inventory management practices is very important. To ensure that the States are able to manage their drug logistics as per RNTCP guidelines, regular trainings & re-trainings on Drug Logistics Management were conducted by Central TB Division for the State & district level staff during the year. These trainings were imparted to State level officials, District TB Officers (DTOs), State and District level **Pharmacists** along with respective RNTCP Medical Consultants. Such trainings were conducted for the officials in Madhya Pradesh, Kerala, Orissa, Maharashtra, Tamil Nadu, Puducherry, A & N Islands, Punjab and Chandigarh. In addition, all the RNTCP Medical Consultants were also sensitized to Drug Logistics Management practices during the Biannual National Review Meeting held at Gurgaon, Haryana in January, 2010. About 450 RNTCP officials/Consultants have been trained during the year on Drug Logistics Management. The DTOs are expected to further train their sub-district level staff involved in drug logistics in their respective districts. To assess the impact of such trainings, CTD is also regularly re-visiting some of the States already trained. Jharkhand, Uttar Pradesh, Assam and Bihar were visited during the year by teams from CTD. Some improvements have been noticed but the lack of commitment by concerned officials at State and District levels is still seen as a major drawback. Some of the common observations noticed are:

1. Poor drug storage conditions &and lack of infrastructure at the drug store
2. Lack of contracted transportation arrangements from SDS to district drug stores
3. No full time pharmacist/store-keeper at the SDS and no designated officer to monitor drug logistics activities in the states visited.
4. No system of trainings/re-trainings conducted by the states visited for Drug Logistics Management.
5. Logistics management of 2nd Line drugs is still a challenge under **DOTS**-Plus in RNTCP. Cycloserine and Ethionamide with a short- shelf life require continuous monitoring and regular Inter-State transfers to ensure maximum utilization and minimum expiry of these drugs. Currently, 10 States viz Andhra Pradesh, Delhi, Haryana, Gujarat, Kerala, Maharashtra, Orissa, Rajasthan, West Bengal & Tamil Nadu have already implemented the **DOTS**-Plus program in their respective States and more states are preparing to start the treatment services under **DOTS**-Plus during the next year. Training on 2nd line drug logistics is also being imparted during the regular trainings on Drug Logistics Management to State & district level staff. The same has been included in the Standard Operating Procedures (SOP) Manual for both State and District Drug Stores.

11. Private pharmacies in tuberculosis control : Chennai experience

Int J Tuberc Lung Dis. 2009 Jan;13(1):112-8.

Resource Group for Education and Advocacy for Community Health (REACH) lead project in Chennai sensitized **Pharmacists** through sensitization workshop /one to one interviews. The sensitization focused on guidance for referral of chest symptomatic patients to REACH or the nearest government microscopy center or a private doctor for diagnosis, guidance for referral of patients who bought ATT from their pharmacies. Posters publicizing the availability of free drugs for TB through **DOTS** were distributed to the **Pharmacists** for display. Advocacy and counseling of patients are needed for regular medication by the **Pharmacists**.

Brochures containing relevant information on tuberculosis symptoms, diagnosis, treatment and precautionary advice were given for distribution to patients buying Anti Tubercular Treatment.

The project demonstrated:

- Improved knowledge of the **Pharmacists**
- Improved referrals to the RNTP
- Increased number of patients put on **DOTS**
- Improved capacity of the **Pharmacists** in patient counseling

12. Biopharmaceutic and pharmacokinetic aspects of variable bioavailability of rifampicin.

Panchagnula R, Agrawal S. Int J Pharm. 2004 Mar 1;271(1-2):1-4.

The treatment outcome of tuberculosis can be questionable due to variable bioavailability of rifampicin. The study at National Institute of Pharmaceutical Education and Research at Mohali, India, reported the bioequivalence trials in the form of a figure that provides a comprehensive look at the rifampicin bioavailability literature, provides understanding of the problem and clears 'myths and assumptions' regarding rifampicin bioavailability from FDCs. It was found that FDCs containing rifampicin with reduced or increased relative bioavailability are available in the market. In addition, 'rifampicin alone' formulations also show variability in bioavailability.

7. MEMORANDUM OF UNDERSTANDING (MoU) WITH RNTCP FOR ENGAGING RETAIL PHARMACIES IN RNTCP

During the FIP World Congress 2011 in Hyderabad **FIP/WHO Joint Statement** on the role of **Pharmacists** in **TB Care and Control** was adopted (*See Annexur-3*). The joint statement called for seven collaborative actions between the NTPs and the NPAs.

Consequent to the FIP/WHO Joint Statement a follow up a Round Table of stakeholders to utilize **Pharmacists** in **TB Care and Control** in India took place during the 2011 FIP World Congress in Hyderabad. To provide joint stewardship the round table recommended development of policy guidance and resource mobilization to engage **Pharmacists** in **TB Care and Control**. It was further recommended that there needs to be a formal national plan or strategy to engage **Pharmacists** in the RNTCP. A Pan-India **Working Group**, led by the IPA and working in close collaboration with all stakeholders, especially AIOCD, Pharmacy Council of India and SEARPharm Forum, should be established as soon as possible and help develop this plan in line with the RNTCP program objectives 2012 to 2017.

Subsequently, Memorandum of Understanding between The Central TB Division Directorate General of Health Services, and Indian Pharmaceutical Association (IPA) All India Organization of Chemists & Druggists (AIOCD), Pharmacy Council of India (PCI) and SEARPharm Forum was signed (*Annexure-4*)

8. CONCLUSION

The FIP Challenge on TB Round 1 project showed that **Pharmacists** involvement in India in prevention and care is still at a nascent stage. However, it very clearly brought out that there is an immense potential for **Pharmacists** in India to participate in the Revised National Tuberculosis Program and contribute to the different areas of the intervention. The available case studies showed few **Pharmacists**' activities in TB Prevention and Care. The **MoU** brought out following mitigation strategy needs to be used urgently by the IPA with RNTCP:

1. Training and education of **Pharmacists** and up-gradation of curriculum at all levels.
2. Creating awareness that **Pharmacists** are playing important role in **TB Care and Control**.
3. Strengthening of the distribution and retailing of TB medicines by adequate training.
4. **Pharmacists** as **DOTS** provider can improve proper use of anti TB medicines, prevent misuse and help in early case **Detection** and referral to RNTCP.
5. Partnership in Implementation of standard treatment guidelines and continuing education with other healthcare providers.
6. Creating awareness through counseling. The most accessible practicing **Pharmacists** cover most areas of the country, including rural areas) in the health system and thus often the first port of call for patients.

ANNEXURE

REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

INDIA'S NATIONAL SITUATION (STATEWISE)

(RNTCP Report 2010)

STATE	Population (inlakh) covered by RNTCP1	No. of suspects examined	Suspects examined per lakh population per quarter	No. of smear positive patients diagnosied2	% of S+ve cases among suspects	Total patients registered for treatment3	Annualized total case detection rate	New smear positive patients registered for treatment	Annualized new smear positive case detection rate(No.)	Annualized new smear positive case detection rate(%)
LAKSHADWEEP	0.7	223	80	8	4%	24	34	10	14	19%
GOA	17	12178	182	1220	10%	1897	113	648	39	48%
BIHAR	953	348652	91	46255	13%	82401	86	35152	37	49%
JAMMU & KASHMIR	128	85403	167	8042	9%	13164	103	6001	47	49%
MANIPUR	27	14668	138	1481	10%	4239	159	1069	40	54%
CHHATISGARH	240	106034	110	12976	12%	27463	114	10573	44	55%
MADHYA PRADESH	705	307362	109	48419	16%	83276	118	30807	44	55%
TRIPURA	36	21832	154	1817	8%	2851	80	1519	43	57%
UTTARAKHAND	96	70203	182	9984	14%	14300	148	5300	55	58%
HARYANA	241	166345	172	24865	15%	38241	158	13790	57	60%
MAHARASHTRA	1083	642266	148	75972	12%	137705	127	51587	48	60%
KARNATAKA	580	441850	190	43368	10%	67744	117	26614	46	61%
PUNJAB	269	176578	164	24266	14%	38641	144	15905	59	62%
TAMIL NADU	669	609722	228	44848	7%	82634	123	32874	49	65%
D & N HAVELI	3	1686	156	264	16%	386	142	144	53	66%
KERALA	346	306859	222	15505	5%	27019	78	11592	34	67%
ORISSA	403	216910	135	30197	14%	52145	129	23001	57	67%

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REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

UTTAR PRADESH	1944	1198412	154	176501	15%	283317	146	123211	63	67%
DAMAN & DIU	2	2271	294	173	8%	326	169	115	60	74%
WEST BENGAL	889	569475	160	67120	12%	105816	119	49102	55	74%
ASSAM	304	148688	122	22975	15%	39910	131	17097	56	75%
JHARKHAND	304	142864	117	21658	15%	39569	130	17273	57	76%
RAJASTHAN	657	382379	145	70033	18%	111501	170	40198	61	76%
GUJARAT	572	407584	178	60578	15%	80575	141	35100	61	77%
MIZORAM	10	8547	215	799	9%	2538	256	570	57	77%
ANDHRA PRADESH	830	537639	162	77380	14%	114074	137	49935	60	80%
NAGALAND	22	13860	157	1695	12%	3614	163	1332	60	80%
HIMACHAL PRADESH	66	64566	244	8175	13%	13743	208	5057	77	81%
PUDUCHERRY	11	15774	361	2057	13%	1385	127	684	63	84%
CHANDIGARH	11	14655	337	1905	13%	2572	236	876	81	85%
DELHI	176	170201	242	24994	15%	50693	288	14156	80	85%
MEGHALAYA	26	19641	191	2576	13%	4591	179	1705	66	89%
ARUNACHAL PRADESH	12	11202	230	1180	11%	2432	200	829	68	91%
ANDAMAN & NICOBAR	4	3813	227	415	11%	803	191	298	71	95%
SIKKIM	6	7553	314	752	10%	1720	286	493	82	109%

REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

STATE	% new sputum positive out of total new pulmonary cases	No. of new smear negative cases registered for treatment	No. of new EP cases registered for treatment	% of new EP cases out of all new cases	No. of retreatment cases registered for treatment	No. of smear positive retreatment cases registered for treatment	% of smear positive retreatment cases out of all smear positive cases	No. of pediatric cases out of all new cases	% of pediatric cases out of all new cases	3 mth conversion rate of new smear positive patients	Cure rate of new smear positive patients	Success rate of new smear positive patients
LAKSHADWEEP	50%	10	4	17%	0	0	0%	6	25%		100%	100%
GOA	64%	367	544	35%	337	211	25%	111	7%	91%	83%	84%
BIHAR	57%	26852	5733	8%	14461	7114	17%	5123	8%	89%	82%	89%
JAMMU & KASHMIR	73%	2168	2975	27%	2016	1597	21%	601	5%	92%	88%	90%
MANIPUR		1572	766	22%	829	322	23%	420	12%	85%	83%	84%
CHHATISGARH	50%	10577	3519	14%	2783	1643	13%	1376	6%	89%	82%	87%
MADHYA PRADESH	54%	26376	9978	15%	16081	10895	26%	4786	7%	89%	83%	87%
TRIPURA		549	463	18%	320	242	14%	70	3%	91%	89%	90%
UTTARAKHAND	61%	3357	2244	20%	3322	2596	33%	867	8%	88%	80%	84%
HARYANA	64%	7699	6534	23%	10142	7657	36%	1885	7%	90%	85%	85%
MAHARASHTRA	61%	33025	25564	23%	27448	15696	23%	7755	7%	90%	83%	85%
KARNATAKA	64%	14921	12997	24%	13138	9100	25%	3680	7%	86%		81%
PUNJAB	70%	6927	7746	25%	8045	6286	28%	2108	7%	89%	85%	87%
TAMIL NADU	60%	21918	16587	23%	11188	8704	21%	6604	9%	91%	85%	86%
D & N HAVELI	62%	90	76	25%	76	45	24%	32	10%	91%	85%	85%
KERALA	67%	5800	6238	26%	3357	2588	18%	3100	13%		81%	83%
ORISSA	64%	12875	9568	21%	6658	4122	15%	2638	6%	88%	82%	86%
UTTAR PRADESH	61%	77797	33605	14%	48234	36835	23%	16121	7%	91%	85%	88%
DAMAN & DIU	56%	92	38	14%	62	29	20%	15	6%	93%		
WEST BENGAL		19936	17542	20%	19199	12470	20%	4664	5%	88%	84%	85%

REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

ASSAM	61%	11151	5073	15%	6564	3656	18%	1633	5%	90%	86%	88%
JHARKHAND	57%	13098	3225	10%	5896	2978	15%	2225	7%	91%	85%	89%
RAJASTHAN	56%	31033	14469	17%	25787	20980	34%	4776	6%	91%	88%	89%
GUJARAT		10831	10962	19%	23629	17216	33%	3953	7%	92%	87%	87%
MIZORAM		753	777	37%	429	189	25%	296	14%	91%	91%	93%
ANDHRA PRADESH	63%	29541	12657	14%	21734	16329	25%	3911	4%	92%	87%	89%
NAGALAND	60%	882	661	23%	724	429	24%	402	14%	92%	90%	90%
HIMACHAL PRADESH	68%	2374	3223	30%	3064	2207	30%	543	5%	93%	88%	90%
PUDUCHERRY		221	279	24%	201	178	21%	96	8%	89%	87%	87%
CHANDIGARH	67%	422	788	38%	486	301	26%	192	9%	92%	87%	88%
DELHI	62%	8816	16089	41%	11548	6958	33%	5745	15%	89%	87%	87%
MEGHALAYA	66%	879	1054	29%	931	573	25%	350	10%	86%	82%	83%
ARUNACHAL PRADESH	57%	629	394	21%	566	303	27%	227	12%	90%	86%	88%
ANDAMAN & NICOBAR	61%	190	203	29%	110	90	23%	61	9%	93%	87%	89%
SIKKIM	56%	385	451	34%	391	241	33%	160	12%	87%	87%	87%

REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

STATE	% smear positive patients living in the district placed on DOTS	No. of patients put on Non-DOTS treatment regimen	% of patients put on Non-DOTS treatment regimen	No. of initial defaulters	% of initial defaulters	No. of all smear positive cases started RNTCP DOTS within 7 days of diagnosis	% of all smear positive cases started RNTCP DOTS within 7 days of diagnosis	No. of all smear positive cases registered within one month of starting RNTCP DOTS treatment	% of all smear positive cases registered within one month of starting RNTCP DOTS treatment	No. of cured smear positive cases having end of treatemnt follow up sputum done within 7 days of last dose	% of cured smear positive cases having end of treatemnt follow up sputum done within 7 days of last dose	No. of cases registered receiving DOT through a community volunteer	% of cases registered receiving DOT through a community volunteer
LAKSHADWEEP	0%	0	0.00%	0	0%	7	100%	7	100%	5	100%	2	18%
GOA	87%	37	3.50%	98	9%	691	85%	738	91%	596	92%	346	24%
BIHAR	92%	61	0.10%	3155	7%	34409	88%	35857	92%	22857	73%	12113	31%
JAMMU & KASHMIR	96%	6	0.10%	277	4%	6842	97%	6802	96%	5227	92%	1355	26%
MANIPUR	93%	8	0.60%	80	6%	1286	97%	1146	87%	813	85%	642	41%
CHHATISGARH	91%	36	0.30%	1044	8%	9772	83%	11391	96%	6621	72%	8505	43%
MADHYA PRADESH	91%	424	1.00%	3574	8%	32327	85%	35579	93%	22307	68%	26827	45%
TRIPURA	92%	35	2.10%	99	6%	1361	81%	1642	98%	1149	77%	1054	51%
UTTARAKHAND	86%	82	1.00%	997	12%	5825	84%	6688	97%	4195	83%	5548	59%
HARYANA	93%	79	0.40%	1361	6%	16467	89%	16868	91%	11793	87%	6044	28%
MAHARASHTRA	90%	1592	2.40%	5251	8%	53767	86%	59169	95%	39748	79%	20012	22%
KARNATAKA	91%	258	0.70%	3134	8%	27695	82%	31303	93%	18176	77%	18260	41%
PUNJAB	93%	364	1.60%	1110	5%	18547	90%	19776	96%	14079	92%	3354	12%
TAMIL NADU	94%	456	1.20%	1915	5%	31193	81%	36855	96%	23991	78%	15199	26%
D & N HAVELI	84%	0	0.00%	33	16%	160	90%	177	100%	135	88%	27	12%

REPORT: FIP CHALLENGE ON TB ROUND 1 ANNEXURE-A

KERALA	93%	119	0.80%	829	6%	12019	90%	12107	88%	8330	80%	10982	57%
ORISSA	91%	207	0.70%	2192	8%	21137	82%	24700	97%	13757	72%	16028	46%
UTTAR PRADESH	91%	118	0.10%	14816	9%	133635	90%	142260	96%	104715	88%	133330	66%
DAMAN & DIU	92%	0	0.00%	8	8%	97	72%	97	72%	40	85%	115	54%
WEST BENGAL	90%	77	0.10%	6283	10%	46302	79%	54008	92%	37900	80%	19194	26%
ASSAM	91%	72	0.30%	1852	8%	17264	87%	18268	92%	12623	81%	9119	30%
JHARKHAND	95%	27	0.10%	1109	5%	16821	86%	18908	97%	11320	74%	12138	41%
RAJASTHAN	93%	355	0.60%	3698	6%	46361	83%	53315	95%	39024	82%	10441	12%
GUJARAT	93%	613	1.10%	3139	6%	43085	89%	47200	98%	34315	87%	28562	45%
MIZORAM	98%	9	1.20%	7	1%	632	99%	628	99%	715	97%	530	31%
ANDHRA PRADESH	93%	166	0.20%	5115	7%	53121	88%	57502	95%	39861	80%	70467	78%
NAGALAND	98%	0	0.00%	37	2%	1811	83%	1422	88%	1139	83%	1576	63%
HIMACHAL PRADESH	89%	85	1.20%	598	8%	6250	96%	6183	93%	4739	89%	1201	14%
PUDUCHERRY	91%	25	2.70%	57	6%	663	80%	745	90%	574	90%	96	21%
CHANDIGARH	96%	16	1.30%	35	3%	947	89%	1042	98%	808	95%	15	1%
DELHI	91%	281	1.40%	1391	7%	17281	91%	18654	98%	15421	98%	3687	10%
MEGHALAYA	88%	29	1.20%	266	11%	1851	89%	1911	91%	1247	88%	1876	60%
ARUNACHAL PRADESH	87%	97	9.00%	38	4%	934	92%	982	94%	783	86%	746	44%
ANDAMAN & NICOBAR	87%	7	1.80%	46	12%	117	67%	178	83%	111	91%	79	88%
SIKKIM	94%	18	2.80%	20	3%	581	91%	602	94%	476	78%	429	32%

FIP CHALLENGE ON TB ROUND 1

India Working Group

1. Prafull D. Sheth (FIP)
2. Teera Chakajnarodom (SEARPharm Forum)
3. C. G. K. Murty (IPA)
4. Raj Vaidya (IPA)
5. Manjiri Gharat (IPA)
6. Pradeep Mishra (SEARPharm Forum)
7. Mohammad Ahmed Khan (SEARPharm Forum)
8. Alok Ghosh (Lupin Labs)
9. Kapil M Khambolja (Novartis)
10. M Mitra (Former Deputy Drug Controller, India)
11. N K Gurbani (IIHMR)
12. E. R. Babu (The Union)
13. R. N. Gupta (IPA)
14. Satish Kaipilyawar (PATH)
15. Subhash Mandal (IPA)
16. Shibu Vijayan (RNTCP)
17. Deepesh Reddy (WHO-CO)

THE ROLE OF PHARMACISTS IN TUBERCULOSIS CARE AND CONTROL

Background

Every year, more than 9 million new cases of tuberculosis (TB) occur and nearly 2 million people die of the disease. Nearly half a million cases have the multidrug-resistant form of the disease.

While Asia bears the largest burden of the disease, sub-Saharan Africa has the highest incidence of drug-susceptible TB and Eastern Europe has the highest incidence of multidrug-resistant TB (MDR-TB).

Considerable progress has been made over the past decade: between 1995 and 2009, proper TB care and control averted up to 6 million deaths and cured 41 million people. A great deal of concerted effort is still required if the TB-related Millennium Development Goals are to be met by 2015 and the Stop TB Partnership's vision of a world free of TB is to be realized by 2050.

In several countries, national TB programmes have made significant progress in involving diverse public, private, voluntary and corporate health-care providers in TB care and control. Pharmacists constitute an important and essential part of the health work-force. In many countries, pharmacists are the frontline health-care providers and often a first point of contact for people with symptoms of TB. Systematic efforts to involve pharmacists in TB care and control therefore need to be undertaken as a part of strengthening health systems in general and health work-force in particular.

Working together: WHO and FIP

The World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) intend to intensify their collaboration towards care and control of TB and MDR-TB globally. While recognizing the broader role of pharmacists in the development and use of anti-TB medicines, this joint statement focuses on the role of pharmacists directly involved in delivering care for people with TB.

This statement builds on WHO's mandate in public health and FIP's previous collaboration with WHO on important public health issues including the role of pharmacists in the fight against the HIV-AIDS pandemic, good pharmacy practice, prevention of anti-microbial resistance and encouraging adherence to long-term treatments.

Joint action

1. WHO and FIP have jointly drawn up the basis for action-oriented collaboration between national TB programmes and national pharmacy associations in the fight against TB and MDR-TB.

2. WHO undertakes to promote the need for these collaborative actions to WHO Member States, their national TB programmes and drug regulatory authorities as well as to Stop TB partners worldwide.

3. FIP undertakes to promote these actions to national pharmacy associations worldwide and, through them, to individual pharmacists and to the health authorities of respective countries.

4. Both WHO and FIP will use this joint statement to harness the contribution of pharmacists in delivering health services as part of strengthening health systems.

Dr Hiroki Nakatani
Assistant Director-General,
World Health Organization

Dr Michel Buchmann
President
International Pharmaceutical Federation

Collaborative actions

WHO and FIP urge national TB programmes and national pharmacy associations, to develop and implement plans for engaging pharmacists in the fight against TB within the context of national health systems and services. These plans should take into consideration the following actions that would enable national TB programmes and national pharmacy associations to work together to:

1. Provide joint stewardship in developing policy guidance and resource mobilization to engage pharmacists in TB care and control. For this purpose, to undertake, as a first step, situation assessments to understand the current role and potential contribution of pharmacists in health service delivery in general, and TB care and control in particular. The process should also entail consultation and collaboration with relevant stakeholders to identify educational, managerial and regulatory approaches to systematically engage pharmacists in TB care and control.

2. Undertake orientation and training of pharmacists to enable their effective contribution to TB care and control, taking into account the local context. To this effect, the training curricula of pharmacy students may require updating to incorporate current knowledge and practices in TB care and control.

3. Facilitate effective contribution of pharmacists to specific areas of TB care and control, including increasing awareness of TB among lay people and patients about health facilities linked to national TB programmes providing quality-assured diagnosis and treatment of TB; referring people with symptoms of TB to appropriate health-care facilities for early diagnosis; providing supportive supervision of TB patients including directly-observed treatment to promote adherence and prevent multidrug resistance; and supporting diverse health-care providers to ensure that national guidelines based on the International Standards for Tuberculosis Care are followed.

4. Promote rational use of anti-TB medicines and ensure that quality-assured medicines are procured and supplied and that fixed-dose combinations recommended by WHO are used. Furthermore, dispensing anti-TB medicines that have not been certified as safe and effective and sale of inappropriate combinations should be stopped. The sale of anti-TB medicines over the counter without a prescription must also be prohibited.

5. Maintain a continuous dialogue with health-care providers to rationalize and strengthen their TB management practices. Pharmacy associations should contribute to developing national guidelines on the rational use of anti-TB medicines and support adherence to these guidelines in practice.

6. Engage pharmacists and their associations to join the Stop TB Partnership's efforts at local, national and global levels. All relevant stakeholders, including the pharmaceutical industry, academic institutions and civil society organizations should understand and support the role of pharmacists in TB care and control.

7. Develop and implement a system to monitor, evaluate and improve collaboration between national TB programmes and national pharmacy associations. Documentation and sharing of experiences and lessons learnt should establish an evidence-base of the role of pharmacists in TB care and control and also help to identify and scale-up successful best practice models.

Hyderabad, India, September 4, 2011

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 SERAPharm 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 World Health Organization (WHO) – International Pharmaceutical Federation (FIP) Forum of 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.

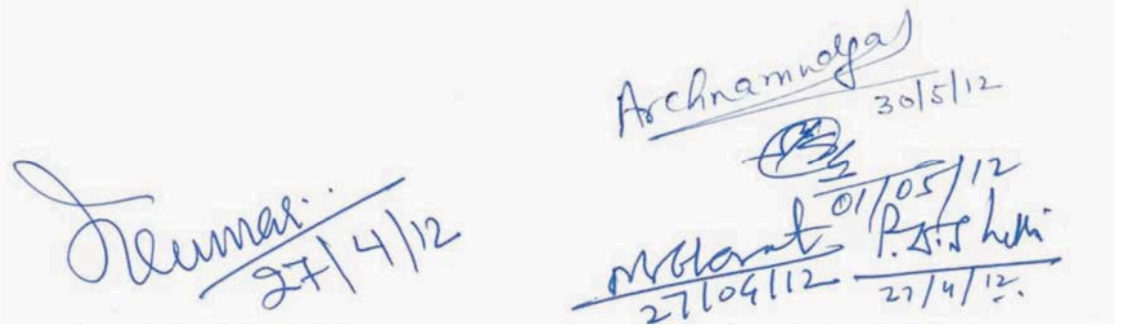
9. Documentation and Reporting

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.



Accepted on behalf of the
Directorate General of Health Services
Central TB Division

Accepted on behalf of
IPA AIOCD PCI SEARPharm Forum

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Revised National Tuberculosis Control Programme

सत्यमेव जयते

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

TRAINING MODULE FOR COMMUNITY PHARMACISTS

2013

Developed jointly by:

Government of India
Central TB Division, Directorate General of Health Services,
Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
www.tbcindia.nic.in

And

Indian Pharmaceutical Association (IPA)
www.ipapharma.org

Acknowledgment

This training module has been funded by the Lilly MDR-TB Partnership

Revised National Tuberculosis Control Programme

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

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www.ipapharma.org

About the Training Module for Community (Retail) Pharmacists

AIM OF MODULAR TRAINING:

This module aims to train pharmacists in various aspects of tuberculosis and role of pharmacist in Tuberculosis (TB) care and control.

The content of the module is similar to RNTCP training module for Multi Purpose Workers, however modified to adapt for training of pharmacists.

At the end of this modular training, the participants will be able to:

- Get introduced to Global and Indian TB scenario
- Understand basics of Tuberculosis (TB) and Drug Resistant TB
- Understand the principles and strategy of Revised National Tuberculosis Control Program (RNTCP) and Directly Observed Treatment Short course(DOTS)
- Understand Role of pharmacist in generating community awareness on TB, identification and referral of TB suspects, DOT provision, recording and reporting and rational use of anti TB drugs.

INDEX

ABBREVIATIONS

Abbreviation	Full Form
TB	Tuberculosis
MDRTB	Multidrug - Resistant TB
XDRTB	Extensively Drug- Resistant TB
PTB	Pulmonary TB
RNTCP	Revised National Tuberculosis Control Programme
TNF	Tumor Necrosis Factor
STLS	Senior Tuberculosis Laboratory Supervisor
MO	Medical Officer
DTC	District Tuberculosis Centre
AFB	Acid-Fast Bacilli
HIV	Human Immunodeficiency Virus
FDCs	Fixed Dose Combinations
WHO	World Health Organization
DOTS	Directly Observed Treatment Short Course
I P	Intensive Phase
CP	Continuation Phase
DST	Drug Susceptibility Testing
DR-TB	Drug Resistant TB
FIP	International Pharmaceutical Federation
IPA	Indian Pharmaceutical Association
FDA	Food and Drug Administration
PHI	Peripheral Health Institution
STS	Senior Treatment Supervisor
STLS	Senior TB Lab Supervisor
IEC	Information, Education And Communication

CHAPTER 1

INTRODUCTION

1.1 What is Tuberculosis?

Tuberculosis (TB) is a highly infectious bacterial disease caused by Mycobacterium tuberculosis. TB can affect any part of the body. When it affects the lungs it is called pulmonary TB. The commonest form of TB is pulmonary TB. TB in any other part of the body (i.e. other than lungs) is called extra pulmonary TB.

1.2 Mode of Infection

TB germs usually spread through air. When a patient with pulmonary tuberculosis coughs or sneezes, TB germs are spread in the air in the form of tiny droplets. When these droplets are inhaled by a healthy person s/he gets infected with tuberculosis. This infected person will have a 10% lifetime risk of developing tuberculosis.

1.3 Source of infection and exposure

Patients suffering from smear positive pulmonary TB (PTB) constitutes the most important source of infection. The infection occurs most commonly through droplet nuclei generated by coughing, sneezing etc., inhaled via the respiratory route. The chances of getting infected depend upon the duration, the frequency of exposure and the immune status of an individual.

Tuberculosis is an infectious disease caused predominantly by Mycobacterium tuberculosis. M tuberculosis was first discovered in 1882 by Robert Koch, hence is also called as the “Koch's bacillus.(You will also commonly hear doctors refer to pulmonary tuberculosis as “ pulmonary kochs).

1.4 Risk of infection

A smear positive pulmonary TB case in the general community may infect 10 – 15 other persons in a year, and remain infectious for 2 to 3 years if left untreated.

1.5 Risk of developing disease

All those who get infected do not necessarily develop TB disease. The life time risk of breaking down to disease among those infected with TB is 10–15%, which gets increased to 10% per year amongst those co-infected with HIV. Other determinants such as diabetes mellitus, smoking tobacco products, malnutrition and alcohol abuse also increase the risk of progression from infection to TB disease.

CHAPTER 2

TUBERCULOSIS
A PUBLIC HEALTH PROBLEM

2.1 Extent of TB problem in the world

Every year, more than 9 million new cases of tuberculosis (TB) occur and nearly 2 million people die of the disease. Nearly half a million cases have the multidrug-resistant form of the disease. While Asia bears the largest burden of the disease, sub-Saharan Africa has the highest incidence of drug-susceptible TB and Eastern Europe has the highest incidence of multidrug-resistant TB (MDR -TB).

2.2 Extent of TB problem in India

The extent of the TB problem is generally described in terms of incidence, prevalence and mortality. Incidence is the number of new events (infection or disease) that occur over a period of one year in a defined population. Prevalence is total of new and existing events (infection or disease) at a given point of time in a defined geographical population. India accounts for 26% of the total global TB burden *i.e.* 2.0-2.5million new cases annually. In Out of all TB notified cases in India, 53% are smear positive cases and 285 are smear negative cases and 19% are extra pulmonary cases. Only 2.1% of TB cases are MDR TB cases and there are only 6% of HIV positive TB patients in India. The table below shows the estimated figures for TB burden globally and for India provided by WHO for the year 2011

2.3 Magnitude of TB - Global and Indian scenario*

	Incidence of disease	Prevalence of disease	Mortality	HIV prevalence among incident cases
Global	(125/lakh/yr)	(170/lakh/yr)	(14/lakh/yr)	13%
India	(181/lakh/yr)	(249/lakh/yr)	(24/lakh/yr)	4.2%

- *Source: Global TB Report2012*

The Millennium Development Goal (MDG) target to halt and reverse the TB epidemic by 2015 has already been achieved. New cases of TB have been falling for several years and fell at a rate of 2.2% between 2010 and 2011. The TB mortality rate has decreased 41% since 1990 and the world is on track to achieve the global target of a 50% reduction by 2015.

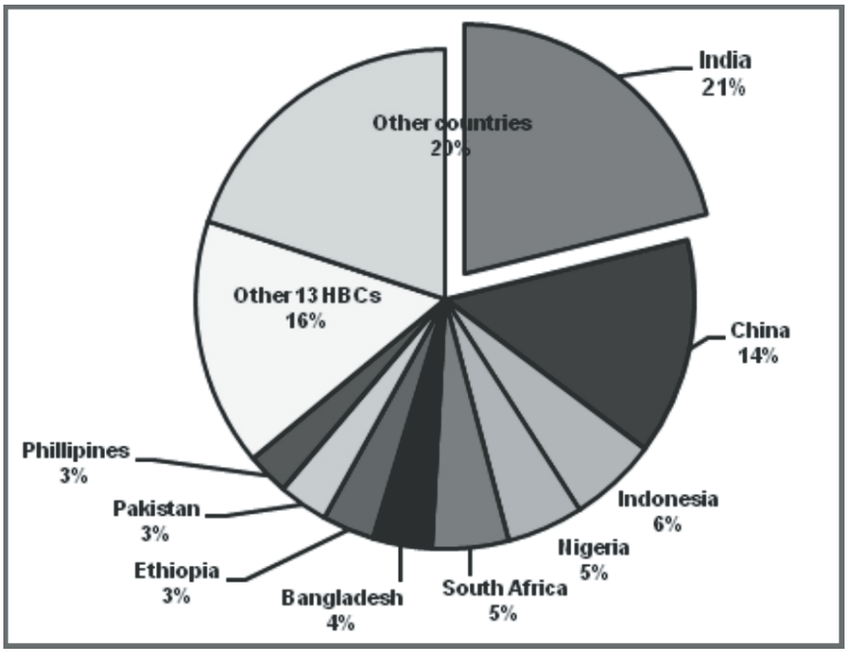


Fig. 1. India is the largest TB burden country accounting for one-fifth of the global incidence

One untreated case of pulmonary TB can infect 10 to 15 persons in one year.

2.4 HIV Co infection among TB patients

In India, it is estimated that 2.31 million individuals are living with HIV infection, which equates to approximately 0.34% of the adult population of the country. Based on available country data of 2007, it is estimated that 4.9% of new adult TB patients in India are HIV positive. Hence, the TB epidemic in India continues to be predominantly driven by the pool of HIV negative TB infected individuals.

Tuberculosis is the most common opportunistic infection amongst HIV-infected individuals. It is a major cause of mortality among patients with HIV and poses a risk throughout the course of HIV disease, even after successful initiation of antiretroviral therapy (ART). In India 55-60% of AIDS cases reported had TB, and TB is one of the leading causes of death in '*People living with HIV/AIDS'* (PLHA).

2.5 Paediatric TB

Children in the first five years of their life are likely to suffer from serious and fatal forms of TB, more so, if not vaccinated with BCG. Globally, it is estimated that about1.1 million new cases are reported and1,30,000 deaths occur annually due to TB among children. Reliable data on the

Incidence and prevalence of the disease is not available due to the difficulties in diagnosis of pediatric TB under field conditions. However, limited data available reveals that prevalence of TB among children in the age group 0-14 years is estimated to be0.3%of radiological casesand0.15% of bacteriological cases.

The extent of TB in children is a reflection of the pool of infectious adult smear-positive pulmonary tuberculosis cases in the community and their ability to transmit infection.

2.6 Drug-resistant tuberculosis (DR-TB)

Multi Drug Resistant TB (MDR-TB)is defined as tuberculosis disease where the bacilli is resistant to isoniazid (H) and rifampicin (R),with or without resistance to other drugs. **Irregular consumption and frequent interruption in taking treatment, irrational treatment for TB are the most common causes of acquiring multi drug resistance.** In India, MDR-TB amongst new cases are estimated at 2-3% and amongst re- treatmentcasesat14-17%. **Extensively Drug Resistant TB (XDR–TB)** is a subset of MDR-TB where the bacilli, in addition to being resistant to R and H, are also resistant to fluoroquinilones and any one of the second-line injectable drugs(namely Kanamycin, Capreomycin or Amikacin).Now, most recently, Extremely Drug Resistant (**XXDR TB**) is reported where the bacilli is resistant to all anti –TB drugs.

In India, the great concern is the potential threat of drug resistant TB (DR-TB) with the existing unregulated availability and injudicious use of first and second line anti-TB drugs in the country. The best strategy for management of drug resistant is to prevent its emergence by implementing quality DOTS services. The RNTCP rolled out services for diagnosis and management of multi-drug resistant TB (MDR-TB) in the states of Gujarat and Maharashtra in the year 2007. Complete geographical coverage is expected to be achieved across all districts in the country by March 2013.

The following interventions are being undertaken to enable system strengthening to effectively scale up treatment services of MDR TB:

- Advocate with Indian Drug Manufacturers with Global Drug Facility (GDF) support
- Adhere to WHO Prequalification and GDF Quality Assurance systems,
- Develop second-line drug production plans to meet national drug demand,
- Integrated national on-line electronic recording and reporting system,
- Advocate rational use of anti-TB drugs (Fluro Quinolones in respiratory cases) with all professional associations and practitioners.

2.7 TB Notification in India

2.7.1 Background

Tuberculosis was never a notifiable disease nationally in India. Though in some of the states it was for quite a long time, it was never properly implemented due to many reasons. India's National TB Control programme provides quality assured diagnostic and treatment services to all the TB patients including necessary supportive mechanisms for ensuring treatment adherence and completion. But these services cannot be made available to large number of patients availing services from private sector, as they are not currently reported to the programme.

A large number of patients are not benefitted with these programme services and leads to non adherence, incomplete, inadequate treatment leading to M/XDR TB, mitigating all the efforts of the programme to prevent emergence and spread of drug resistance. If the TB patients diagnosed

and treated under private sector are reported to public health authorities, the mechanisms available under the programme can be extended to these patients to ensure treatment adherence and completion. The impending epidemic of M/XDR TB can only be prevented to a large extent by this intervention.

To curb this situation, Govt of India declared Tuberculosis a notifiable disease on 7th May 2012 with the following objectives:

2.7.2 Objectives of TB Notification

- To have establish Tuberculosis surveillance system in the country
- To extend mechanisms of TB treatment adherence and contact tracing to patients treated in private sector
- To ensure proper TB diagnosis and case management and further accelerate reduction of TB transmission
- To mitigate the impeding Drug resistant TB epidemic in the country

2.7.3 Implementation tools and methods

For the purpose of notification, the contact details of the nodal officer at district level and the reporting formats are available on the website www.tbcindia.nic.in. All the health establishments throughout the country in public as well as private and nongovernmental sector are expected to notify TB cases. For the purpose of notification the definition of TB cases is as below:

Microbiologically-confirmed TB case – Patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP-approved Rapid Diagnostic molecular test positive for tuberculosis.

OR

Clinical TB case – Patient diagnosed clinically as tuberculosis, without microbiologic confirmation and initiated on anti-TB drugs.

2.7.4 List of RNTCP endorsed TB diagnostics

Smear Microscopy (for AFB):

Sputum smear stained with Zeil-Nelson Staining or Fluorescence stains and examined under direct or indirect microscopy with or without LED.

Culture:

Solid (Lowenstein Jansen) media or Liquid media (Middle Brook) using manual, semi-automatic or automatic machines e.g. Bactec , MGIT etc.

Rapid diagnostic molecular test:

Conventional PCR based Line Probe Assay for MTB complex or Real-time PCR based Nucleic Acid Amplification Test (NAAT) for MTB complex e.g. GeneXpert

2.8 Nikshay

Improving TB surveillance by transitioning to Case Based Web Based recording and reporting (Nikshay):

RNTCP since implementation followed international guidelines for recording and reporting for Tuberculosis Control Programme with minor modifications. With the objective to improve TB surveillance in the country, programme has undertaken the initiative to develop a Case Based Web Based application named Nikshay. This ICT application (Nikshay) was launched on 15th May 2012 by NIC (HQ) and Central TB Division.

The data entry of the individual TB cases is being done at the block level DEOs (Data Entry Officers) of NRHM .Till Sept 2012, more than 2,00,000 patients are already registered under this system.

2.9 Ban on Commercial Serological Tests

In July 2011 - WHO released a policy, concluding that, since the "the harms/risks [Currently available commercial serodiagnostic tests] far outweigh any potential benefits (strong recommendation) these tests should not be used in individuals suspected of active pulmonary or extra-pulmonary TB, irrespective of their HIV status.After this WHO policy, the RNTCP published an advisory statement against the use of serological TB tests in India.

Subsequently, an expert committee convened by the Drug Controller General of India (DCGI) reviewed the evidence on 1 December 2011 and unanimously recommended a ban on sero diagnostics for TB in India as these tests provide inconsistent and imprecise results. The DCGI recommendations were formally approved and notified by the Ministry of Health and Family Welfare.

CHAPTER 3
CLINICAL MANIFESTATIONS OF TUBERCULOSIS

3.1 Symptoms of tuberculosis

3.1.1 *Pulmonary tuberculosis (PTB):*

The most common symptom of PTB is a **persistent cough of two weeks or more, with or without expectoration**. It may be accompanied by one or more of the following symptoms:-

Fever, night sweats, weight loss

Chest pain, haemoptysis (expectoration (coughing up) of blood or blood stained sputum)), shortness of breath, tiredness and loss of appetite.

Such patients should be selected and subjected for sputum examination. This enhances the chances of detection of the bacilli in the smear microscopy.

3.1.2 *Extra pulmonary tuberculosis:*

A person with extra-pulmonary TB may have symptoms related to the organs affected along with constitutional symptoms stated above. For example:

- Enlarged cervical lymph nodes with or without discharging sinuses (TB Lymphadenitis)
- Chest pain with or without dyspnoea (difficulty in breathing) in pleural TB
- Pain and swelling of the joints in bone tuberculosis (fever, backache, deformity in spinal TB)
- Signs of raised intra-cranial tension like irritability, headache, vomiting, fever, stiffness of the neck and mental confusion in TB meningitis
- Painless haematuria (blood in urine) or sterile pyuria (pus in urine) in renal tuberculosis
- Infertility in genito-urinary TB.

3.2 Pulmonary TB suspects

Pulmonary smear-positive tuberculosis patients expel tubercle bacilli into the air while coughing/sneezing. Contacts of undiagnosed/untreated pulmonary smear-positive patients become infected when they inhale these tubercle bacilli.

A pulmonary TB suspect is defined as:

- An individual having cough of 2 weeks or more.
- Contacts of smear positive TB patients having cough of any duration.
- Suspected/confirmed extra-pulmonary TB having cough of any duration
- HIV positive patient having cough of any duration.

Persons having cough of *2 weeks* or more, with or without other symptoms, are referred to as pulmonary TB suspect. They should have *2 sputum samples* examined for Acid Fast Bacilli (AFB).

It is important to suspect tuberculosis among the chest symptomatic patients and subject them for sputum examination. If TB is not suspected, patients with smear-positive pulmonary TB will not be identified. These patients will continue to spread the infection and it is likely that more than half of them will die by three years. Hence, every pulmonary TB suspect should be referred for sputum examination in time.

Community pharmacists, all health workers and community volunteers should be encouraged to identify and refer TB suspects for early diagnosis and treatment to prevent further spread of the infection.

CHAPTER 4
DIAGNOSIS OF TUBERCULOSIS

4.1 How to diagnose Tuberculosis?

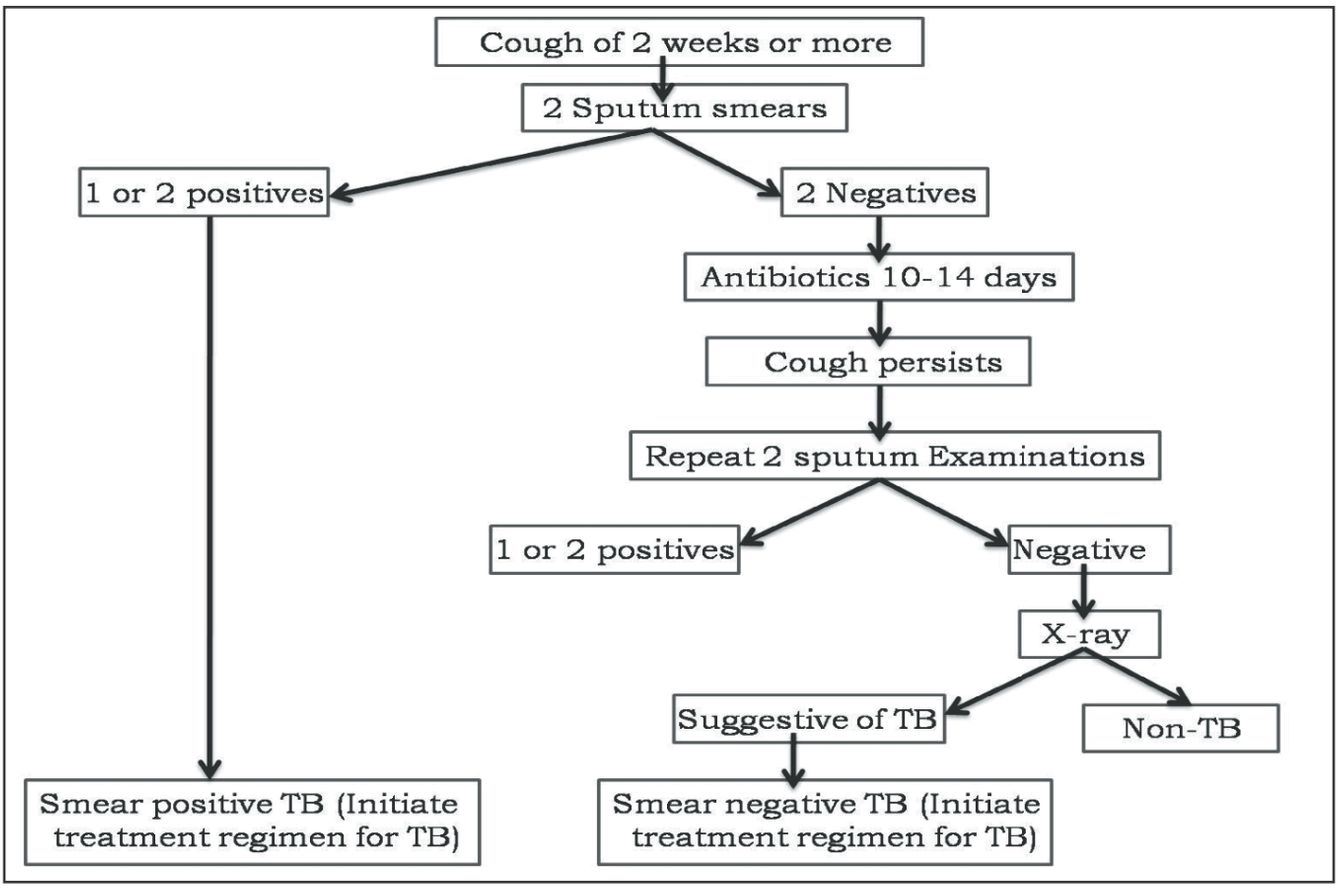
Tools for diagnosis of Pulmonary TB in adults:

- Sputum smear microscopy
- Chest X-ray
- Sputum culture
- Newer diagnosis ,including Molecular diagnosis, GeneXpert etc

Sputum examination is the main tool for diagnosing pulmonary TB.

At least 2 sputum samples (spot – morning) should be collected, preferably within two days, and examined by microscopy in the laboratory. *Diagnosis is done free of charge in the Designated Microscopy Centers (DMCs) of the Government Hospitals and selected private hospitals.*

Diagnostic Algorithm of Pulmonary TB



The diagnostic algorithm given above should be strictly followed. If not followed, patients may either be treated unnecessarily based upon X-ray results or left untreated.

On seeing the fast spread of Tuberculosis in the country and the mortality caused by it, the Government put into place a policy which would help us curb the deadly disease which, if detected in time can prevent the spread and is completely curable. The policy is described in short below. Its overview will help us understand the methods of diagnosis and treatment better.

4.2 Chest X-ray

Chest x-ray as a diagnostic tool is more sensitive but less specific with higher inter and intra reader variation. However, it should be used judiciously. It is also useful for diagnosing extra pulmonary TB, by detecting pleural effusion, pericardial effusion, mediastinal adenopathy and miliary TB. **Miliary tuberculosis** ,also known as "disseminated tuberculosis", is a form of tuberculosis that is characterized by a wide dissemination into the human body and characterized by the tiny size of the lesions (1–5 mm).

RNTCP does not recommend the serological (Blood Antigen) test as confirmatory test for detection of tuberculosis.

4.3 Diagnosis of Extra Pulmonary TB

Demonstration of AFB in a smear from extra pulmonary site is often difficult because of low bacillary load. The clinical features pertaining to the system affected should be considered in the diagnosis of extra pulmonary tuberculosis. However, the following are some of the special investigations which are helpful in diagnosing extra pulmonary tuberculosis. These may be radiological, cytological / pathological, biochemical and immunological.

(a) Fine Needle Aspiration Cytology (FNAC) and direct smear examination
(b) Excision / Biopsy of specimen for histo-pathological examination
(c) Fluid for cytology, biochemical analysis and smear examination
(d) X-ray of the involved region
(e) Ultra Sonography for Abdominal Tuberculosis
(f) Culture for *Mycobacterium tuberculosis* (*M.Tb*)

Precise diagnosis of some forms of extra pulmonary tuberculosis is a challenge to the physicians as they present symptom complex with extraordinary diversity. Delay in the diagnosis can be fatal or result in life threatening sequelae as in the case of meningeal TB. Patients with symptoms suggestive of extra pulmonary tuberculosis should be referred to the respective speciality for further investigations.

4.4 Diagnosis of TB among HIV co-infected patients

Central TB Division (CTD) and the National AIDS Control Organization (NACO) have adopted the policy of routinely offering voluntary HIV counselling and testing to all TB patients as part of an

intensified TB/HIV package of services.

The services under the intensified TB/HIV packages are :-TB patients with unknown HIV status are to be referred to the nearest and most-convenient place where NACO HIV counselling and testing is offered. This may be an ICTC or any PHI where whole blood testing is offered for HIV screening. The referral should be made at the earliest after TB diagnosis, but may be made at any time during TB treatment of HIV status remains unknown. Treating physicians and paramedical workers should explain the need and importance for patients to be certain about their HIV status, and also that HIV testing is voluntary and not mandatory. This offer should be made at least once during the course of TB treatment. HIV-infected TB patients not already on ART should be referred as soon as possible to an ART centre for pre-ART registration and free CD4 testing, using the standard "ART Centre referral form". Most HIV-infected TB patients will be eligible for ART. Intensified case finding activities are to be specifically monitored among HIV infected pregnant women and children living with HIV.

4.5 Diagnosis of Paediatric TB

Early and prompt diagnosis of TB in children is often difficult. A battery of tests is required to arrive at accurate diagnosis of TB in children. Generally, diagnosis should be made by a Medical Officer and the existing RNTCP case definitions are to be used for all cases diagnosed.

High index of suspicion of TB in a child is the first step in the diagnosis. Tuberculosis should be suspected among children presenting symptoms of prolonged / unexplained fever and / or cough for more than 2 weeks, with no weight gain or history of failure to thrive.

It is to be remembered that cough may not be the predominant and constant symptom unlike in an adult. Children presenting neurological symptoms like irritability, refusal of feeds/failure to thrive, headache, vomiting or altered sensorium and convulsions, may be suspected to have TB meningitis.

The National guidelines on Pediatric TB diagnosis and management were updated based on the recent evidence and advances in Pediatric TB diagnosis and treatment in consultation with Indian Academy Pediatrics during January- February 2012. A new diagnostic algorithm is developed for pulmonary TB, the commonest type of extra pulmonary TB (Lymph node TB) and for other types of extra-pulmonary TB. The diagnostic algorithms for the diagnosis of pulmonary TB and Lymph node tuberculosis are provided in Annexure.

All efforts should be made to demonstrate bacteriological evidence in the diagnosis of Pediatric TB. In cases where sputum is not available for examination or sputum microscopy fails to demonstrate AFB, alternative specimens (Gastric lavage, Induced sputum, broncho-alveolar lavage) should be collected, depending upon the feasibility, under the supervision of a pediatrician. A positive Tuberculin skin test / Mantoux positive were defined as 10 mm or more induration. The optimal strength of tuberculin 2 TU (RT 23 or equivalent) to be used for diagnosis in children.

There is no role for inaccurate/inconsistent diagnostics like serology (IgM, IgG, IgA antibodies against MTB antigens), various in-house or non- validated commercial PCR tests and BCG test. There is no role of IGRAs in clinical practice for the diagnosis of TB

4.6 Diagnosis of Drug Resistant Tuberculosis

Drug resistant TB is difficult to diagnose and requires set up of quality assured laboratories for culture and drug susceptibility testing (C/DST) which are resource intensive. RNTCP is currently in the process of setting up 43 C/DST laboratories across the country for diagnosis and follow up of patients of drug resistant TB. RNTCP is also accrediting existing laboratories in private sector, medical colleges, NGOs, ICMR to supplement the C/DST capacity.

4.6.1 MDR Suspect Criteria

Criteria A –

- All failures of new TB cases
- Smear +ve previously treated cases who remain smear +ve at 4th month onwards
- All pulmonary TB cases who are contacts of known MDR TB case

Criteria B –
in addition to Criteria A:

- All smear +ve previously treated pulmonary TB cases at diagnosis
- Any smear +ve follow up result in new or previously treated cases

Criteria C –
in addition to Criteria B

- All smear -ve previously treated pulmonary TB cases at diagnosis,
- HIV TB co-infected cases at diagnosis

In other words, for districts implementing MDR Suspect Criteria B, any smear-positive diagnostic (except in a new patient) or any smear-positive follow-up result, should prompt a referral for DST. For districts implementing MDR TB Suspect Criteria C, all patients should be referred for DST at diagnosis of TB, except new patients (smear positive and smear negative) at without HIV infection. Refer to PMDT guideline in **www. tbcindia.nic.in** for further details

4.6.2 Diagnostic tools for MDR-TB / XDR TB

Culture and drug sensitivity

- o Solid culture
- o Liquid culture

Newer diagnostics

- o Line Probe Assay(LPA), Cartridge Based Nucleic Acid amplification Test – (CB-NAAT- Gene Xpert)

Newer tools under evaluation include, Gene Xpert – a completely closed automated system using real-time PCR which has as ensitivity of 70-90% even for smear negative cases and can also detect the presence of rifampicin resistance.

CHAPTER 5

TREATMENT OF TUBERCULOSIS

Treatment of tuberculosis under RNTCP is based on Direct observation of treatment (DOT) ensures the best possible result. Here an observer watches and assists the patient in swallowing the tablets, thereby ensuring that the patient receives the medication. Many patients who do not receive directly observed treatment stop taking drugs after two months because they feel better. Studies in India and many other countries consistently shows that at least one third of patients do not take medicines regularly.

It is neither possible to predict who these patients will be nor to reliably prevent non-adherence through health education. Studies have shown that there will be poor treatment outcome and high death rates in the absence of direct observation, even when regular supply of drugs is ensured. Hence, by observing the patients during the entire course of treatment, one ensures that they receive the right drugs, in the right doses, at the right intervals and for the right duration.

The duration of treatment is usually 6 to 9 months (Drug susceptible) . There are two phases in the treatment of tuberculosis: the intensive phase (IP) of 2-4 months and the continuation phase (CP) of 4-5 months, depending upon the category of treatment. During IP, all doses are given under direct observation, three times a week on alternate days for 2-4months. Thereafter, sputum is examined, and if found negative, the CP is started.

During CP, the first dose of every week must be administered under direct observation. The patient collects the rest of the drugs for that week from the DOT Provider and consumes them at home. The following week, the patient comes with the empty blister pack, hands it over to the DOT Provider, takes the first dose under direct observation and collects drugs for the rest of the week to be consumed at home.

Category of patients	Type of patient	Regimen[1]	
		Intensive Phase(IP)	*Continuation Phase(CP)*
I	Sputum smear-positive Sputum smear-negative Extra-pulmonary Others	2H3R3Z3E3	4H3R3
II	Smear-positive relapse Smear-positive failure Smear-positive treatment after default Others[2]	2H3R3Z3E3S3 /1H3R3Z3E3	5H3R3E3

The table below indicates the treatment regimen, type of patients and regimens prescribed.The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. The dosage strengths are as follows:

Isoniazid (H) 600mg, Rifampicin (R) 450mg, Pyrazinamide (Z) 1500mg, Ethambutol(E) 1200mg Streptomycin(S) 750mg. Patients who weigh 60kg or more receive additional rifampicin 150mg.

5.1 Management of Contacts of Sputum-Positive Cases

Any person who has a productive cough of any duration and is in contact with a smear positive case, sputum samples should be examined as soon as possible for diagnosis, and if negative, s/he should be evaluated by the Medical Officer and also followed up three months later. Children who cannot produce sputum should be examined with other recommended investigations like chest X-ray and tuberculin testing. For all such cases contact the Medical Officer.

5.2 Treatment of Paediatric TB

The intermittent therapy will remain the mainstay of treating pediatric patients. However, Among seriously ill admitted children or those with severe disseminated disease/ neuro-tuberculosis, the likelihood of vomiting or non-tolerance of oral drugs is high in the initial phase. Such, select group of **seriously ill admitted patients should be given *daily supervised therapy during their stay in the hospital*** using daily drug dosages.

The following are the daily doses (mg per kg of body weight per day) Rifampicin 10-12 mg/kg (max 600 mg/day), Isoniazid 10 mg/kg (max 300 mg/day), Ethambutol 20- 5mg/kg (max 1500 mg/day), PZA 30-35mg/kg (max 2000 mg/day) and Streptomycin 15 mg/kg (max 1gm/day).There will be six weight bands and three generic patient wise boxes will be used in combination to treat patients in the six weight bands. The dose of INH for chemoprophylaxis is 10 mg/kg (instead of currently recommended dosage of 5 mg/kg) administered daily for 6 months. The details of the new weight bands and the new generic boxes are provided in Annexure.

5.3 Chemoprophylaxis

INH TB preventive therapy should be provided at 10mg/kg to:

a. All asymptomatic contacts (under6yearsofage) of a smear positive case, after ruling out active disease and irrespective of their BCG or nutritional status.
b. ChemoprophylaxisisalsorecommendedforallHIVinfectedchildrenwhoeither had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (>=5mm induration) but have no active TB disease

5.4 Treatment of TB disease in HIV-infected patients

Early diagnosis and effective treatment of TB among HIV-infected patients are critical for controlling the disease, minimizing the adverse impact of TB on the course of HIV, and interrupting the transmission of TB in the community. Treatment of TB is same as that in the HIV-negative TB patients. Patients are to be treated with the RNTCP "New" or "Previously Treated" regimen according to the patient's history of previous anti-TB treatment.

In addition to TB treatment under RNTCP, all HIV-infected TB patients must be provided access to care and support for HIV disease, including antiretroviral therapy. ART reduces TB case fatality rates (reduces deaths) and the risk of recurrent TB.

5.5 Cotrimoxazole preventative therapy (CPT)

Cotrimoxazole preventative therapy has been shown to reduce mortality among HIV-infected TB patients, and is recommended by NACP for all HIV-infected patients. All HIV-infected TB patients should therefore be provided CPT.

5.6 Treatment of MDR TB

- Treatment based on Rifampicin DST results
- Initial hospitalization followed by ambulatory care

Standardized treatment Regimen for MDR TB – daily DOT

- Intensive phase (IP) for 6-9 months Km Lfx Cs Eto Z Emb
- Continuation phase (CP) for 18 Lfx Cs Eto Emb
- Scope of strengthening the regimen in baseline Ofx / Km resistance
- PAS used as a substitute drug in case of intolerance to any drug
- Weight bands for < 16 kg, 16-25kg, 26-45kg, 46-70kg and > 70kg

Standardized treatment Regimen for XDR TB – daily DOT

- Intensive phase (IP) for 6-12 months Cm, PAS, Mfx, High dose-H, Cfz, Lzd, Amx Clv
- Continuation phase (CP) for 18 months PAS, Mfx, High dose-H, Cfz, Lzd, Amx-Clv
- Clr and Thz used as a substitute drug in case of intolerance
- States to locally procure drugs using national technical specification

CHAPTER 6
ROLE and RESPONSIBILITIES OF THE PHARMACIST

Pharmacists are on many occasion first and repeated point of contact to the community. Given the situation of TB, pharmacist could be the point of contact for a chest symptomatic, and a TB patient who is on treatment (from Public and private). The roles depicted in this chapter positions pharmacist as an integral part of TB control initiatives in India. An accurate diagnosis and treatment of the tuberculosis not only cure the patients but also prevent the TB in the community by preventing the transmission.

6.1Community Awareness

- Distribution of TB information leaflets to TB patients, TB suspects as well as to any other patient who wish to know/need to know more about TB
- Creating awareness about DOTS programme by displaying posters/boards/stickers in the Pharmacy.
- Arrange and conduct group awareness activities
- TB and DOTS awareness sessions among schools, community etc

6.2 Patient Counselling

During first meeting with a patient, one has to find out whether the patient has previously been treated for tuberculosis. A patient should be made aware that tuberculosis is a life-threatening disease and tuberculosis treatment is only effective if all prescribed drugs are taken regularly for the entire prescribed duration.

Then he has to be explained about the following about tuberculosis:

- What is tuberculosis, and how it spreads.
- Symptoms of tuberculosis.
- Treatment of tuberculosis. either from private or public sector
- Information about Directly Observed Treatment (DOT).
- Importance of contact examination and chemoprophylaxis of children below 6 yrs of age.
- Taking some of the drugs or irregular taking of drugs is dangerous and makes the disease incurable.
- Motivation of the patient with respect to treatment requirements and expected duration of the treatment.

The following information should be communicated to the patients:

- Amount, frequency and duration of drugs
- Possible side-effects of drugs
- Frequency and importance of sputum examinations, ii sputum positive cases
- Inform importance of evaluation of symptomatic contacts (e.g. family member with TB symptoms) of sputum positive patients.
- Inform patient regarding the infectiousness of TB to children and hence the medical officer should be consulted about requirement of preventive treatment in children and possible infection control measures preventing the domestic transmission
- Ask patient to use handkerchief/tissue while coughing .Orange/ red discoloration of the body fluids especially urine which is commonly encountered due to rifampicin is not an adverse reaction and patient should be made aware of this.
- if on OCPs should be advised to use alternative methods of contraception.
- Patients who smoke should be motivated to make an informed decision to stop smoking. All cases should be informed personally about the harmful effects of smoking on health in general and the potential for poorer outcomes of anti-TB treatment with continued smoking
- Give a copy of any TB information leaflet available

6.3 Case detection and referral of TB suspects

When to refer a patient to TB Clinics (or to any Doctor for TB evaluating) and how to identify chest symptomatic cases:

- Any patients with cough more than two weeks
- Greet the patient, asking the patients who are seeking cough medication about how long the patient has the cough.
- Asking for other symptoms if the cough has persisted for a long time.
- Asking for specific TB symptoms *i.e.* persistent cough, sputum or blood in cough, chest pain, fever, night sweats, weight loss, loss of appetite, *etc*.
- Asking whether the suspect has consulted a doctor.
- Telling the patients about the importance of TB diagnosis and effective TB treatment which is free in government hospitals& also can be made available from the pharmacy.
- Counsel the suspect refer, to nearby Designated Microscopy Center (DMC) with referral form for sputum examination. Use carbon paper and keep a copy of referral form with address and phone number of the patient at the pharmacy.

Pharmacist needs to fill up at least the patient details in the referral form and keep a carbon copy at the pharmacy. Use pharmacy stamp and sign the form.

- Try to contact the DMC or STS /TB HV after sending the TB suspect for diagnosis. Try to call patient in 2 days to know if patient did go diagnosis or not. If suspect doesn't go for diagnosis, inform patient details to TB HV to follow up and convince the suspect for diagnosis
- For patient with prescription from private physician, suggest talking with the physician. Inform about DOTS.
- Provide IEC materials i.e TB leaflets, pamphlets to the suspect. Provide Sputum cup and educate about sputum expectoration.

6.4 Contact Tracing

Acquiring infection and developing TB is higher among contacts of TB patients. Therefore, pharmacists should help in tracing all child contacts and symptomatic adult contacts of smear positive cases, irrespective of the duration of symptoms should be traced, counselled and referred by pharmacists, to identify and treat TB cases and to provide preventive treatment to children.

6.5 Referral Form

Laboratory Form for Sputum Examination

Name of Referring Health Facility: Date:

Name of patient: Age: Sex: M/F

Complete address:.....

.....

Contact Phone number / Mobile No.:.....

Type of suspect / disease: Pulmonary Extra-pulmonary Site:.....

Reason for examination: cough for more than 2 week, fever, loss of weight, haemoptysis

Diagnosis

Repeat Examination for Diagnosis

Follow-up examinations

For new and previously treated cases - Month of follow-up ……...

For MDR-TB cases – Month of follow-up ……

Treatment Regimens (tick √ appropriate box):

New cases Previously treated MDR-TB

(**Name and signature of referring pharmacist with Pharmacy stamp)**

Flowchart: How to identify chest symptomatic cases

Identify the patients who repeatedly visit the Pharmacies for cough and fever medicines
A) Patient on Self medication (without prescription) or with Prescription

⇩

Interact with the patients, Enquire how long and what exactly the symptoms are

⇩

If symptoms are suggestive of TB, then counsel the patient ,advise for check up, direct the patient to Designated Microscopy Center by providing exact address

⇩

Use referral form, use Pharmacy stamp on referral form, keep a copy for record

6.6 DOTS provision at Pharmacy

Below is the details sequence of activities, once a TB patient is willing to take DOT from the pharmacy

- TB Health Visitor brings the DOTS box (patient wise box with 6 months medicines) with treatment record card to the pharmacy
- Keep the patient wise DOTS medicine box and the treatment record card appropriately in the Pharmacy
- Decide timing suitable to patient and to you for DOTS
- Patient starts visiting Pharmacy on alternate day in intensive phase and once in a week in continuation phase.
- Call patient inside the pharmacy and offer to sit .Give medicines from kit and let patient swallow it in front of you. Offer drinking water and use disposable cup (some patient may prefer to get the water bottle from home) Do not offer DOT in air-conditioned part of the Pharmacy. Let the administration be in the well ventilated part of Pharmacy but also care for patient's privacy and ensure patient is comfortable to take medicines.
- Enquire about how is patient feeling and record his body weight if there is Weighing Balance in the Pharmacy.
- Make appropriate entry in the treatment record card.and keep card in secure place in a file
- **If the patient doesn't visit on scheduled day, immediately make phone call to the patient or immediately informing Health Visitor about the default.**
- Ensure that all doses in the intensive phase and the first dose of each weekly blister during the continuation phase are taken under direct observation. Also ensure collection of empty blister packs which should be preserved till the end of treatment.
- Remind patient to go for follow up sputum test (if patient is sputum positive) and give a copy of

referral form

- Discuss if patient suffers from any side effects and advice patient to go to Medical Officer if needed.(Refer to table on Adverse Drug Reaction to anti-TB drugs, page)
- Ensure that partially used PWBs and treatment record cards of such cases (of patients who have died / defaulted / failed treatment / transferred out) are taken back by HWs from the pharmacy
- Allow supervision of boxes ,treatment cards anytime by RNTCP staff
- Train the assistants in the Pharmacy for DOT administration and supervise the work. This is important as to maintain continuity of medicine administration, even in absence of pharmacist.

6.7 Documentation: Making entries in the Record Card

Appropriate entries need to be made in the treatment record cards. It is easy and doesn't take much of the time.

6.8 Providing information on DOTS to all TB patients

All patients, who come with anti-TB prescription first time, can be explained following. Concentrate especially on the low economic status patients as these are patients who may not afford treatment for prescribed period and leave it half way& can become DR TB patients later.

- Explain to the patient ,the importance of direct observation of treatment
- Explain the entire DOTS treatment is free and can be made available even from the pharmacy

6.9 Rational Use of Antibiotics and anti-TB drugs

Irrational use of antibiotics by doctors, patients and pharmacists leads to drug resistance . Hence there is necessity to follow these guidelines:

- No sale of first or second line drugs (MDR-TB medicines) without prescription. Discourage self medication
- No sale of any antibiotic, especially flouroquinolones (ofloxacin, ciprofloxacin etc) without prescription. Patients need to be counseled for inappropriate self medication of these drugs and how it can lead to resistance, or can mask symptoms of active TB etc.
- Over-the-counter sale of around 92 antibiotic and anti-tuberculosis drugs in India will be restricted soon. Drug Controller General of India has written to the Union health minister to notify a new schedule, H1, in the Drugs and Cosmetics Rules. Once notified, following clearance from the law ministry, these drugs cannot be sold without prescription. The drugs will also have to carry a prominent label in red color on the left corner with the following

warning: "It is dangerous to take this prescription except in accordance with medical advice and not to be sold by retail without the prescription of the registered medical practitioner."

- The drugs to come under H1 includes Moxifloxacin, Meropenem, Imipenem, Ertapenem, Doripenem, Colistin, Linezolid, Cefpirome, Gentamicin, Amikacin, Pencillin, Oxacilin, Zolpidem, Cefalexin, Norfloxacin, Cefaclor, Cefdinir, Tigecycline, Tobramycin, Tramadoland Vancomycin

6.10 Patient awareness

Patient should be aware of:

- The number, type and the color of drugs issued.
- The duration of treatment and importance of completion of treatment.
- The location and working hours of the pharmacy
- The importance of taking all the prescribed drugs.
- Awareness of importance of direct observation of every dose in the intensive phase.
- Awareness of frequency and importance of sputum examination, and understanding of sputum results.
- Awareness of the symptoms and infectiousness of tuberculosis.
- Importance of contact examination.
- Awareness of whom to see and where to find them in case of any problems
- Regarding treatment or otherwise.
- Awareness regarding safe sputum disposal and other preventive measures.

6.11 Patient activities related to DOTS

- Swallowing of drugs during the intensive phase of treatment in the presence of DOT Provider.
- Swallowing of the first dose of the weekly course of the continuation phase under direct observation of the health functionary and bringing the empty blister-pack during the next weekly collection of drugs.
- Going for follow up sputum test
- Bringing all symptomatic contacts to the nearest heath unit for a checkup.

6.12 Patient Communication

The skills involved in good interpersonal communication include:

- Listening and Understanding
- Demonstrating caring, concern and commitment
- Problem solving and Motivating

6.13 Do's and Dont's

Some key points for improving listening and understanding skills include:

6.13.1 DO:

- Greet, smile, Call person seat inside or outside Pharmacy ,as possible.
- Allow sufficient time for the interactionMaintain eye contact
- Move your head to indicate you are paying attention
- Apologize for any unforeseen interruptions
- Ask open-ended questions (questions that cannot be simply answered with a “yes”or “no”) such as questions that begin with “What”, “Why” or “How”. These questionsrequire more than just a few words in the answer
- Periodically summarize what the other person has said to ensure that you have understood; use their own words to repeat the ideas back to them.
- Convey that you understand their fears and apprehensions
- Make them comfortable
- Repeat important information in different ways each time you meet
- Emphasize that your job is to help them
- Emphasize that they will be cured
- Use examples from your own experience
- Tell them that this is what you would recommend to your family members
- Compliment the other person on what they have done well
- Recognize their progress
- Emphasize that their welfare is your concern/job

6.13.2 DON'T:

- Use technical words
- Ignore the efforts the other person has made so far
- Overlook their fear and anxiety
- Ignore or minimize practical barriers

6.14 Management of patients in special situations

Situation	Management
Treatment of TB during pregnancy and postnatal period	Streptomycin is absolutely contraindicated during entire pregnancy. Breast feeding can be continued even when mother is on treatment for TB but mother should continue to practice cough hygiene. Child should be administered preventive chemoprophylaxis as per guidelines.
Treatment in patients with renal failure	Rifampicin, isoniazid and pyrazinamide can be safely given as they are excreted in entero-hepatic circulation. Dosage of streptomycin and ethambutol, should be adjusted according to the creatinine clearance.
Women on oral contraceptive pills	Rifampicin decreases the efficiency of oral contraceptives by increasing their metabolism. Increase in dosage of the oral contraceptive or switch over to alternate methods of contraception is advisable

CHAPTER 7

ADVERSE DRUG REACTION TO ANTI TB DRUGS

No drug is free from side effects and hence, the anti-tubercular drugs are no exception. But the patient should immediately report the side effects to the concerned doctor or the pharmacist and should not stop the treatment on his own. Adverse Drug Reactions (ADR) observed during treatment for tuberculosis are comparatively less in the intermittent (alternate day) therapy than what is seen in daily regimens. Symptom-based approach to evaluation of possible side effects of anti-TB drugs

Symptom	**Drug (abbreviation)**	**Action to be taken by Pharmacist**
Gastrointestinal (vomiting or epigastric discomfort)	Any oral medication	Reassure patient. Inform patient to take drugs **with less water** and over a longer period of time (e.g. 20 min). Do not give drugs on an empty stomach.
Itching/Rashes	Isoniazid (and other drugs also)	Reassure patient If severe, refer patient to MO
Tingling/burning/numbness in the hands and feet	Isoniazid	Refer to MO
Joint pains	Pyrazinamide	Reassure that it is a self limiting condition. Encourage patients to increase intake of liquids. If severe, refer patient to MO for evaluation
Ringing in the Ears. Loss of Hearing. Dizziness and loss of balance	Streptomycin	Immediately refer patient for evaluation
Jaundice	Isoniazid ,rifampicin, pyrazinamide	Refer for evaluation

CHAPTER 8
IMPORTANT CONCERN IN MANAGEMENT OF TB

8.1 Tobacco smoking and tuberculosis

The diagnosis of TB disease is an opportune moment for imparting behaviour change in the patients' smoking habit, with patients more likely to accept the behaviour change needed for improving their health. Tobacco smoking may lead to delayed sputum conversion in sputum smear positive PTB cases, lower treatment success rates and higher rates of relapse of TB disease and death. Hence the past and present history of tobacco smoking (cigarette / beedi / pipe / cigar / hukka) should be elicited from each TB case at the time of initiating treatment. Smoking cessation advice to current smokers should become an integral part of TB case management. Such interventions may help improve outcomes of anti-TB treatment and reduce transmission of infection in the short term, and improve the quality of life of TB cases by preventing chronic respiratory and other disease associated with smoking in the long term. Tobacco cessation advice has been demonstrated to be successful in TB cases even in the absence of costly Nicotine Replacement Therapy.

Patients who smoke should be motivated to make an informed decision to stop smoking. All cases should be informed personally about the harmful effects of smoking on health in general and the potential for poorer outcomes of anti-TB treatment with continued smoking.

The potential benefits of stopping smoking to the health of the individual should be suitably communicated. The patient's past experience with cessation and relapse of smoking may be discussed in an understanding atmosphere. Patients may be told that they can be successful even if they have not been able to quit smoking at earlier attempts. During the conversation, the patients are asked to identify situations and moods that trigger smoking (working/getting out of bed/having a cup of coffee/pleasant moments/while dealing with personal or professional problems/ group smoking). They are encouraged to devise their own ways to respond to the circumstances that encourage smoking.

Patients should also be advised not to smoke in the presence of others, since increased frequency of coughing due to smoking increases the risk of TB infection among their household and other contacts. That smoking is prohibited in public places according to 'Prohibition of Smoking in Public Places Rules, 2008' may be clearly communicated to them.

8.2 5 'A's Approach to tobacco cessation

This is a form of counseling. Before saying anything to motivate the patient to quit tobacco use, the health professional needs to identify the tobacco user and find out the stage of readiness

to change that the patient is in, by asking a few questions.

1. Ask the patient if he/she is a tobacco user.
2. Briefly Advise against continuing tobacco use and link the current condition/ailment to continued tobacco use, where possible e.g. “Quitting smoking/tobacco use would improve your health and will aid in early recovery”.
3. Then Assess readiness to quit by asking the patient whether he or she is ready to quit at this time. e.g. “How recently have you thought about quitting tobacco?”

   If the patient appears ready to change (quit), next steps are :
4. Assist the tobacco user in making a quit plan.
5. Arrange for follow-up by setting the next contact.

8.3 5 'R' s approach for non willing tobacco users

If the tobacco user is not yet thinking about quitting tobacco use (pre contemplation), the doctor will *promote greater awareness* of the relevance to the patient of the advice to quit, the risks of use and rewards (benefits) of quitting. Many tobacco users are largely unaware of the potential harm that tobacco use can do to them. If the patient is not ready to quit, the doctor must not push the patient. People usually need time to change (incremental nature of change).

If the patient is at least thinking about (contemplating) quitting, the doctor can find out the patients roadblocks (barriers) to quitting and help the patient see ways to overcome these. This process may be enough to help the patient get ready to quit (without pushing).

At the next visit, this process should be repeated so that the information about **r**elevance, **r**isks of continuing and **r**ewards of quitting can sink in a little more and some roadblocks removed.

As you can see, the doctor must try to make the tobacco user think about quitting. This is important because there are so many other forces acting that are difficult to control, physiological compulsions to use tobacco, learned habits, social pressures, accessibility etc,. Engaging the mind of the tobacco user, bolstering it with new knowledge and a sense of caring by the person counseling can help motivate him/her to change. Follow-up is important to help keep the tobacco user on track until he or she is confident about remaining tobacco free.

8.4 Diabetes and treatment of tuberculosis

There is conflicting evidence on the role of diabetes, it's control and response to TB treatment. Some studies suggest that there is no co-relation between the two, whereas others suggest that sputum conversion is delayed and treatment outcomes are poorer in diabetics who are poorly controled during their treatment for TB.

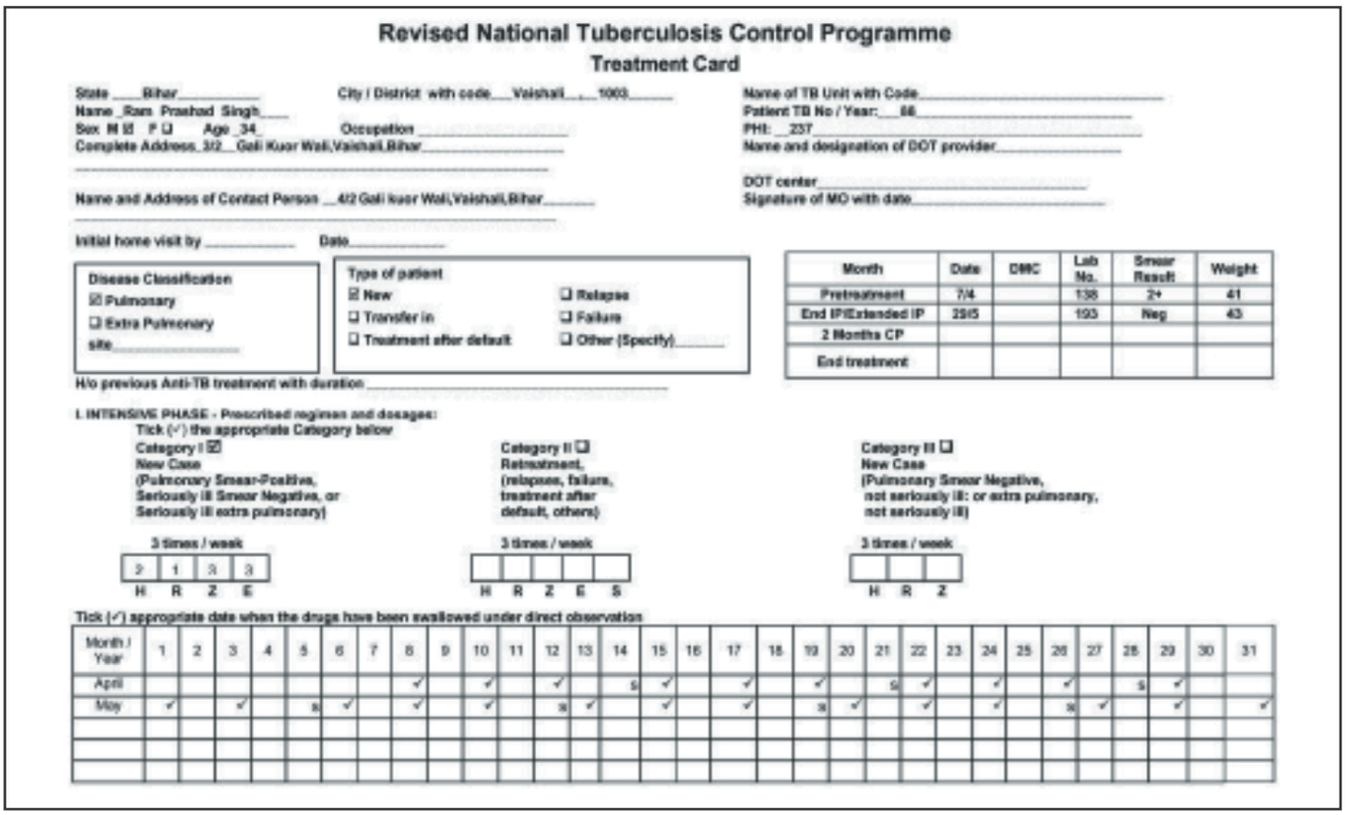
However in general the treatment for TB in patients with diabetes is the same as for those patients who are non-diabetic. In a few cases, rifampicin may induce early phase hyperglycemia due to augmented intestinal absorption. Although relapse rates themselves are unchanged, in

diabetics who relapse the prognosis is poorer.

Principles of the management of co-existent TB and diabetes comprise:

1. Proper care and hospitalization in patients with poor diabetic control;
2. Ideally insulin should be used to control blood sugar during anti-TB treatment, however oral hypoglycaemics can be used if the patient is well stabilized on them;
3. Drug interactions with rifampicin need to be kept in view and recognised if they occur:
4. Glycaemic equilibrium is essential with goals of maintaining fasting blood sugar < 100mg% and glycosylated HB < 6% should be aimed towards.
5. Monitoring for adverse effects, particularly of hepatic and nervous systems should be done as Isoniazid may lead to peripheral neuropathy; and
6. Use of potentially neuropathic agents in patients with peripheral neuropathy demands special consideration and administration of pyridoxine.

8.5 Documentation: Entries in the treatment record cards



Revised National Tuberculosis Control Programme

Treatment Card

State ____Bihar_____ City / District with code___Vaishali___1003_____ Name of TB Unit with Code_____

Name _Ram Prashad Singh____ Patient TB No / Year:___88_____

Sex M ☑ F ☐ Age _34_ Occupation _____ PHI: __237_____

Complete Address_3/2__Gali Kuor Wali,Vaishali,Bihar_____ Name and designation of DOT provider_____

DOT center_____

Name and Address of Contact Person __4/2 Gali kuor Wali,Vaishali,Bihar_____ Signature of MO with date_____

Initial home visit by _____ Date_____

Disease Classification	Type of patient		
☑ Pulmonary	☑ New	☐ Relapse	
☐ Extra Pulmonary	☐ Transfer in	☐ Failure	
site_____	☐ Treatment after default	☐ Other (Specify)_____	

Month	Date	DMC	Lab No.	Smear Result	Weight
Pretreatment	7/4		138	2+	41
End IP/Extended IP	25/5		193	Neg	43
2 Months CP					
End treatment					

H/o previous Anti-TB treatment with duration _____

I. INTENSIVE PHASE - Prescribed regimen and dosages:

Tick (✓) the appropriate Category below

Category I ☑ New Case (Pulmonary Smear-Positive, Seriously ill Smear Negative, or Seriously ill extra pulmonary) — 3 times / week — H 3 R 3 Z 3 E

Category II ☐ Retreatment, (relapses, failure, treatment after default, others) — 3 times / week — H R Z E S

Category III ☐ New Case (Pulmonary Smear Negative, not seriously ill: or extra pulmonary, not seriously ill) — 3 times / week — H R Z

Tick (✓) appropriate date when the drugs have been swallowed under direct observation

Month / Year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
April								✓		✓		✓		S	✓		✓		✓		S	✓		✓		✓		S	✓		
May	✓		✓		S	✓		✓		✓		S	✓		✓		✓		S	✓		✓		✓		S	✓		✓		✓

- Date of initiation of treatment- The date of initiation of treatment regimen prescribed is ticked (√) on the appropriate box under the date against the month. Subsequently, the dates on which the drugs were consumed under observation are also ticked. In this phase, patient comes three times a week on alternate days. Daily blisters are given either on Mondays, Wednesdays and Fridays or alternatively Tuesdays, Thursdays and Saturdays.
- The date/day (for example on 10th April) on which patient fails to attend for DOT, is denoted by a circle (0) in the appropriate box. In case the patient attends to collect the drug the next day (for example on 11th April) the drugs missed are administered on that day and continues to take the drugs as per scheduled day (for example on 12th of April).

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14
April	√		√		√			√		0				

- On the other hand, if the dose is entirely missed and the patient does not report to the health facility even on the next day then the dose is given on the next scheduled day. It should be ensured that all the doses in the intensive phase, should be administered before the continuation phase is initiated. For example, patient was scheduled to come on 17th April but does not turn up on 17th or even on 18th but reports on 19th. Hence, the dose due on 17th is given on 19th and so on and so forth.

Month	15	16	17	18	19	20	21	22	23	24	25	26	27	28
April			0											

- Only under exceptional circumstances unsupervised drug administration can be allowed for a limited number of doses. For instance, if a patient is being discharged from hospital after initiation of treatment, s/he will have to be provided with 3 doses of treatment so that her/his treatment does not get interrupted during her/his transfer to a nearby PHI. In such circumstances, the entry for unsupervised doses should be recorded by encircling the tick mark on the Tuberculosis Treatment Card and the reason for the same should be stated in the Remarks column of the treatment card.

8.6 Continuation phase

- Drug administration in the continuation phase is recorded on the reverse side of the treatment card. Treatment regimen prescribed for the patient is ticked appropriately in the box provided. Number of tablets of the drugs prescribed in the regimen is also recorded in the boxes provided above the drugs.
- During the continuation phase of treatment, patients collect the weekly blisters once a week on a designated day. First dose of the weekly blister is administered under direct observation and the remaining doses in the weekly blister are given to the patient for self-administration. The month and the year in which the patient will be collecting drugs during the continuation phase are written under the Month and year column in the table on the reverse of the Tuberculosis Treatment Card. An 'X' is recorded in the appropriate box (according to the dates of the month 1 – 31 as the case may be) to indicate the day the drugs were consumed under direct observation. A line is drawn through the remaining days.

CHAPTER 9
SUPERVISION and MONITORING OF PHARMACIST

RNTCP staff is responsible for ensuring the quality of health care provided to tuberculosis patients in their area.

9.1 Objectives of Supervision

- To have a firsthand look into the difficulties faced by pharmacists and effectively address them.
- To boost the morale and motivate the pharmacists.
- To promote team work.

9.2 Supervision of pharmacies by field staff:

- Is Pharmacy neat and clean? Potable Water facility available? Sitting arrangement made for patients
- Ensure TB IEC material is displayed in the pharmacy appropriately
- If DOT box is ongoing, supervise no. Of blisters ,treatment record card,
  follow up check date for patients and remind /advice pharmacist about the same.
- Enquire with pharmacist if there have been any new referrals for sputum test& check the referral book& collect patient details
- Request pharmacists to refer as many cases as possible of chest symptomatic to the DMC
- Ensure that the Lab staff enters the name of pharmacy in the lab register for referred case

ANNEXURE 1

Guidelines for the facilitators

Facilitators: CTO/DTO/MO TBs and WHO RNTCP Consultants
RNTCP field staff also need to be present

Training duration: 4 hours

Contents and delivery of training:

1) Power point Presentation/Talk on
TB : details as a disease : 45 min
- Simple and easy to understand PowerPoint with talk in English/Hindi/local language
- No much technical language to be used
- TB as a disease, global scenario, cause, risk factors ,Symptoms, types, diagnosis ,suspect detection, referrals to be discussed
- Treatment : private/DOTS : What is DOTS and how it is different than the private sector treatment

2) Power point Presentation/Read from Module
Role of Pharmacist : to be dealt in detail as given in the module 60 min

3) Patient Communication: From the Module 15 min

4) Activities: 20 min
- Documentation practice (Practice for filling Treatment Record Cards ,Referral form for sputum test and introduction to Patient Identity Card)
- Observation and handling of DOT kits

5) Interaction/linking of Pharmacists with RNTCP Field Staff 20 min
- Introduction of RNTCP staff (STS,HVs etc) and area wise linking of staff to pharmacies, area wise .Exchange phone numbers of each other .

6) Pre and Post test 20 min

7) Question/Answers 15 min

8) Attendance sheet for participant pharmacists (names with contact details) to be collected by RNTCP and chemist association leader ,at the end of the training session. 10 min

9) Undertaking form to be signed by pharmacists (if not submitted before to Chemist Association) for participation of pharmacists in RNTCP (format enclosed at the end of Module) 5 min

10) Copy of MOU to each pharmacist and get it signed by pharmacist 10 min

11) After the training, issue an authorization letter (format enclosed at the end of Module) or certificate to participants

Training material to be given to pharmacists:

- Copy of Training Module,
- RNTCP IEC material such as Board and leaflets, posters, stickers ,calendars
- Referral forms with carbon copy
- Copy of DOTS directory or address list of RNTCP staff and Designated Microscopy Centers

Venue: TB Society Training Hall or Chemist Association Hall (if available)

Timing: Between 1.30 to5.30 p.m. or as per mutual convenience

Who will get trained: Pharmacists from retail pharmacies

Who will do selection of pharmacists: Local Chemist association will select the willing pharmacists and will coordinate with them and RNTCP

Criteria for selection: Only those to be trained who are engaged in service delivery (actually work at the counter)

- Preferably owner pharmacists
- Willingness of pharmacists
- Location of Pharmacy in TB burden area
- Interested pharmacy owners who actually handle the counter

ANNEXURE 2

Format (can be modified suitably)

Undertaking by the pharmacist for participation in DOTS (to be kept by Chemist Association)

I,..... the undersigned retail pharmacist wish to participate in Revised National TB Control Programme (RNTCP). I am willing to keep the patient wise DOTS medicine boxes provided by District/City TB Society for the TB Patients in my pharmacy shop. It will be convenient for the nearby patients to visit the Shop and take the medicines under our observation.

I am awarethat these medicines will ONLY BE FOR THAT PARTICULAR PATIENT SENT by TB society &i will keep the record of the medicines dispensed to these patients in a TREATMENT RECORD CARD given by the Corporation. I will never have any intention to sale these medicines. In case the patient skips the doses, I will inform the TB Health Visitors (TB HVs) and they will follow up with the patient. I will also make sincere effort to contact the patient.

I will make an effort to detect Chest Symptomatic TB suspects and refer them to the nearest Designated Microscopy Centers (DMCs). I will keep all treatment record cards and DOTS boxes available for supervision by RNTCP.

By becoming DOTS providers, I will be getting socio-professional satisfaction of utilizing our services for the SOCIETAL BENEFITS.

Thank you

Yours faithfully,

Name of pharmacist with detail address and phone number

ANNEXURE 3

Format for "Authorization Letter or Certificate from RNTCP" on letter head (may be modified suitably)

(Copy to be kept by each pharmacist and copy to be submitted to local FDA by Chemist Association)

Authorization letter OR CERTIFICATE

This Is to inform that City/District TB office of …….has carried out DOTS training of ……number of pharmacists on ……..……date ……..…….at venue.

List of pharmacies with detail addresses OR Address of one pharmacy if individual letter/certificate is planned

These pharmacists are participating in DOTS and are authorized to stock patient wise DOTS boxes in their pharmacies, issued by City/District TB office .RNTCP staff will supervise the DOTS medicine boxes utilization at the pharmacies. Pharmacists will also refer the TB suspects to nearby Designated Microscopy centers.

Sign and stamp of RNTCP officer

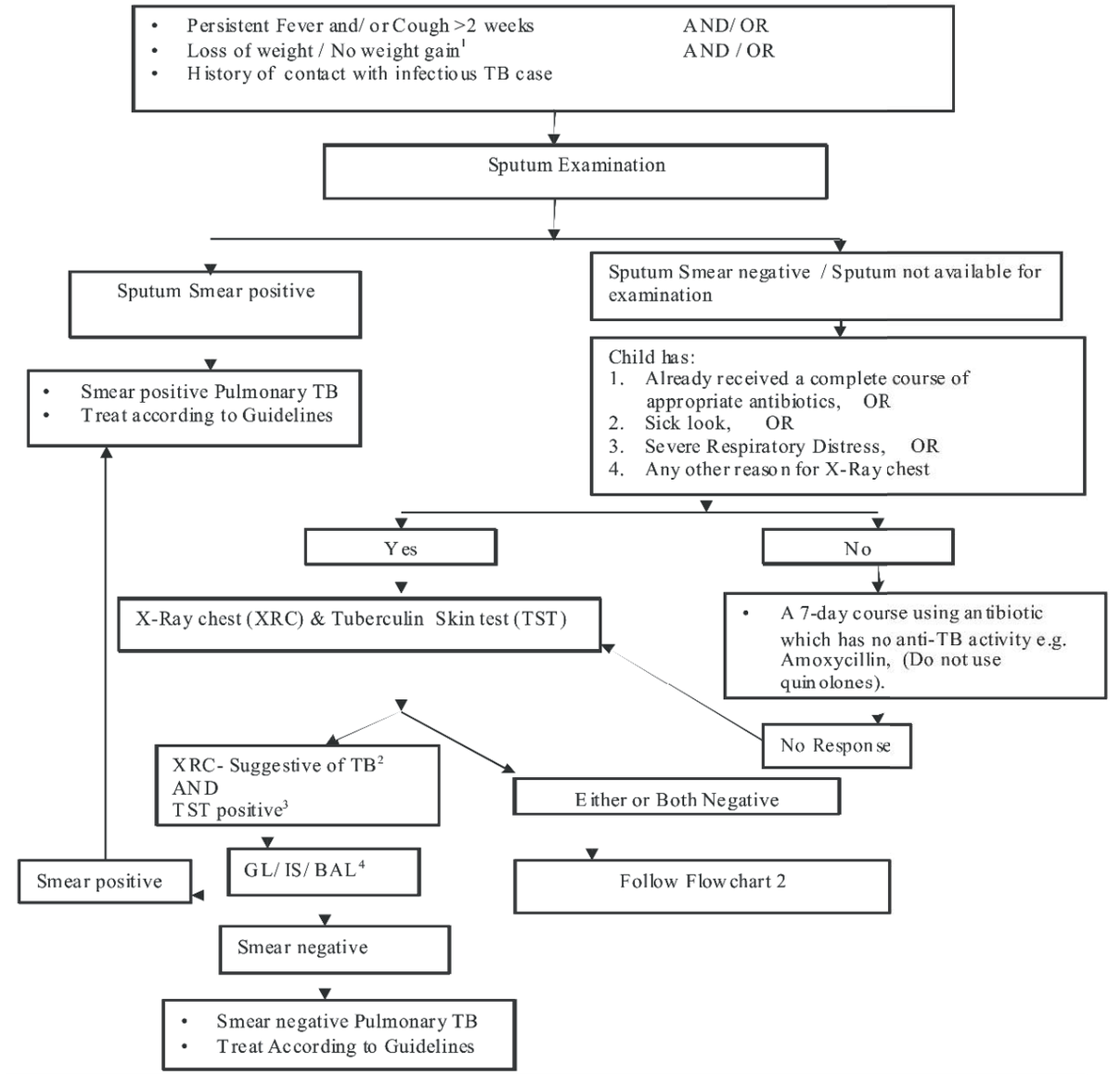
ANNEXURE 4

Format for attendance sheet for Training Programme (Copy to be kept by RNTCP and by Chemist Association for future partnership and coordination)

Name of Pharmacy	Name of Pharmacist	Address & Phone Numbers	Sign of pharmacist

Diagnostic Algorithm for Pediatric Pulmonary Tb

Flowchart 1



[1] History of unexplained weight loss or no weight gain in past 3 months; Loss of weight defined as loss of more than 5% body weight as compared to highest weight recorded in last 3 months.
[2] Radiological changes highly suggestive of TB are Hilar/paratracheal lymphadenitis with or without parenchymal lesion, Miliary TB, fibrocavitary pneumonia,.
[3] If the radiological picture is highly suggestive of TB, then proceed to do further investigations irrespective of the TST result as the sensitivity of the test is not 100%.
[4] All efforts including Gastric Lavage (GL)/ Induced sputum (IS) or Bronchoalveolar lavage (BAL) should be made to look for Acid fast bacilli (AFB) depending upon the facilities.

Treatment Categories and Regimens for Pediatric Tuberculosis

Category of treatment	Type of patients	TB treatment regimens	
		Intensive phase	Continuation phase
New cases	• New smear-positive pulmonary Tuberculosis (PTB) • New smear-negative PTB • New extra-pulmonary TB.	$2H_3R_3Z_3E_3$*	$4H_3R_3$
Previously treated cases	• Relapse, failure to respond or treatment after default • Re-treatment Others	$2S_3H_3R_3Z_3E_3$ + $1H_3R_3Z_3E_3$	$5H_3R_3E_3$
H=Isoniazid, R= Rifampicin, Z= Pyrazinamide, E= Ethambutol, S= Streptomycin			

**The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week.*

Pulmonary TB refers to disease involving lung parenchyma. Extra Pulmonary TB refers to disease involving sites other than lung parenchyma. If both pulmonary and extra pulmonary sites are affected, it will be considered as Pulmonary for registration purposes. Extra Pulmonary TB involving several sites should be defined by most severe site.

***Smear positive**: Any sample (sputum, induced sputum, gastric lavage, broncho-alveolar lavage) positive for acid fast bacilli.*
***New Case**: A patient who has had no previous ATT or for less than 4 weeks.*
***Relapse**: Patient declared cured/completed therapy in past and has evidence of recurrence.*
***Treatment after Default**: A patient who has taken treatment for at least 4 weeks and comes after interruption of treatment for 2 months and has active disease.*
Failure to respond: A case of pediatric TB who fails to have bacteriological conversion to negative status or fails to respond clinically / or deteriorates after 12 weeks of compliant intensive phase shall be deemed to have failed response provided alternative diagnoses/ reasons for non-response have been ruled out.
***Others**: Cases who are smear negative or extra pulmonary but considered to have relapse, failure to respond or treatment after default or any other case which do not fit the above definitions.*

TB NOTIFICATION FORMAT

Period of reporting: From ...../...../..... To ...../...../..... Monthly report

Name of the health facility / practitioner / Laboratory :.....
Registration Number:..... Telephone (with STD):..... Mobile number:.....
Complete Address: .....

Sr No	Name of TB Patient / ID of patient	Age (yrs)	Sex (M/F/O)	GoI issued identification number (Aadhaar, etc), if available	Complete residential address	Patient Phone number	Date of TB Diagnosis	Date of TB treatment initiation

Signature:..... Date: ...../...../.....

PIN code, fathers name, centre referred, date of sample collection, DST results

Reporting format for the RNTCP key staff at a TU level (STS)

PHARMACISTS QUARTERLY REPORTING FORMAT

Name of the State:											
Period of Reporting:											
Sl No	District	Total Number of Pharmacists involved in RNTCP	Total Number of Pharmacists trained in RNTCP	Number of Pharmacists trained in RNTCP in this quarter	No of notified cases by Pharmacists	Total number of suspects TB cases referred by Pharmacists	No of MDR cases under treatment	No of TB cases under treatment at the Pharmacy	Number of pharmacists acting as DOTS provider	No of pharmacists acting as sputum Collection/ transport centre	No of pharmacists using IEC material for awareness on TB
Name of the Reporting Person/Institution:										Signature:	
Designation:										Contact Details:	

Z-28015/2/2012-TB
Government of India
Ministry of Health and Family Welfare

Nirman Bhavan, New Delhi
Dated: 7th May 2012

Notification of TB cases

TB continues to be a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the corner-stone of TB prevention and control strategy. Inappropriate diagnosis and irregular/incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.

In order to ensure proper TB diagnosis and case management, reduce TB transmission and address the problems of emergence and spread of Drug Resistant-TB, it is essential to have complete information of all TB cases. Therefore, the healthcare providers shall notify every TB case to local authorities i.e. District Health Officer / Chief Medical Officer of a district and Municipal health Officer of a Municipal Corporation / Municipality every month in a given format (attached).

For the purpose of case notification, a TB case is defined as follows:

- A patient diagnosed with at least one sputum specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP endorsed Rapid Diagnostic molecular test positive for tuberculosis

OR

- A patient diagnosed clinically as a case of tuberculosis, without microbiologic confirmation, and initiated on anti-TB drugs.

For the purpose of this notification, healthcare providers will include clinical establishments run or managed by the Government (including local authorities), private or NGO sectors and/or individual practitioners.

For more detailed information, the concerned State TB Officers / District TB Officers, whose details are available on www.tbcindia.nic.in, may be contacted.

Encl: As mentioned

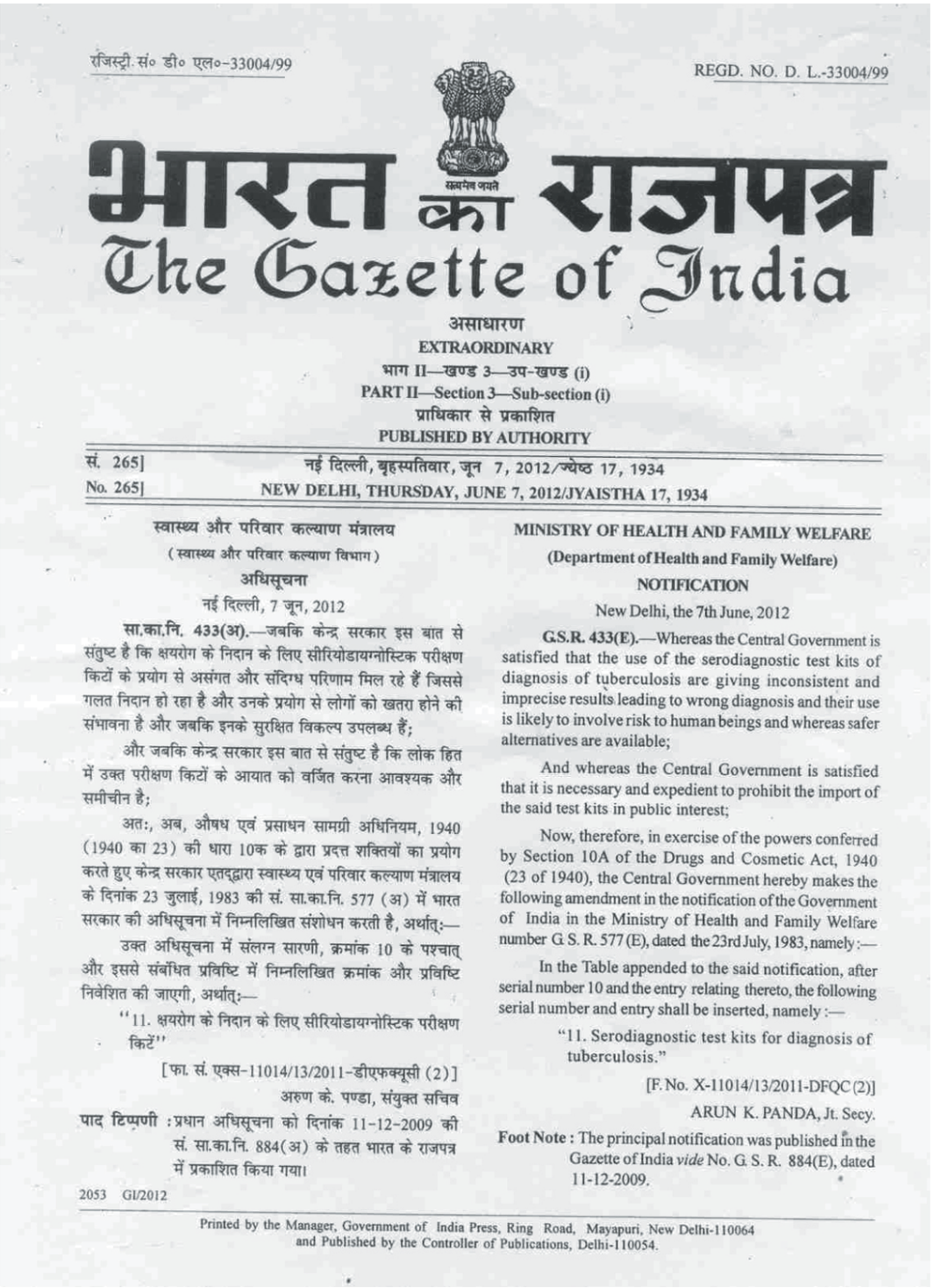
(Manoj Sinha)
Under Secretary to the Government of India

Copy for immediate further necessary action, to:

1) All Principal Secretaries / Secretaries of Health of States / UTs
2) All Directors of Health Services of States / UTs
3) All State TB Officers of States / UTs

With the request to kindly immediately bring this order to the notice of all concerned for compliance, in their respective State / UT

TB NotificationOrder,7th May 2012 Govt. of India, RNTCP



रजिस्ट्री सं० डी० एल०-33004/99

REGD. NO. D. L.-33004/99

सत्यमेव जयते

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 265] नई दिल्ली, बृहस्पतिवार, जून 7, 2012/ज्येष्ठ 17, 1934
No. 265] NEW DELHI, THURSDAY, JUNE 7, 2012/JYAISTHA 17, 1934

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 7 जून, 2012

सा.का.नि. 433(अ).—जबकि केन्द्र सरकार इस बात से संतुष्ट है कि क्षयरोग के निदान के लिए सीरियोडायग्नोस्टिक परीक्षण किटों के प्रयोग से असंगत और संदिग्ध परिणाम मिल रहे हैं जिससे गलत निदान हो रहा है और उनके प्रयोग से लोगों को खतरा होने की संभावना है और जबकि इनके सुरक्षित विकल्प उपलब्ध हैं;

और जबकि केन्द्र सरकार इस बात से संतुष्ट है कि लोक हित में उक्त परीक्षण किटों के आयात को वर्जित करना आवश्यक और समीचीन है;

अतः, अब, औषध एवं प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 10क के द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए केन्द्र सरकार एतद्द्वारा स्वास्थ्य एवं परिवार कल्याण मंत्रालय के दिनांक 23 जुलाई, 1983 की सं. सा.का.नि. 577 (अ) में भारत सरकार की अधिसूचना में निम्नलिखित संशोधन करती है, अर्थात्:—

उक्त अधिसूचना में संलग्न सारणी, क्रमांक 10 के पश्चात् और इससे संबंधित प्रविष्टि में निम्नलिखित क्रमांक और प्रविष्टि निवेशित की जाएगी, अर्थात्:—

"11. क्षयरोग के निदान के लिए सीरियोडायग्नोस्टिक परीक्षण किटें"

[फा. सं. एक्स-11014/13/2011-डीएफक्यूसी (2)]

अरुण के. पण्डा, संयुक्त सचिव

पाद टिप्पणी : प्रधान अधिसूचना को दिनांक 11-12-2009 की सं. सा.का.नि. 884(अ) के तहत भारत के राजपत्र में प्रकाशित किया गया।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th June, 2012

G.S.R. 433(E).—Whereas the Central Government is satisfied that the use of the serodiagnostic test kits of diagnosis of tuberculosis are giving inconsistent and imprecise results leading to wrong diagnosis and their use is likely to involve risk to human beings and whereas safer alternatives are available;

And whereas the Central Government is satisfied that it is necessary and expedient to prohibit the import of the said test kits in public interest;

Now, therefore, in exercise of the powers conferred by Section 10A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment in the notification of the Government of India in the Ministry of Health and Family Welfare number G.S.R. 577 (E), dated the 23rd July, 1983, namely :—

In the Table appended to the said notification, after serial number 10 and the entry relating thereto, the following serial number and entry shall be inserted, namely :—

"11. Serodiagnostic test kits for diagnosis of tuberculosis."

[F. No. X-11014/13/2011-DFQC (2)]

ARUN K. PANDA, Jt. Secy.

Foot Note : The principal notification was published in the Gazette of India *vide* No. G.S.R. 884(E), dated 11-12-2009.

2053 GI/2012

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The Gazette of India - Notification, Ban on Serological test kits for TB

EXERCISE

Exercise 1

Tick the appropriate answer.

1. Tuberculosis is transmitted by

   (a) Blood transfusion _____
   (b) Faecal infection _____
   (c) Droplet infection _____
   (d) Oral infection _____

2. The most infectious form of tuberculosis is

   (a) Extra-pulmonary TB _____
   (b) Smear-positive pulmonary TB _____
   (c) Smear-negative TB _____
   (d) Miliary TB _____

3. The commonest form of tuberculosis is

   (a) Extra-pulmonary TB _____
   (b) Bone and joint TB _____
   (c) Renal TB _____
   (d) Pulmonary TB _____

4. When do you suspect pulmonary tuberculosis? Mention four common symptoms.

   (i) _____
   (ii) _____
   (iii) _____
   (iv) _____

5. How do you classify tuberculosis?

   (i) _____
   (ii) _____
   (iii) _____

6. Which is the best way to diagnose pulmonary tuberculosis?

_____

7. When do you label a patient as smear-positive pulmonary tuberculosis?

_____

8. Case Studies (Tick the appropriate answer).

Case Study One

(i) During your routine work, you come across Ram who complains of fever. On enquiry you find that he has been coughing for more than 3 weeks. What would you do?

a) Give him advice and medicines for fever

b) Advise him to go to the nearest RNTCP DMC and get his sputum test done

c) Advise him rest and good food

(ii) Gopal has been having fever for more than a month and a cough for two weeks. Two of his sputum examinations have been reported as positive for AFB.He is suffering from

(a) Sputum-negative tuberculosis_____

(b) Extra-pulmonary tuberculosis _____

© Sputum-positive tuberculosis _____

Case Study Two

Person, appears to be from lower socio-economic strata, comes to you with anti-TB prescription from private doctor. What would you do?

Case Study Three:

Person comes to you asking for some anti-biotic without prescription .Person informs he has been coughing for several days.What would you do?


DOTS
Pura course, Pakka ilaaj


THE INDIAN PHARMACEUTICAL ASSOCIATION


SEAR Pharm Forum
South East Asian FIP-WHO Forum of Pharmaceutical Associations


the Lilly
MDR-TB
partnership


AIOCD

SEARPharm Forum

South East Asian FIP-WHO Forum of Pharmaceutical Associations

AN UPDATE

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

For the Period of
2011- 2012

Compiled by:

Ms. Pooja Khaitan
Dr. Sohail Hasan

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

Background

Definition of counterfeit medicines:

In its 2003, FIP Statement on Counterfeit Medicines, FIP adopted the 1992 WHO definition of a counterfeit medicine, that is to say: "the deliberate and fraudulent mislabelling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product. Counterfeiting can apply to both branded and generic products and to traditional remedies. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with false or misleading packing; they may also contain different, or different quantities of, impurities both harmless and toxic."

This WHO definition was officially endorsed in a meeting, convened in Geneva, 1-3 April 1992, which gathered experts from governmental institutions of WHO member states, INTERPOL, World Customs Organization (at the time known as Customs Cooperation Council), International Narcotics Control Board, IFPMA, International Organization of Consumer Unions, and the International Pharmaceutical Federation (FIP).

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

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

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

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

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

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

The Secretariat has been regularly updating such data since 2001. It is now submitting the updates on the incidents of counterfeit medicines for the year 2011-2012. This list does not reference every media report published, nor does it contain any confidential information.

Prafull D. Sheth
SEARPharm Forum Secretariat

16th September 2012
New Delhi

REPORTED INCIDENCES

INDIA

- **Vigilance raids unearth sale of spurious drugs**
  The Hindu, August 11, 2012 / The Times of India, August 11, 2012

Thiruvananthapuram: A large section of the public could be naively consuming spurious medication for a whole slew of ailments ranging from hypertension and diabetes to epilepsy, according to Vigilance and Anti-Corruption Bureau (VACB) officials who conducted State-wide surprise checks at medical stores, public health centers, warehouses of distributors of pharmaceutical products, and stockiest of prescription drugs on Friday.
Director General, VACB, Venugopal. K. Nair and Additional Director N. Sankar Reddy ordered the operation code-named 'tablet.'

Anti-corruption enforcers also inspected district offices of the State Drugs Control Department, the agency tasked to tackle the menace of spurious and adulterated drugs by regulating the manufacturing, sales, and distribution of pharmaceutical and cosmetic products.

The VACB found that at least two pharmaceutical distributors in the State stocked large quantities of lethal methanol, alcohol made deliberately unfit for human consumption, without license and in violation of the State's poison rules.

The VACB also found that corrupt doctors at scores of rural public health centers had a stake in local medical stores and that they helped their business partners by not availing themselves of a whole range of medicines available at subsidized rates from State-run pharmacies. They forced the public to buy prescription drugs of dubious quality at higher rates from private stores.

The agency also found that renewal and issuance of licenses for operating medical stores was a major avenue of corruption. Investigators found hundreds of pending applications in various drug controllers' offices. Investigators also found several drug enforcers had more money on their person than what they had declared when they entered office.

- **FDA Haryana seizes 600 Amps of Oxytocin Injections**
  www.webindia123.com, August 02, 2012

Rewari: A Team of FDA Haryana led by Lalit K Goel, Senior Drugs Control officer along with K K Garg, DCO and members of animal cruelty act Haryana raided grocers shop of Tilak Raj situated at subzi mandi, Rewari (Haryana). The team recovered 600 ampoules of Oxytocin Injection.

The team seized all the stock and taken custody orders from CJM court. "These injections are stocked without bill, license and not found in blister pack" said Goel, SDCO.

"Action is taken under section 18 A, 18 C and Rule 105 of Drugs Act. FIR has also been lodged against Tilak Raj under Drugs Act at Police Station, city Rewari. Many complaints are received regarding illegal sale of Oxytocin Inj", said Goel.

- **APDCA seizes substandard Cofcin syrup worth Rs.6.5 lakhs from Gaba Pharma in Hyderabad**
  The Pharma Biz, July 19, 2012

Hyderabad: In another case of seizer of substandard drugs in Andhra Pradesh, the state drug control authorities (APDCA) have recently seized Cofcin (Chlorpheniramine Oral Solution BP) Syrup worth Rs.6.5 lakhs from Gaba Pharmaceuticals Private Limited in Hyderabad. Over the past few days, the APDCA has been actively working in pinning down the defaulting pharmaceutical units in the state. As part of its series of investigations the state DCA has been successful in digging out the fraudulent activities of the defaulting drug manufactures in the state. "Upon inspecting the premises of Gaba Pharmaceuticals private Limited, we have found not-of-standard drugs worth Rs.6.5 lakhs. We have stopped the consignment consisting of 14,384 bottles containing (450 milliliters in each bottle) Cofcin syrup (chlorpheniramine Oral Solution BP) with batch numbers 549, 567 to 576. If not booked, these drugs were supposed to be distributed to Andhra Pradesh Medical Services and Infrastructure Corporation (APMSIDC). And part of the consignment was also meant for marketing to other clients," said RP Thakur, DG, APDCA, who has been playing an active role in bringing to book the defaulting drug manufacturers in the state.

Earlier the DCA office had cancelled the company's license for Gaplex B-Complex syrup in June 2012 for manufacturing not of standard quality drugs in the state. Government analysts from Maharashtra and Central Drugs Laboratory from Kolkata have also confirmed the same and declared the drugs, Gaplex B-Complex Syrup, with batch number-08, Salbutamol Syrup (For Asthma) with batch number-158 and Grovit (Multivitamin Drops) with batch number-75, as not of standard drugs manufactured by the company.

It was believed that the company was flouting the norms frequently and manufacturing substandard drugs. In view of this, the DCA officials had kept a

serious vigil on the company's activities and conducted thorough inspection and found that the company was resorting to grave non-compliance of provisions and manufacturing rules while producing the medicines. The DCA authorities are further investigating the issue and very soon the authorities are expected to take appropriate action against the defaulters.

- **APDCA seizes Rs.9 lakhs worth cough syrups produced without license from S K Healthcare**
  The Pharma Biz, June 02, 2012

Hyderabad: In a big haul of cache, the Andhra Pradesh Drug Controller Authority (APDCA) has seized illegally manufactured drugs worth Rs.9 lakh and froze 50 kgs of 'codeine phosphate' (an addictive ingredient used in Cofcare syrup) from S K Healthcare Formulations Pvt. Ltd. here in Hyderabad.

Moving forward with the intention to crack down all those firms violating the laws and regulatory norms, R P Thakur, IPS, director general of APDCA, has initiated a special drive to investigate all those firms which have been illegally manufacturing, distributing and selling the drugs without a valid license and also without following the various provisions of drugs acts, as they may have far reaching consequences in the public health.

According to official sources from APDCA, S K Healthcare has been manufacturing Cofcare and Bro-cofdex syrups along with New Okaril expectorant without having any license from the drug control authorities in the state. The Cofcare syrup is meant for treating patients suffering from cough while Bro-cofdex and New Okaril expectorant are anti-cold decongestants. Incidentally, all the above three brands belong to Cipla Limited and are manufactured by S K Healhtcare and marketed by Cipla itself. Upon conducting inspections, the officials found that the company S K Healthcare, which is located at Bachupally in Quthubullapur Mandal of Rangareddy district, is acting as a third party manufacturer for Cipla and the firm does not have any licenses for manufacturing these formulations.

Taking serious note of the issue, the APDCA had already issued notices to Cipla and S K Healthcare and had ordered a recall of entire stocks of drugs sold by them under their mutual marketing agreement.

Cipla, being an internationally reputed drug maker in the country, should have had minimum diligence to cross check or verify the manufacturing license of the S K Healthcare formulations. They have done a grave mistake by not verifying the firm's license. They should take corrective steps at the earliest, otherwise law will take its own course, opined the DG.

Cofcare syrup contains an addictive substance called codeine phosphate and that falls under narcotic drug psychotropic substance list. Use of this substance in disproportionate ratio will have unsafe health repercussions in the patients and may become addictive to the drug. "Since the company had

also violated the Narcotic Drug Regulations (NDPS) Act, we have informed Narcotic Control Bureau about this issue. Once we get a detailed report we will prosecute and charge sheet all those involved in this illegal business," informed the DG.

- **Fake medicine factory busted in Ghaziabad; five arrested**
  NDTV, May 17, 2012

Ghaziabad: Five men were on Wednesday arrested from a factory in Modinagar where a fake variant of Unani medicine 'Safi' was allegedly manufactured.

Harish Goyal, Amit, Shivam, Tiloo and Sanju were taken into custody and 400 bottles of the fake medicine recovered, SSP Preshant Kumar said. Several machines used for sealing and cleaning the bottles were also seized, he said. The company of the original brand, Hamdard, has been informed of the fake product.The five men have been sent to 14 days judicial custody after being presented before a judicial magistrate.

- **Fake Malaria medicines found in India**
  The Times of India, May 22, 2012

A third of malaria drugs, used around the world to keep the spread of the disease at bay, are counterfeit, a recent data has suggested. According to a study published in the reputed journal The Lancet, around 7 per cent of the drugs tested in India was found to be of poor quality with many being fake.

Researchers who looked at 1,500 samples of seven malaria drugs from seven countries in Southeast Asia said poor-quality and fake tablets are causing drug resistance and treatment failure. Data from 21 countries in sub-Saharan Africa, including over 2,500 drug samples, showed similar results. From 1999 to 2010, seven multi-country surveys with data from seven countries in Southeast Asia included chemical assays or packaging analysis for 1,437 samples of seven anti-malarial drugs. Of the total 437 samples of drugs, 497 (35 per cent) failed chemical analysis, 423 (46 per cent) of 919 failed packaging analysis, and 450 (36 per cent) of 1,260 were classified as falsified. "6,55,000 and 1.2 million people die every year from Plasmodium falciparum infection. Children in sub-Saharan Africa and Southeast Asia have the highest risk of contracting and dying from malaria," it added.

Researchers add caution, as they believe that poor-quality anti-malarial drugs are very likely to jeopardize the unprecedented progress and investments in control and elimination of malaria made in the past decade. Anti-malarial drugs comprise 25 per cent of the drugs consumed in malaria-infected countries, and when these drugs are of poor quality, they afflict the most vulnerable populations.

❖ **Drugs seized, Counterfeit racket busted**
The Sangai Express, May 08, 2012

Imphal: A large quantity of pharmaceutical drug Acti-Feel, which is abused by a section of youngsters as intoxicating substance, has been seized by Imphal West District Police from Imphal Airport.

Speaking to media persons at district police headquarters today, Imphal West SP K Jayenta said that the 21 cartons containing 700 strips of Acti-Feel were seized from the airport this afternoon. The seized drugs were sent from IGI Airport, New Delhi. It was not known who sent the drugs and to whom as the consignments did not specify its recipient, said the SP adding that investigation has been launched to ascertain the facts. Authorities of the three airlines, Air India, Kingfisher and Indigo would be asked to cooperate in the police investigation and also to take up necessary action if there was any lapse on the part of their staff.

Acti-Feel tablets have been already banned in Manipur in view of its large scale abuse by some sections of youngsters.

❖ **Cure-all drugs seized in raids**
IBN Live, May 12, 2012

Kochi: The Drugs Control Department continued its search operations for the second day in Ernakulam and Idukki districts. The search was conducted at the ayurveda medicine wholesale shops, which have been allegedly misleading the public through false claims and advertisements of the 'cure-all' drugs.
Drugs worth Rs 2.75 lakh were seized from the stockists during the search operations conducted at Aluva. Drugs worth Rs 1.15 crore were seized from Thodupuzha.
The Drugs Control Department had initiated the move against some ayurveda companies, which had been allegedly misleading the public through false claims and advertisements. Drugs worth Rs 51 lakh were seized on Thursday in different parts of the state by the department.
Drugs Controller Sathish Kumar said that prosecution steps were initiated against the ayurveda companies for flouting the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. According to the act, no product should be sold with false and misleading claims.

❖ **DCA Chhattisgarh seizes cough syrup Phensedyl**
The Pharma Biz, April 18, 2012

Chennai: In a recent raid conducted in various parts of the state, the Chhattisgarh drugs control administration has seized 8,79,981 bottles of restricted drug, Phensedyl cough syrup manufactured by Nicholas Piramal,

from various shops in Raipur and nearby areas. The seized items would worth about Rs.6.15 crore.

The inspectors could not find the sale detail records of the drugs during the inspections in any of the raided shops, said S Babu, director FDA, Chhattisgarh. The drug was brought from Mumbai by agents and was planning to export to Bangladesh through Meghalaya, said the director.

According to the director, during raids the officials could not find any sale detail records of these bottles. Records showing from where these abundant quantities of drugs were brought to the stores and to whom those were sold, were not found in the shops during raids. Cases have been filed against the company and the traders, whose sale licenses were also cancelled.

Speaking to this reporter, S Babu said with the marketing of this cough syrup, the volume of sale of Nicholas has increased and the company stopped manufacture of other products for a short period taking advantage of the situation. He added that in the boom period Nicholas sold one of its divisions to Abbot Lab promising them a huge turn over. Following the deal, the sale of the drug was stopped due to seizure by various enforcement agencies in several parts of the country.

- **Rs 17-lakh worth illegal cough syrup seized**
  The Times of India, April 20, 2012

Kozhikode: The drug control department has seized 20,000 bottles of illegally made cough syrup worth Rs 17 lakh after it was found being sold here among students as a sedative.

A seven-member squad seized the medicine 'Cofcare' from a local distributor at Puthiyara on Thursday. Officials say an unlicensed firm in Hyderabad made the medicine. The manufacturing company did not have any valid licence for commercial production and sale of the syrup from the Andhra Pradesh government.

According to assistant drug controller P K Sreekumar the drug contains huge quantity of Codeine Phosphate, which blurs vision and creates breathing discomfort apart from loss of consciousness among regular users.

- **APDCA unearth expired medicines worth Rs.65,000 from corporate hospital pharmacies**
  The Pharma Biz, March 31, 2012

Hyderabad: The drug control administration in Andhra Pradesh has raided four premises of a corporate hospital in Hyderabad and found expired, sub-standard drugs worth Rs.65000, stored illegally in unauthorized premises.

Based on a tip off, the Drug Control Authority of Andhra Pradesh raided corporate pharmacies attached to the hospitals and found huge quantities of substandard, expired medicines stocked in the premises.

Earlier, the DCA had raided retail pharmacies and found that many of them did not adhere to prescribed rules and norms. It was also found that more than 70 per cent of the pharmacies are operating without registered pharmacists and do not issue regular bills to consumers. The DCA is also working on an action plan to raid all the corporate hospitals in the state and their attached pharmacies.

- **10 Lakh violated bottles Coughed up in Gujarat**
  The Economic Times, March 18, 2012

Ahmedabad: Stocks of over 10 lakh cough and cold syrup bottles worth about Rupees four crore made by some of the well-known companies have been sealed by drug officials in Gujarat at the level of stockists after being found to contain codine, a derivative of opium, a top GFDCA official said today.

“The manufacturers were selling these drugs without mentioning the generic name of the medicine – codine,” he said adding that ten lakh bottles of cough and cold syrups valued at over Rs 4 crore have been restricted from sale here pending further investigations. Around 22 different brands sell cough and cold syrups in Gujarat, of which 20 leading brands were found violating the rules during a week-long drive launched here, Koshia said.

The GFDCA also got 15 chemist shops closed here that were found selling these H-scheduled drugs without prescription or were operating without a pharmacist.

- **2 held for selling fake drugs**
  The Times of India, February 23, 2012

Patna: The Pirbahore police arrested two persons on Wednesday from Govind Mitra Road on charges of selling fake medicine. The police said the arrested persons are Awadhesh Singh and Sunil Singh, owners of Shiv Shakti Enterprises and R S Pharma, respectively. They were arrested from Beni Madhav Lane, the police said.

- **Gujarat FDCA busts racket making IV sets without license near Ahmedabad**
  The Pharma Biz, March 06, 2012

Mumbai: The Gujarat Food and Drug Control Administration (FDCA) recently busted a racket involved in the business of manufacturing Intravenous (IV) stents without having a valid license from Vutva near Ahmedabad. During the raid, the officials from the drug licensing authority successfully seized IV

stents and some of its components worth Rs.12 lakh from their manufacturing unit at Vatva. The raid was carried out in a company called Tridhara Surgicals after receiving a tip off on its questionable activities through the state FDCA's toll free number 100 233 5500. The FDCA officials found that the company was involved in illegal activity of manufacturing IV stents and its components without license and selling it within the state to various sources under fake identity. Some of the seized product samples have been sent to Baroda food and drugs testing laboratory for checking its safety and efficacy. Once the drug regulators get confirmation on the whether the manufacturers have compromised with the quality of the products, they will further probe into the activities of the company.

Since IV stent is one of the few notified medical devices in the country and is considered as a drug under the Drugs and Cosmetics (D&C) Act, all the provisions of the Act is thus applicable to it as well. According to Dr H G Koshia, commissioner, Gujarat FDCA, law of the country states that for any person to manufacture IV stent in the country it is essential for him to procure a valid licence with due diligence failing to which his actions will be deemed punished under the law. Moreover, due to the low cost involved in manufacturing the products it has a huge market both within the country and internationally, acting as a potential attraction for wrongdoers as well. To avoid any discrepancies that may arise out of illegal activities that may affect quality of the products coming out of the state, we keep a close watch on all the activities of the medical device industry within the state," Dr Koshia added.

- **Spurious drugs claim four, seven taken ill**
  Express Buzz, February 07, 2012 / IBN Live, *February 08, 2012*

Cuttack: At least four persons died and seven others were taken seriously ill allegedly due to overdose of medicinal formulations with high alcohol content at several villages under Cuttack Sadar police limits late on Monday.

While the Excise Department and police have arrested two persons, including a woman, in this connection, the nature of the brew has come as a shocker. The bottles, recovered from the house of the main accused and supplier, Baidhar Bhoi of Tukulpada, who also lost his life, were found to have contained Orange Tincture and Epeecarm.

Orange Tincture BP is a solution with an ethanol content as high as between 62 and 69 per cent. It is used mainly as a flavouring agent during manufacture of pharmaceutical drugs. Epeecarm also has high concentration of alcohol but more dangerously has high beladona content, which can cause poisoning. It is also used a flavouring and colouring agent in drug making.

How the raw materials were procured or supplied for consumption as a substitute of liquor has raised several questions on the efficacy of drug control and monitoring mechanisms in the State. According to reports, the victims were all daily labourers working at different brick kilns in the Sadar area while Baidhar was a known bootlegger.

On Monday night, they had reportedly boozed together at Baidhar's house. About 20 bottles, including three of Orange Tincture BP, and the rest Epeecarm had been consumed as the empty bottles reflect. The people soon complained of chest pain and nausea and were rushed to the Mahidharpada PHC and then referred to the SCB Medical. Three died at the hospital while Baidhar died at his house.

As Excise officials led by SP Pradipta Patnaik and Sadar police raided the house they found the empty bottles as well as two unconsumed ones that were hidden inside a clay pot. Baidhar's wife Chhabi and son Benudhar, who had been assisting him in the illicit liquor business, were immediately arrested.

- **81-year-old doctor let off after over 28 yrs of trial**
  Daily Bhaskar, February 19, 2012

A Delhi court has let off an 81-year-old doctor, caught manufacturing and selling spurious drugs and cosmetics over 28 years ago and sentenced to three years in jail for his crime, on probation.

Additional Sessions Judge (ASJ) Savita Rao let off Dr H R Kanwal on a year's probation after modifying the three-year jail-term, imposed by the magisterial court upon him, to a year. The court enlarged the convict on probation saying though the offences committed by him have grave social and economic implications, sending him to jail will not serve any purpose in the given circumstances. The sessions court also took note of the convict's pleading for leniency on the ground that he faced the trial for 28 years, during which his only son was murdered.

"Though the trial court has rightly observed that the offence committed by the appellant have grave social repercussions upon the consumers who were using it believing it to be a genuine product and there is also heavy revenue loss to the company having license to manufacture the same, thereby affecting the economy of the country, but considering the reasons as stated above, no purpose would be served by sending him behind the bars," the ASJ said. The ASJ ordered Kanwal's release on one year probation on furnishing a bond of Rs 50,000 with one surety of like amount. Dr Kanwal was caught nearly three decades ago by a Drug Inspector and the trial court in September last year had sentenced him to three years in jail, while also imposing a a total of Rs 35,000 as fine for offences punishable under various provisions of Drugs and Cosmetics Act dealing with manufacture and sale of misbranded, adulterated and spurious drugs.

- **Spurious drug makers arrested**
  www.webindia123.com, *December 28, 2011*

Two individuals charged with making and supplying spurious ayurvdedic medicines have been arrested, one from Badayun district, Uttar Pradesh, and

the other from Red Fort, Delhi. The duo, from whose possession spurious ayurvedic medicines have been recovered, had a drug factory in Bareilly. A third person believed to be involved in the racket – a factory owner, is on the run.

- **Fake cosmetics nabbed in Nagpur**
  The Times of India, December 01, 2011

The city's Crime Branch has busted a racket involving the sale of counterfeit cosmetics in Nagpur. Acting on a tip off, the social service department of Nagpur city's Crime Branch has seized misbranded cosmetics worth Rs. 1.80 lakhs. The products carried the names of leading brands and were meant for sale to unwary rural consumers. One Rajesh Sachdeo, believed to be the kingpin in the racket, was arrested from a godown. His aide managed to flee the police net.

- **Blacklisted 9 firms' drugs**
  Deccan Chronicles, December 15, 2011

Hyderabad: Drugs of 9 pharmaceutical companies were found to be substandard and have been blacklisted by the Andhra Pradesh Medical Services and Infrastructure Development Corporation (APMSIDC).
The following drugs meant for common ailments have failed the quality test. They are
Karnataka Antibiotics and Pharmaceuticals Ltd Injection Verclov 1.2gm (Amoxycillin+Clavulanic Acid), Batch no. 3401410
* Cipco Pharmaceuticals Tablet Dicyclomine HCL 10mg, Batch No. CT-91201
* Hindustan Pharmaceuticals Etophylline and Theophylline injection, Batch No. 426
* Vital Health Care (P) Ltd. Prednisolone Acetate Opthalmic Suspension USP Batch No. V9094
* Jackson Laboratories (P) Ltd. Pentasol Injection, Batch No. I.P.B NO.1-3236
* Bengal Chemicals Ciprofolxacin Tablet 250mg, Batch No. 0578002
* The Swastik Pharmaceuticals Povidone Iodine Solution, Batch No. 2667
* Eurokem Laboratories (P) Ltd. Nifidifine Tablet I.P 10mg Batch No. F62
* Agron Remedies (P) Ltd. Diclofenac Sodium Tablet, Batch No. DDF-35

- **Busted in Baddi**
  Consumer Conexion, November 13, 2011

In a raid on the premises of a drug manufacturing unit operating from Bagvania village near Baddi, sleuths from Delhi Zone of the Directorate of Revenue Intelligence, along with police officials, unearthed a massive hoard of veterinary and allopathic medicine, which the drug manufacturing unit, Ten Star, had not been licensed to manufacture. According to Drug Controller Navneet Marwaha, who received a tip off from a Joint Director in the Directorate of Revenue Intelligence and participated in the bust, the

pharmaceutical formulations seized in the raid were found to be fraudulently labeled with the names of companies like Torranto Welcare Pharmaceuticals, Tranesia Bioceuticals, MPPL Rudrapur and Excel Biolife Private Limited. On completion of investigations, a case will be registered against Ten Star under Sections 18(a)(i) of the Drugs and Cosmetics Act, Mr. Marwah said.

- **Pharma unit found making spurious medicines**
  The Times of India, May 28, 2011

CHANDIGARH: The state drug control department in Haryana on Friday unearthed a racket involving manufacturing of spurious medicines of a Goa-based pharma unit from the premises of Jorker Pharmaceutical Ltd in HSIIDC complex at Rai in Sonipat.

The department has lodged a criminal case against company director Ranjan Kumar, manufacturing chemist Umesh Gupta and annalist chemist B K Pandeyat at Rai police station. At the same time, the department has initiated criminal prosecution against Jorker Pharmaceutical, Rai, the errant pharma unit, under various provisions of Drugs and Cosmetics Act. The department has also cancelled the licence of the manufacturing unit.

On Tuesday the drug control department seized 2.5 lakh tablets of Coscold, a cough tablet sold by Cosmo Pharma Ltd from the premises of Jorker Pharma. After the Goa-based company confirmed the counterfeits, a complaint was lodged with the police.

The counterfeit drugs are learnt to have been largely supplied to defense as well government supplies. This is in addition to supplies in local markets of Goa and Maharasthra, an official said, adding that further details were awaited. "Samples tested at Chandigarh laboratory confirmed zero trace of Pseudo Aphedrine (a salt used to heal cough problem) as mentioned on the cover. So was the case with four other medicines, which were manufactured by Jorker under their own brand names. Tests suggested only 50 to 60 per cent of traces of salts mentioned on pickings," said P K Das, secretary health, Haryana.

Elaborating more, additional drug controller G L Singhal informed that preliminary investigations suggested some other serious lapses were also found during investigation carried out by them. Other four medicines manufactured by Jorker Pharma, which failed the test included Rimole tablets 500mg (an alternate of paracetamol), Roxyin 150 MG (antibiotic containing Roxythromycin) and Jorcycline 500 (tetracyclin) and Cipbid (ciprofloxacin with einidazole).

❖ **Fake Maroperam injections likely cause of several deaths: Report**
The Times of India, September 06, 2012

Jaipur: The fake antibiotic injection of Maroperam provided to patients through the life line stores of the Mahatma Gandhi Hospital and Mathura Das Mathur Hospital in Jodhpur has caused death of patients.

The shocking suggestion has been made in a report prepared by the principal of SN Medical College in Jodhpur in response to the police queries regarding a fake medicine racket. The report has given the police ground to book the 10 accused arrested so far in the case under Section 27 of the Drug and Cosmetic Act, apart from other sections of the IPC.

The police had seized nearly 1,000 Maroperam injections from a drug store on May 26. The police have since then arrested nine people including the kingpin, Rajesh Purohit, who was running a bogus pharmaceutical firm, a life line store owner and a nursing tutor. Police are gathering evidence against at least 12 doctors suspected to be involved in prescribing fake medicines manufactured by this bogus pharmaceutical company to earn hefty commissions.

❖ **Vigilance raid unearths sale of fake drugs**
The Times of India, August 11, 2012

Kochi: The surprise raids conducted by the state vigilance and anti-corruption bureau at the offices of drug controllers and drug testing laboratories in the state on Friday unearthed large scale irregularities and sale of spurious drugs. The raids, code-named 'Operation Tablet', were conducted as per the direction of vigilance director Venugopal K Nair and were coordinated by vigilance ADGP N Shanker Reddy.

According to officials, spurious drugs were being sold in the state under different brand names.
"We found test results of sample drugs were not submitted at the offices of the drug controllers in the state. We will get a clearer picture only after studying the final report from the officers. Preliminary probe points towards irregularities in collecting drug samples for tests and renewal of licenses of various drug stores," said Reddy.
He said it would take minimum two months for the department to prepare the report.

❖ **New Delhi: Spurious drug racket busted**
Criminal Record India, June 15, 2011

The police busted an organized gang selling spurious drugs and those meant for CGHS, MCD, ESI and even the Director-General of Armed Forces Medical Services (DGAFMS) for the past 10 years. This is the first time that such a racket has involved the DGAFMS. A special investigation team said raids

were carried out at central Delhi's medical wholesale market, Bhagirath Place, and subsequently also in Agra. Raids in the city were conducted on June 3 and drugs worth Rs. 8 lakh were seized. The Agra raids were conducted on June 6 and yielded drugs worth Rs. 34 lakh.

- **Gang selling spurious, 'free' medicines busted**
  The Times of India, February 15, 2011

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Racketeers may have stamped the spurious medicines with the names of different government agencies to authenticate them so that people will assume that these medicines are genuine and purchase them," said DCP (crime) Ashok Chand said.

Additional DCP Joy Tirkey said medicines recovered from Agra were past the expiry date. "They were pushed into north Indian markets after recycling. Worse, a senior official of a pharmaceutical company, who accompanied the raiding party, told the police that 45 ampoules of seized 'Susten 100' injections, used by pregnant women, and were also spurious. Other medicines include those meant to cure heart ailment and diabetes.

While the raids in Delhi were conducted on June 3, the Agra raids were conducted on June 6. "We have recovered Rs 8 lakh worth of spurious drugs in Delhi and another Rs 34 lakh worth of drugs in Agra. We have now written to the concerned government agencies to ascertain whether the medicines, which are stamped, have been siphoned off from their stocks. For this, the manufacturing date and batch numbers have been preserved."

- **Cops bust fake drug racket**
  The Indian Express, August 21, 2012

The arrest of three persons in the Temple City on Sunday night for their alleged involvement in spurious drug trade has revealed that a gang with well-entrenched networks has been involved in supply of counterfeit drugs in Southern districts and the Textile City of Coimbatore for almost a year now.
Preliminary investigations reveal that the gang has been operating from Chennai.

The main accused - Malieek of Villupuram - had been despatching fake 'Vicks Action 500' tablets from Chennai for packing to one Thamaraiselvan of Madurai.

Thamaraiselvan (43) of Anupanadi, who is alleged to have been involved in preparing fake carton boxes for various items such as asafoetida, had designed them for the drug also from printing units in Sivakasai.
Based on a complaint from senior employees of IPR Vigilance Service, (which was engaged by the Procter and Gamble to prevent the supply of fake products of their brands), it was found that fake Vicks Action 500 was in circulation in Madurai.

Following this, a special police team arrested Thamaraiselvan and two others - Anand (23) of Anupanadi and Mariselvam (42) of Solaialagupuram and seized 20 boxes (each box containing 9,600 counterfeit tablets). The packed spurious drugs would be sent back to Chennai in private buses and from there, the gang would circulate them across the State. A senior police official who was investigating the 2010 expired drugs case in Chennai said that most of the spurious drugs were manufactured in Puducherry, where many pharmaceutical companies were functioning.

Meenakshi Sundaram, the main accused in the expired drug case, also owned pharmaceutical establishments in Puducherry, he said. The official also pointed out that gangs involved in spurious drugs trade were mostly involved in producing either cheaper drugs or costlier ones, which have more demand in the market.

- **Fake medicines racket busted in Faridabad, Three detained**
  Pardaphash, July 16, 2011

New Delhi: Three people have been arrested for making fake drugs of leading pharmaceutical firms and spurious medicines worth lakhs of rupees have been seized, said the official on Friday. The racket has been broke out in Faridabad, Haryana.

Ramesh Gupta, Food and Drugs Administration Commissioner was informed that fake drugs of well known companies like Glaxo and Alcum were being manufactured in Faridabad city, neighboring Delhi, said a department spokesman in Chandigarh.

The spokesperson added, "A special team of the department, along with crime branch officials, raided the premises in Faridabad's Sector 6 and recovered huge cache of fake drugs worth lakhs of rupees." Daya Shankar Misra, owner of the factory was arrested in Delhi earlier also and a large amount of spurious medicines seized from him.

According to Delhi Police's Deputy Commissioner Ashok Chand, "Misra (55) and Dinesh Sahu (52) were arrested from Old Delhi Railway Station on

Monday following a tip-off that spurious medicine racket was operating in Delhi and Faridabad."

According to police's rough estimate, they supplied fake medicines worth more than Rs.8 crore in Delhi and other states in the last five years.

❖ **Drugs seized**
The Sangai Express, September 28, 2012

Imphal: Together with impounding a briefcase containing Actisun tablets having banned Pseudo-ephedrine Hydrochloride content from Imphal airport, Imphal East District Police have arrested three persons.

Displaying the seized drugs at Porompat police station today, a senior police officer said that the drugs were seized by a special unit together with a team of Porompat police station at about 1 pm today.

The tablets were being brought to Imphal on an Air India flight from Delhi by Md Riyaj Ahmad (38) s/o Md Siraj Ahmad of Sangaiyumpham Nung-phou Bazar who works in the CISF at Delhi. He has been apprehended.

Along with Riyaj Ahmad, Md Ajim Khan (25) s/o Abdur Salam and Md Imraz Hussain (22) s/o Md Iboyaima of Keirao Makting Mayai Leikai who came to receive the consignment have also been arrested, said the officer. It is estimated that the seized tablets would cost around Rs eight lakhs at the rate of Rs 8 per strip. Each uncoated Actisun tablet contains 2.5 mg of Triprolidine Hydrochloride and 60 mg of Pseudoephedrine Hydrochloride. The case would be handed over to Singjamei police station for further investigation, added the officer.

❖ **5 nabbed for selling fake cosmetics**
The Times of India, July 12, 2012

Patna: Patna police on Wednesday raided three shops on Nala Road under Kadamkuan police station area and recovered fake cosmetics of a reputed company worth about Rs 2 lakh.

City SP Kim, along with officials of the cosmetic company, raided the three shops and arrested five persons in this connection. The mastermind behind the fake cosmetics racket, Mukesh Kumar, is absconding, Kim said.

She said police had information regarding the fake cosmetics being sold at some reputed stores. "Police collected a few samples and sent it to the company for quality check. When the company confirmed that the fake cosmetics were being sold in its brand name, we decided to raid the shops," she said.

Mustafa Hussain, a legal department official of the cosmetic company, said, "There are many shops in the city which openly sell fake products of the top brands. The mastermind behind the racket, however, escaped." He said the company was searching the factory where such fabricated cosmetics were being manufactured. The arrested persons are Kamal Dubey, Md. Alam, Shashi Kumar, Sunil Tiwari and Dilip Thakur. However, they could not give much information to the police about the factory and the supply chain.

THAILAND

- **Dirty Laundry Deals in Drugs**
  The Pattaya People, November 04, 2011

On Wednesday night, the police from the Special Suppression Department, led by its Chief Pol. Lt. Col. Kwanpichai Mano-jarern-sahb entered the laundry of Mr. Soheep Farudee aged 25 and Mr. Faisal Nadeem aged 40, both from Pakistan, after being informed that these 2 men were selling many types of sexually enhancing illegal drugs. The officers discovered a large shipment of Viagra and other drugs, plus sleeping pills worth 1,900,200 Baht in the premises. The impounded drugs were mostly manufactured in India, and some were fake drugs from China. The so-called erectile dysfunction drugs were mostly for foreign tourists, and the sleeping pills were mostly for bar girls and prostitutes. The men were remanded for legal proceedings and further investigation.

- **Five nabbed in Thai fake sex drugs swoop: Police**
  The Sunday Times, August 02, 2011

Bangkok: Bangkok authorities arrested five men in a crackdown on sex drugs sold illegally to tourists in streets around the city's red light districts, Thai police said Tuesday. Raids on July 25 and 28 netted several fake or unlicensed drugs such as Viagra, which is normally prescribed for men suffering from erectile dysfunction. In total five men, two Myanmar nationals and three Thais, were arrested in the two raids, carried out in the China Town and Nana areas of the city. They were charged over offences including the illegal sale of drugs and selling fake and unlicensed drugs. If convicted they could face up to 20 years in prison. Police released a list of items seized in the operation, which were estimated to be worth a total of 500,000 baht ($16,800). These included various types of Viagra, “Waman penis enlarging tablet”, Kamagra oral jelly -- in banana, apple and blackcurrant flavours -- and an item intriguingly listed as “Night fire heartily burnable lady's intense emotion”. “This has tarnished Thailand's tourism image,” said an official from the Thai Food and Drug Administration, which also took part in the raids.

BANGLADESH

- **One arrested while making fake drugs**
  The Daily Star / Metropolitan, June 04, 2012

A man was held in the port city yesterday allegedly for producing and selling fake medicines. The arrestee was Masud Rana, 32, of the city's Char Patharghata.

Detective Branch (DB) of police caught Masud along with fake drug items, worth Tk 50,000 while he was making fake medicines in a room beside a pharmacy around 3:00pm at a pharmacy in Char Patharghata, said Deputy Commissioner of DB Mohammad Maniruzzaman at a press briefing in CMP Headquarters yesterday.

Masud confessed before the press that he did the acts under the company name 'SAMA Marketing Company,' which has no existence. He used to collect Calcium tablets from different medicine companies, adulterate and pack those into fake packets of medicine company Beximco Pharmaceuticals and then sell those to the retailers in the name of 'Vitamin tablets,' he said. A case was filed with Karnaphuli Police Station under the Special Power Act in this regard.

- **Youth held with fake medicine**
  The Daily Star, June 02, 2012

Rapid Action Battalion members detained a youth on charge of selling fake medicines in Chittagong on Thursday. The detainee was identified as Alam, 27, son of Md Shamsul Alam of Nolanda village under Patiya upazila in Chittagong.

Following a tip-off, a team of Rab-7 men conducted a special drive at Hasina Medico, a pharmacy located at the city's GEC intersection, around 9:15 pm, said a press release.

The law enforcers led by Lt Zakir Hossain caught Alam red handed while he was selling fake medicines at the shop. They also seized fake drugs worth around Tk 5 thousand from his possession. During primary interrogation, Alim confessed that he had been selling fake medicines to different pharmacies in the city under the brand name Novogen Bangladesh, the release added. Filing of a case in this regard was under process, said Rab-7 officer SM Nurul Huda.

❖ **Fake phensidyl factory**
The Daily Star, September 21, 2011

Rapid Action Battalion (Rab-12) on Monday unearthed a fake phensidyl factory at Atua near the district town. The elite force raided the residence of Riazul Haque Shimul of the area where he set up the spurious phensidyl factory. Mehedi Hassan Shourav, 25, son of Riazul was repacking the drug made of water and other chemicals when Rab raided the place. Shourav fled the scene but the elite force arrested his wife Ritu from the spot.

❖ **Two men arrested with fake medicine**
The Daily Star/ Metropolitan, October 4, 2011

Detective Branch (DB) of Police arrested two men with fake medicine from the city's Uttara on Sunday. However, the medicine factories are yet to be busted. The arrestees Mizanur Rahman alias Rubel, 30, and Yusuf Zaman, 35, at a press conference at DB headquarters yesterday, admitted their crimes. DB officials said the arrestees are involved with a gang producing, packing and selling fake medicine at pharmacies in Uttara and adjacent areas.

The medicine bottles labelled “One To Nine”, “Nervicon” and “Soya Protein” claimed to be dietary supplements and were marked as products from the US. At the press conference, Additional Deputy Commissioner (DB-South) Molla Nazrul Islam said Rubel distributed the medicine and was caught while packing them at his Sector 9 house in Uttara around 4:30pm.

For the past six months, a man named Kamal used to provide the coloured tablets which Rubel packed in plastic bottles, bought from Old Dhaka, and stuck the labels, which came from printing presses in Nilkhet, said Rubel.

❖ **Fake medicine factory**
The Daily Star, November 16, 2011

Dinajpur: A mobile court on Monday sealed an illegal drug factory and jailed five people in Rajbari area of the district town. Police said the court led by executive magistrate Tasnin Jebin Binte Sheikh raided Bengal Ayurvedic Laboratories in the area and found syrups being produced in an unhygienic condition and without any chemist. Officer in-charge of Dinajpur police station Hasan Shamim Iqbal said the owner of the factory could not able to show certificates of Directorate General of Drug Administration and Bangladesh Standard Testing Institute (BSTI) for producing the drugs.

NEPAL

- **Fake vaccinators apprehended in capital**
  My Republica, April 03, 2011

Kathmandu: Police apprehended four people for administering fake hepatitis B vaccine to the public in Boudha following the tip-off from the District Public Health Office (DPHO), Kathmandu.

DPHO Chief Bisho Ram Shrestha said the police have handed over the quack vaccinators to Kathmandu District Administration Office for punishment. Claiming such vaccines can have disastrous impact on human health, Shrestha said, "Preventing fake vaccinators from selling unapproved vaccines has become a major challenge for us."

According to DPHO, all vaccines must have quality approval from World Health Organization (WHO) before being administered. Likewise, vaccines must also get approval from the Department of the Drug Administration (DDA). The vaccines administered by the arrested vaccinators had approval from neither of the agencies.

"We have not given consent to any organization in the country to administer hepatitis B vaccines," Shrestha said. The government does not have a policy to give consent for administrating hepatitis B vaccine. The vaccines for hepatitis B, the most common serious liver infection, are administered in Nepal only through those authorized by the government.

The arrested vaccinators were found to possess identity cards of a fake non-governmental organization.

"We confiscated bills and identity cards of ´Heal Nepal´ and ´Janasewa Nepal´ from them," Dhurba Adhikari, a public health officer at DPHO, Kathmandu, revealed. Adhikari said the vaccinators smuggled unapproved vaccines from India. "We do not know about the quality of the vaccines they were using. It could be distilled water or something else," Adhikari said.

The vaccinators were found charging Rs 50 for administering vaccine to children aged 10 years, and Rs 100 to those above the age. DPHO chief Shrestha revealed that such fake vaccinators influence school principals to sell vaccine to students. Due to open border, the DDA faces difficulty in curbing the flow of unapproved medicines into the Nepali market. Though DDA has prohibited pharmacies from selling unregistered drugs, the agency´s latest report indicate their existence in the market.

❖ **Fake anesthetic in market**
My Republica, May 27, 2011

Biratnagar: Fake vials of Vacuron, an anesthetic injection used for major surgeries, have been found in the market. The fake vials that look exactly like the genuine ones, work for barely five minutes in patients.

The sale of fake vials of the anesthetic came to light after a patient who underwent gall stone surgery at a private hospital in Biratnagar regained consciousness just five minutes after being administered with 4 mg of the anesthetic.

The genuine Vacuron that is manufactured by Sun Pharmaceuticals of Gujarat, India, is capable of keeping a patient sedated for 20 minutes. A vial of the genuine medicine costs Rs 127, while the fake one is being sold for Rs 45 per vial in Biratnagar. According to sources, the fake vials are brought to Nepal by traders entering Nepal from Bihar, India.

INDONESIA

- **Fake Viagra pills confiscated**
  The Jakarta Post, June 23, 2011

Jakarta: A joint team set up by the Jakarta administration raided on Wednesday illegal drug vendors in a number of spots in the city, confiscating 700 fake Viagra pills. Officials from the East Jakarta Health Agency, Public Order Office and the Food and Drug Monitoring Agency (BPOM) raided 20 illegal drug stores in a number of spots Wednesday including on Jl. Pemuda, Jl. Dewi Sartika, Jl. I Gusti Ngurah Rai and Jl. Raya Bekasi. The raids were conducted from information given by locals who became suspicious after learning that the "blue pills" were offered at a discount price. East Jakarta Health Agency head Yenuarti said as quoted by tempointeraktif.com that the fake Viagra pills could have side effects. Yenuarti said the pill had also been abused by locals to engage in promiscuous activities. "We will conduct a raid every month," she said.

SRILANKA

- **Sri Lanka bans import of Pakistani medicines**
  The Express Tribune, February 02, 2012

Following the PIC medicine debacle, Sri Lanka has banned the import of medicines from Pakistan — a move that would badly hurt the export of locally manufactured medicines, which had surged to over $400 million over the last two years.

The health ministry of Sri Lanka has taken the decision after over 100 people died due to alleged spurious medicines in Lahore. It was further revealed that more countries – including Vietnam, Burma, Philippines, and Yemen as well as countries from Africa and South America – are also considering reviewing their policies to import medicines from Pakistan.

Sri Lanka suspended the sale and use of Pakistani-manufactured Isosorbide Mononitrate 20 mg drug, used for chest pains, said a senior doctor of the National Cancer Institute of Sri Lanka.

On the other hand, officials dealing with the issue revealed that the government was deliberating putting around 12 drugs on the import ban list. However, the final decision will be taken after taking into account the investigation reports received from abroad, added an official of the Punjab Health Ministry.

Islamabad is issuing 32 licenses to pharmaceutical companies on a daily basis, the senator revealed. “So, this is the main reason which led to the use and distribution of substandard medicines.”

MISCELLENOUS REPORTS

- **Maharahstra, TN account for 36% of sub-standard drugs**
  The Times of India, August 22, 2012

New Delhi: Almost one in three drugs (36%) found "not of standard quality" from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone. Around 9.2% of the rest of the sub-standard quality drugs were from Kerala, Gujarat (8.5%), Karnataka (7.2%), Uttar Pradesh (6.9%), Jammu & Kashmir (6.08%) and Rajasthan (5.8%).

Union health minister Ghulam Nabi Azad said on Tuesday that of the 48, 082 drug samples tested by state drug controllers between 2011 and 2012 (till October); 2,186 samples, or around 4.5% failed the quality test. In comparison, 4.9% of the samples tested in 2009-10 and 4.7% in 2011-11 were sub-standard. Of these, around 133 samples — almost 6% — were found to be spurious or adulterated, the minister said. The maximum number of samples tested were from Maharashtra (6,928), followed by Karnataka (5268), Andhra Pradesh (4,758), Tamil Nadu (4,110), Kerala (3,904), Punjab (3,031) and Gujarat (2,874). A very few samples were tested in Delhi (283) of which only 13 samples — around 4.5% — were found to be sub-standard. As far as spurious or adulterated drugs are concerned, which has no active ingredient or is an expired drug that has been re-labeled and sold, Gujarat recorded the highest number of such samples at 64, followed by Maharashtra (19), UP (11) and Delhi (9).

Union health ministry officials say there are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs. Experts say acute shortage of drug inspectors (DI) is hampering the nation's fight against spurious and fake drugs. The Central Drug Standard Control Organization (CDSCO), which lays down standards of drugs, estimates that the nation requires 3,200 DIs for its six lakh chemists, but only about 1,000 DIs are available. The size of India's pharmaceutical industry is pegged at Rs 90,000 crore of which 40% is exported. CDSCO estimates that in the next five years, drug exports may rise from Rs 42,000 crore to Rs 2 lakh crore. Azad said "spurious drugs not only affect the citizens' health but also the prestige of the country's pharmaceutical trade interests". The Union health ministry had earlier formulated a whistleblower policy — to handsomely reward both public and officers who help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices. The policy stipulated a reward of maximum of 20% of the total cost of consignments seized as payable to the informer that won't exceed Rs 25 lakh for a case. However, the policy fell flat. The working group on health for the 12th five year plan has recommended setting up of eight new Central Drugs Testing laboratories for Rs 320 crore, besides upgrading the six existing ones for Rs 15 crore each. Although many labs have facilities for testing of drugs (quality), they aren't equipped to test contaminated substance in drugs, it said.

❖ **Real or fake? Just dial an Interpol registry to find out**
The Hindu Business Line, July 19, 2012

Mumbai: No matter where you are in the world, you may soon be able to check, if the medicine you just bought is a fake or genuine. An Interpol Global Register (IGR) has been created to allow consumers check the authenticity of certain medicines using their unique security features. First off the block on the initiative is PharmaSecure, a drug authentication technology company that has security coded more than one million packets of medicines produced every day in India. It has provided drug-makers what is known locally as the SMS-check on medicines. Medicine strips have a mobile number and an SMS code printed on them. A consumer in doubt about the authenticity of the drug, can SMS the code to the number and get a confirmation. Drug companies such as Lupin and Unichem, for instance, have adopted the technology to empower consumers to check the authenticity of medicines, said Mr Kishore Kar of PharmaSecure in India. Google Ideas developed a 'proof of concept' model for the IGR, unveiled at the Google INFO summit in Los Angeles, where its functionality was first demonstrated. Searches can be conducted by entering details manually or scanning a code via mobile applications available on the Android, Apple, Microsoft and BlackBerry platforms which will then deliver fast, accurate and location-based information.

❖ **Pharma units in Himachal under scanner for spurious drugs production**
The Times of India, June 21, 2012

Shimla: Seeing around 25000 crore pharmaceutical industry of Himachal Pradesh facing credibility crisis, due to the production of sub standard drugs, state government has finally started acting against the drug manufacturing units by suspending their licenses. Recently, the licenses of seven companies were suspended after drugs manufactured by them failed the test. Considering the fact that 600 pharmaceutical industries located in Himachal Pradesh caters to around 50% demand of country, over the years Himachal Pradesh has become the largest suppliers of drugs and almost all the states in India are getting supplies from Himachal. But in recent past, quality of drugs manufactured in the hill state have come under the scanner after states like Maharashtra, Karnataka and others returned the supplies for their being sub standard. While, the state government has allowed hundreds of pharmaceutical units in the state, but it has not been able to ensure required manpower in the state drug controlling authority to check the quality which is resulting into frequent complaints from other states regarding the poor quality of drugs supplied to them, sources said. In Baddi-Barotiwala-Nalagarh (BBN) area, seven licenses were suspended, while one has been cancelled permanently for violations. Similarly one license has been cancelled in Paonta Sahib too, as during check 30 types of medicines were found to be of sub standard quality, which includes those, manufactured in other states too.

❖ **Government cracks down on fake drugs**
Mail Today, June 18, 2012

The government is taking major steps to crack down on the fake drugs menace in India. The health and family welfare ministry has hired about 100 inspectors to check spurious medicines, while the department of pharmaceuticals has issued notifications asking pharma companies to use nanotechnology for identifying such drugs. According to a World Health Organization report, almost 20 per cent medicines sold in India are fake. Dr Jagdish Prasad, director general of health services in the health ministry, said: "There are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs. We are in the process of increasing the man force to check counterfeit drugs." National Pharmaceutical Pricing Authority (NPPA) director and central public information officer K.K. Jain confirmed a notification had recently been issued for a nonclonable ID nanotag for pharmaceutical companies. "They can affix it on a strip or blister provided that the manufacturing or marketing company concerned has no objection in providing and sharing the data contained in the tag with the NPPA and government," Jain said. He added that the cost per tag on the packaging of tablets and capsules will come to Rs.1.02. "Not many companies are using it currently because of the costs involved. They prefer holograms to check drug piracy as they are cost-effective," Jain said.

❖ **National Consultation on Safe and Quality Healthcare organized by PSM India**
Safe Medicines India, February 11, 2012

Hyderabad: The country's pharma industry might be the third largest in the world in terms of volume and 14 in terms of value but Indian medicines carry the "sub-standard" tag in the international market. "The perception has gained ground due to poor manufacturing practices but it is not true", asserted Mr. Bejon Misra, founder, Partnership for Safe Medicines (PSM) India. Similarly, the percentage of spurious drugs or substandard drugs in the state is only two per cent contrary to some reports of their widespread penetration, pointed out K Subbi Reddy, regional director, Pharmaceuticals Export Promotion Council. They were speaking at a National Consultation on Consumers' Right to Safe and Quality Healthcare organised by Partnership for Safe Medicines (PSM) India, here on Thursday. The event also marked the silver jubilee celebrations of the Consumer Protection Law in India and it also saw the launch of a national campaign against spurious medicines in the supply chain. Minister for Consumer Affairs , Govt. of A.P., Shri. D. Sridhar Babu, who inaugurated the program, stressed on the need for ensuring easy accessibility of good quality medicines to the poor at affordable prices. Most of the speakers, however, focused on the brighter side and suggested measures to effectively end the supply of spurious drugs. "The percentage of substandard drugs is only 2 per cent in the state when compared to 11 per cent in the country over the last 5 years…and the percentage of spurious drugs in the market amounts to only 0.2 per cent in the state compared to the national average of 0.4 per cent over

the last 5 years," explained Subbi Reddy, pointing out that the state was a leader in the export of 'bulk drugs' in South East Asia. Dr Praful Naik, chief scientific officer, Bilcare technologies Ltd, called for the usage of 'track and trace technology' to counter supply of spurious drugs.The Pune-based company claims to have invented a solution for prevention of duplication using a unique ID which even the inventor cannot duplicate.According to Dr Naik, the technology is being used in defence and other high-security sectors and can be made available for pharmaceutical sector as well without any added cost. According to B Vaidyanathan, chief mentor, Consumer Protection Council, Rourkela, "Indian health infrastructure matched only the sub-Saharan countries.Only 11 per cent of Indians are covered under Health Insurance and 25 per cent have access to quality healthcare." Concluding the consultation program, Bejon Misra said the government should mandate the use of technologies to overcome the problem of spurious drugs.He further added, "The government needs to come up with a portal which identifies low-cost generic replacements for the costly branded medicines." He also urged consumers to make use of The PSM India toll free helpline 1800-11-4424, to bring cases of spurious drugs or overcharging of drugs to the notice of the authorities.

- **5% drugs in Indian market sub-standard, says Union health ministry**
  The Times of India, November 05, 2011

New Delhi: The Union health ministry says around 5% of drugs in India's one lakh crore pharmaceutical industry is sub-standard drugs. At a conservative estimate, drugs worth about Rs 5, 000 crore could be sub-standard - popping of which would not result in optimum effect.

Alarmed, the drug controller general's office has decided to put in place proper guidelines on what needs to be done when the quality of drug is found to be sub-standard through lab tests, and by when they need to be taken off the shelves at retail outlets.

A meeting of all state drug controllers has been called on November 14 on "how to combat India's growing problem of sub-standard drugs and to put in place a three-member committee that will finalize the guidelines". A ministry official said, "Now, once a lab in Maharashtra confirms that a batch of drugs found in Delhi is of sub-standard quality, nobody knows who should take action and what it should be. In reality, such drugs need to be taken off the shelf as soon as they are found sub-standard before they reach the consumers who won't benefit from them. The guidelines will specify the action for all state drug controllers and also for the first time quantify within how much time the sub-standard drug needs to be taken off the shelves of all retail outlets."

Drugs of poor quality - both irrational and sub-standard drugs - flooding Indian market have been a serious concern even among the Planning Commission. The report said of the top 10 products, which accounted for 10% of the

medicines sold in the market in the last few years, two belong to the category of irrational vitamin combinations and cough syrup, while the other is a liver drug of unproven efficacy.

Drug Controller General of India (DCGI) estimates that about 46 banned fixed dose combination drugs (FDCs) continues to be marketed, irrespective of the ban. About 1,067 FDCs are freely marketed with the state drug controllers' approval, but without the DCGI's concurrence.

It added, "A recent government survey of drugs reveals that 0.3% of all sample drugs were found to spurious, while 6%-7% of drugs in the country are found to be sub-standard in quality," it adds. In India, less than 1% of the drugs manufactured are tested. Each of the 26 government labs test a small amount of drug samples annually and have backlogs of about six-nine months.

- **National Rural Health Mission under CBI scanner**
  Hindustan Times, December 29, 2011

A probe into drug purchases of the National Rural Health Mission by the Central Bureau of Investigation has uncovered massive irregularities. Though a tender for medicines-supply floated by the Director-General (Medical Health) of the National Rural Health Mission was meant to procure branded drugs, unbranded products from Lucknow based companies were allegedly slipped in by the pharmaceutical wholesaler, Jain Medical, which had been contracted to supply Rs. 3 crore worth of drugs to government hospitals in 24 districts of U.P. This was uncovered by the Central Bureau of Investigation (CBI), whose sleuths found also that as much as four-fifths of the drugs stocked by the Central Medical Store Department (CMSD) were unbranded. The investigative agency had been probing the National Rural Health Mission in Lucknow and 72 districts on the directions of the Lucknow Bench of the Allahabad High Court. District Magistrates and Chief Medical Officers, who hold top-level positions in district health societies, as well officials of the health and family welfare department, are under the CBI scanner. The firms involved in the racket made profits to the tune of 500%, and the probe into these firms is ongoing.

- **Alarm & optimism in Kashmir**
  Consumer Conexion, November 28, 2011

Alarmed by reports of a flourishing spurious drugs market in Kashmir, world-renowned cardio-thoracic surgeon Dr Naresh Trehan urged governmental action while addressing a school function in Srinagar. Echoing Dr. Trehan's alarm, Dr. Surinder Bazaz, a cardiologist who also participated in the function, said on the occasion that Kashmir had become a den of spurious and substandard drugs". The importance of a healthy life style was another issue that was underscored, with Dr. Trehan counseling proper diet and exercise as a way of keeping heart ailments at bay. Dr. Trehan went on to add that

Medanta, a Delhi based multi-specialty hospital, was preparing to set up a facility in Kashmir in the coming months.

- **Worrisome Statistics**
  Consumer Conexion, November 13, 2011

Government of India sources revealed shocking statistics on the incidence of spurious and sub-standard drugs in India. On a positive note, there are indications of fresh initiatives by means of which the government is gearing up to meet the challenge. Sub-standard and irrational drugs in the Indian market are a matter of serious concern, according to government sources. One such source - the Union Ministry of Health, estimates that out of the one lakh crores worth of drugs produced in India, as many as 5000 crores worth are sub-standard. In a study commissioned by another government body – the Planning Commission, it was found that of the top 25 products sold in the country in 1999, ten - comprising blood tonics, cough expectorants, non-drug formulations, analgesics, nutrients and a liver drug - were hazardous, non-essential, or irrational. Practically all the major drug manufacturers were bringing out irrational formulations, the study also reports (Sinha 2011a). In another damning indictment, the DCGI – the Drug Controller General of India, estimates that 46 FDCs (Fixed Drug Combinations) continue to be available in the market despite being banned, while another 1,067 of them are marketed with the approval of state drug controllers, but without the DCGI's consent (Sinha, 2011a). Two important factors are responsible for the proliferation of spurious and sub standard drugs in the country, according to the Planning Commission study cited above. The first relates to the regulatory instrument – the Drug and Cosmetics Act, which is either not effectively enforced, or is subject to multiple interpretations, making it ineffectual. In an effort to strengthen the regulatory mechanism, guidelines are now being formulated to specify the time frame within which pharmaceutical formulations will have to be taken off the shelves, once they are identified as sub standard. At this time, it is not even clear as to which officials are responsible for taking action (Sinha, 2011a).

- **U.S. Embassy in Sri Lanka hosted workshop on combating counterfeit drugs**
  The Sri Lanka Time, Colombo Page, May 26, 2011
  US Embassy website May 25, 2011

Colombo: The United States Embassy in Colombo, Sri Lanka recently hosted a workshop in Jaffna on combating counterfeit drugs for the pharmacists and law enforcement officials.

The workshop titled "Protecting Sri Lankan Families from Counterfeit Drugs" was organized by the American Chamber of Commerce, the National Intellectual Property Office, and the Sri Lanka Chamber of Pharmaceutical Industry (SLCPI) along with the U.S. Embassy in Colombo.

This was the fourth and the final seminar the Embassy has hosted to educate pharmacists, doctors, the police and other government officials to work together to protect Sri Lankan families from the dangers of counterfeit drugs. The Embassy has hosted previous workshops in Colombo, Galle and Kandy. The U.S. State Department was the principal sponsor of the campaign, the Embassy said.

Speaking at the seminar Mr. Edward Heartney, Economic Counselor of the U.S. Embassy has said that every country has to deal with the problem of fake, counterfeit, and unregistered drugs and he was pleased to see the active participation of Sri Lanka's pharmacists, chemists, pharmacy students, and pharmacy owners at the workshop as they play a critical role in countering the fraud.

GSK pharmaceuticals, a leading drug manufacturer has conducted a session on identification of counterfeit drugs.

- **Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa**
  The Lancet Infectious Diseases, Vol. 12, Issue 6, Pages 488-496, June 2012

Poor-quality antimalarial drugs lead to drug resistance and inadequate treatment, which pose an urgent threat to vulnerable populations and jeopardise progress and investments in combating malaria. Emergence of artemisinin resistance or tolerance in Plasmodium falciparum on the Thailand—Cambodia border makes protection of the effectiveness of the drug supply imperative. We reviewed published and unpublished studies reporting chemical analyses and assessments of packaging of antimalarial drugs. Of 1437 samples of drugs in five classes from seven countries in southeast Asia, 497 (35%) failed chemical analysis, 423 (46%) of 919 failed packaging analysis, and 450 (36%) of 1260 were classified as falsified. In 21 surveys of drugs from six classes from 21 countries in sub-Saharan Africa, 796 (35%) of 2297 failed chemical analysis, 28 (36%) of 77 failed packaging analysis, and 79 (20%) of 389 were classified as falsified. Data were insufficient to identify the frequency of substandard (products resulting from poor manufacturing) antimalarial drugs, and packaging analysis data were scarce. Concurrent interventions and a multifaceted approach are needed to define and eliminate criminal production, distribution, and poor manufacturing of antimalarial drugs. Empowering of national medicine regulatory authorities to protect the global drug supply is more important than ever.

- **Fake Drug Traders Getting Off Easy in Indonesia: US Official**
  Jakarta Globe, April 12, 2012

Weak law enforcement has made Indonesia a safe haven for people distributing fake drugs, a US official says. Peter Fowler of the US Patent and Trademark Office said Indonesia, along with several other countries in

Southeast Asia, has meted out very light punishments to those producing and trading counterfeit medicines. "Some countries like Indonesia and Singapore apply the death penalty for people selling narcotics, while drug counterfeiters get light sentences," he told a discussion in Jakarta on Tuesday. Fowler said counterfeiters get light punishments because Indonesian authorities typically only apply trademark law when prosecuting them. According to him, despite the relatively lighter sentences, drug counterfeiters reap much more in profits than narcotics traffickers. Widyaretna Buenastuti, chairwoman of the Indonesian Anti-Counterfeiting Society (MIAP), said Indonesia actually has several laws that could provide heavy punishments to counterfeiters.

- **Concerns Fake Cancer Medicine on Indonesian Market**
  Jakarta Globe, April 21, 2012

Drug regulators are warning of the possibility that knockoffs of a key cancer medicine may have found their way into the Indonesian market. Endang Woro Tedjawati, director of medicine evaluation and biological products at the Food and Drug Monitoring Agency (BPOM), said on Friday that her office was looking into reports that fake versions of Avastin were now available in Indonesia after cropping up in the United States. "We're still in the process of tracking down the reports, so we can't say for certain yet whether this fake cancer drug is already in Indonesia," she said. Avastin, the trade name for the drug Bevacizumab, is produced by Roche and commonly used to treat breast, lung, kidney and colorectal cancers that have reached the metastatic phase and are spreading to other organs. Endang said that although the BPOM has not yet found fake cancer drugs being distributed in the country, counterfeit versions of drugs to treat illnesses such as malaria were already available. She said the most common knockoffs were those for the popular erectile dysfunction drugs, as well as for the painkiller Ponstan (mefenamic acid) and various medicines to lower cholesterol. Most are openly sold in markets or by mobile vendors. Last year, the BPOM found only eight types of knockoff drugs in the Indonesian market, down from 28 in 2008. Endang denied that the BPOM was not serious about cracking down on counterfeit drugs, saying that officials routinely carried out stings against dealers in addition to raids on drugstores. She added that while the BPOM could censure legitimate pharmaceutical companies for producing fake drugs, it was powerless to take legal action against any perpetrators that it found. "That's the responsibility of the police and courts," she said. She attributed the continued presence of fake drugs in the country to the lack of strong sentences against the perpetrators, which would act as a deterrent.

- **Drug Distribution Better Regulated to Fight Fakes**
  Jakarta Globe, November 22, 2010

Jakarta. The national drug administration has announced a new campaign to control the distribution of medicine and stem the circulation of counterfeit drugs. Lucky S. Slamet, deputy director of the Food and Drug Monitoring Agency (BPOM), said on Monday that of the approximately 7,500 medicines

in current circulation in the Indonesian market, counterfeiters were producing copies of up to 20 of the more popular ones. He said these included "lifestyle medicines" such as Viagra, as well as life-saving drugs such as the antimalarial Fansidar. To deal with the issue, he said, the BPOM had set up the National Single Point of Contact, a post within the agency that would be responsible for the national circulation of medicine. "Besides establishing the SPOC, we're also campaigning through the media for greater public awareness about counterfeit medicines," he said. "We lack the manpower to campaign directly to the public, so we need help from NGOs and the media to run campaigns on how to identify counterfeit medicine. He added in this case, people should only purchase medicine at authorized places, such as pharmacies or hospitals. The Indonesian Consumer Protection Foundation (YLKI) says the lost revenue from counterfeit drugs amounts to Rp 2.5 trillion ($280 million) annually. Meanwhile, Slamet Budiarto, secretary general of the Indonesian Doctors Association (IDI), accused the government of putting the interests of the legitimate producers above those of consumers in this issue. He said this was apparent in the Health Ministry's definition of counterfeit drugs, which makes no mention of harmful ingredients. "It's fine as long as there aren't any harmful ingredients in the drugs, but what if there are such ingredients, which can delay the healing process or even cause death?" he said. He added there was also no official data on deaths caused by the use of counterfeit medicine in the country. Puspo Sumadi, country manager for US pharmaceutical company Eli Lilly, called for harsher punishment for drug counterfeiters. According to World Health Organization statistics, 10 percent of medicines sold worldwide are fake; while in Indonesia, that figure is closer to 25 percent, as stated in a US Trade Representative report. The WHO also estimates some 200,000 people die worldwide every year because of the problem.

- **Third of Malaria Drugs in Southeast Asia Are Fake**
  Jakarta Globe, May 22, 2012

Paris. More than a third of malaria drugs examined by scientists in Southeast Asia were fake, and a similar proportion analyzed in Africa were below standard, doctors warned on Tuesday. "These findings are a wake-up call demanding a series of interventions to better define and eliminate both criminal production and poor manufacturing of antimalarial drugs," said Joel Breman of the Fogarty International Center at the US National Institutes of Health (NIH). Trawling through surveys and published literature, the researchers found that in seven Southeast Asian countries, 36 percent of 1,437 samples, from five categories of drugs were counterfeit. Thirty-percent of the samples failed a test of their pharmaceutical ingredients. In 21 sub-Saharan countries, 20 percent of more than 2,500 samples tested in six drug classes turned out to be falsified, and 35 percent were below pharmaceutical norms. Sub-standard medications are a major problem in the fight against malaria, a disease which killed 655,000 people in 2010, according to the UN's World Health Organisation (WHO). Many of the drugs that are being faked or poorly manufactured are artemisin derivatives, the study said. This is a special worry, for artemisinins are the frontline treatment for malaria, replacing

drugs to which the malaria parasite has become resistant. The study says there are many causes for the problem, ranging from widespread self-prescription of drugs to shoddy controls to monitor drug quality and prosecute counterfeiters. "Poor-quality antimalarial drugs are very likely to jeopardise the unprecedented progress and investments in control and elimination of malaria made in the past decade," said Breman. Last month, the Institute of Health Metrics and Evaluation at the University of Washington in Seattle reported that artemisin-resistant malaria which was first spotted in Cambodia in 2006 has since surged 800 kilometers westward to the Thailand-Burma border.

❖ **Counterfeit drugs 'a serious threat'**
The Jakarta Post, April 12, 2012

An expert has warned that rampant drug counterfeiting may not only lead to financial losses to producers, but also give rise to drug-resistant diseases. Widyaretna Buenastuti, chairwoman of the Indonesian Anti-Counterfeiting Society (MIAP), said on Tuesday that consumer education remains the best way to combat drug counterfeiting, to ensure safe drugs were being distributed. "We won't be able to distinguish whether a product is counterfeit or not. Counterfeiters are really good at coming up with convincing looks for their products," Widyaretna said in a seminar organized by the US Embassy in Jakarta. She suggested that people only buy medicine from reputable pharmacies or licensed drugstores. Counterfeit drugs have caused serious losses to the government, Widyaretna said, with the amount of potential tax revenue lost reaching Rp 43.2 trillion (US$4.76 billion) between 2005 and 2010. Widyaretna also said counterfeit drugs could be harmful to patients. "If you compare it with other sectors, the economic losses from drug counterfeiting makes up only 3.5 percent of the total figure in the past five years, which is not too high. The problem is that counterfeit drugs can be dangerous and can even kill you, no matter how small the percentage is," she said. Meanwhile. US Ambassador to Indonesia Scot Marciel said that more than $75 billion worth of fake drugs were sold globally in 2010. He said the latest estimates suggested over 30 percent of medicine sold in Southeast Asia was counterfeit, resulting in serious problems. "The US and Indonesian companies that are making real medicines lose out to people who are making fake or counterfeit medicines," Marciel said. He said counterfeit drugs could also have severe health impacts. For certain diseases, taking improper medication can contribute to the development of strains of the diseases resistant to regular drugs. In the US, the problem has also affected companies producing drugs for serious illness. Recently, authorities found fake Avastin, a cancer drug produced by Roche, in the market, as well as fake antibiotics, HIV and tuberculosis drugs. But combating counterfeit drugs is not an easy undertaking. Peter N. Fowler, the US regional intellectual property attaché, said most countries, including Indonesia, had regulations against counterfeiting that impose a range of penalties. But in reality, he said, many law-enforcement agencies did not take counterfeiting seriously. Fowler said that the judiciary has also been lax against counterfeiters. "They may get three to six months in jail, they may get fine that they can easily pay because

again, the profit from the activity as a criminal business enterprise is huge," said Fowler. He said some criminals would not be bothered by a six-month jail sentence and would return to counterfeiting upon release. Fowler said counterfeiting drugs is a profitable business, with the profit margin for Viagra could be 2,800 percent of costs, compared to counterfeit tobacco (800 percent), heroin (1,200 percent) and cocaine (1,400 percent). "In Asia, the risk of smuggling narcotics is the death penalty. If you're just involved in counterfeit medicine, it's sometimes seen only as trademark violation — although this is a very significant public-health threat," Fowler said.

- **Illegal drug threat still looms over public**
  The Jakarta Post, February 08, 2012

Unlicensed cure-alls: An official from the Food and Drug Supervision Agency (BPOM) displays a number of unregistered drugs widely sold around the country.

Despite the government's efforts to contain illegal drugs, the public still faces looming threats due to the rampant distribution of the substances. Many people have fallen victim to illegal drugs. This indicates the inability of the Drug and Food Supervisory Agency (BPOM) to deal with the problem. Founded in 2001, the agency may have been able to bring perpetrators to court but, unfortunately, they have only faced light sentences that have not provided a strong enough deterrent. Data from the BPOM shows as many as 209 drug counterfeiters were sent to 1.5 months in jail in 2010. Meanwhile, in 2009, 174 drug counterfeiters were sent to five months in jails and had to pay Rp 5 million (US$560) fine as the heaviest sanction. Obviously, such light sentences have little deterrent effect. The 2009 Health Law stipulates that people who commit the crimes of producing and selling illegal drugs and foods face a maximum of 15 years in jail and Rp 1.5 billion fine. The recent succession in the BPOM chairmanship should now be used as momentum to show the public the agency's power. Speaking after the inauguration of Lucky Oemar Said, the new BPOM chairperson, Health Minister Endang Rahayu Sedyaningsih said the agency should confront food and drug counterfeiting by launching effective and consistent law enforcement. Separately, public health professor Hasbullah Thabrany said the government must take bold measures to protect people from the dangers of illegal drugs. "The government should not only find and seize counterfeit drugs on the market. It must also combat and put an end to counterfeiting," said Hasbullah. During the fourth Pangea Operation in September 2011, the agency seized counterfeit drugs distributed online worth Rp 82 million. The drugs turned out to be medicines for erectile dysfunction and libido boosters.

While praising ongoing efforts, Hasbullah said, the BPOM did not show its power when it came to business-oriented medication. It was quite surprising to know that neither the Health Ministry nor the BPOM investigated alternative therapies, including herbal remedies or body massage with specific techniques, that were massively promoted via the media, whereas no scientific-based research could support their claims. Responding to this condition, Lucky said her office kept on doing its job of supervising food and drugs in the market. "We already have power, but still it is not strong enough.

We need a specific law that regulates drug and food control," she said, adding that the House of Representatives planned to deliberate the long-awaited draft law on drug and food control this year. "With the umbrella law, I'm sure we can conduct firmer action to combat drug counterfeits," Lucky said, adding that the draft law was already in this year's national legislation program. Citing an example, she said the 2009 Health Law still considered drug counterfeiting as not a serious crime. As a result, courts charged most perpetrators with light criminal violations. "They received only four months in jail or a Rp 1 million fine with little deterrent effect. With the new law we'll have significant changes," she said.

- **Bogus Drugs And Counterfeit Viagra In Thailand**
  Bangkok Times, Sep 01, 2011

A viagra-like drug will be launched by the Government Pharmaceutical Organisation next month in a bid to battle counterfeit products and the brand-name pill's steep price.

The GPO's managing director Witit Artavatkun said yesterday the organisation had been given permission by the Food and Drug Administration (FDA) to produce Sidagra, a generic drug with a similar composition to Viagra, to help men with erectile dysfunction.

Sales of Sidagra will begin on Oct 15 in two sizes _ a 50mg tablet at 25 baht and a 100mg pill at 45 baht. The prices of the pills are a lot cheaper than Viagra's retail price of 200 baht per tablet, Dr Witit said. Sidagra will be rolled out to give consumers a safe alternative to counterfeit products and to help elderly men who cannot afford Viagra, he added. Manufacturing processes have been boosted to meet standards in other Asean countries, he said, adding that the factory's capacity now stands at 5 billion tablets a year. Drugs for the treatment of diabetes, high blood pressure and Aids will be produced at the GPO factory and distributed to Myanmar, Laos, Cambodia, Vietnam and Malaysia, he said.

- **Constant demand keeps fake drugs in the market**
  The Jakarta Post, September 25, 2010

The risks of counterfeit drugs have apparently failed to drive people away from buying them. With consistent demand the circulation of fake drugs remains unchecked, an official recently said.

Erita Harun from the United States Department of Justices' International Criminal Investigative Training Assistance Program (ICITAP) Indonesia, said that raids have proven that Indonesia was a haven for counterfeit drugs. "There are gaps [in the pharmacy industry] that can be used by those producing fake drugs, such as gathering used packets to be refilled [by bogus products]," she said in Jakarta during a lecture on intellectual property rights.

Erita said that high demand is part of the reason why illegal drugs are still very common in Indonesia.

Panji Pragiwaksono from the Community for Children with Cancer (C3) said that parents of children with cancer often resorted to drugs that were cheaper but “shady”.

Lucky S. Slamet from the Food and Drugs Monitoring Agency (BPOM) said that bogus drugs make up around 2 to 3 percent of the illegal drugs confiscated during regular raids conducted by 32 of its offices across the country. “There were about 20 bogus brands,” she said. In 2009, BPOM confiscated around 1,000 samples from locations notorious for selling illegal drugs. About 2 percent of these drugs were discovered to be fake.
Lucky said that taking fake drugs carried various risks. From a public health perspective, if a producer tries to copy an anti-diabetic drug but only uses flour as the main ingredient, this may result in ineffective treatment, and even death. During a raid, the agency discovered a counterfeit vaccine in the form of liquid containing mere electrolytes stored inside a used syringe sold as a new one. “There were blood specks on the needle,” she said. Lucky said that typical drugs to be copied were painkillers and sexual performance enhancers. Lucky pointed out that places that officially sell medical products, such as licensed pharmacists, were usually free from counterfeit drugs.

- **Indonesia's pharma IP problems**
  Komodo Dragon Blog, June 22, 2011

There are constant complaints about the prevalence of counterfeit medicines in Indonesia. Given the lack of effective overall enforcement in Indonesia, alternatives are being tried. The bureau of food and drugs, BPOM took part on a joint raid this week with the East Jakarta local government health office to raid 20 outlets and seized some 700 fake Viagra pills. The news reports say there was a tip off, but this usually means the IP holder's investigations identified the fakes.

The interesting point is that these agencies don't really have a proper enforcement role, but the difficulty of working with the police makes finding such alternatives necessary. For example BPOM has powers of supervision over medicine sales but not arrest. While it can work on retail targets, finding the suppliers typically is much harder since they are found in the wholesaler markets and distribute to pharmacies more covertly to avoid detection.

In late 2010, BPO announced a campaign to fight the circulation of counterfeit drugs. The deputy director indicated then that counterfeiters were selling copies of 20 of the more popular ones. The Indonesian Consumer Protection Foundation (YLKI) has estimated that lost revenue from counterfeit drugs amounts to Rp 2.5 trillion ($280 million) annually.

Meanwhile, the International Pharmaceutical Manufacturers' Group chairman complained at a press con fence this week at the restriction on foreign

ownership in distribution. Indonesia requires that medicines be made locally, in order to be distributed locally by international pharma companies. At present ownership restrictions mean that unless a medicine is made locally, the distribution must be turned over to a local Indonesian distributor. This means turning over all the regulatory data for marketing approvals, which research based companies are reluctant to do.

- **Expired, Fake Medicines Flood Pharmacies in Nepal**
  Global Press Institute, September 12, 2012

As Nepalis rely on local pharmacies for everything from prescriptions to abortions, many get sick and even die from the fake and expired medicine that is flooding the market here. The government acknowledges that pharmaceutical monitoring has been weak and is striving to strengthen industry regulation as well as consumer awareness.

Although Nepalis frequent pharmacies to obtain medicine to ease a variety of symptoms and ailments, they often end up feeling worse thanks to expired and fake products that have flooded the market. Expired and fake drugs have been linked to countless deaths, injuries and ailments here. Authorities attribute victims' susceptibility to illiteracy and lack of awareness. Although the government has various regulatory measures and bodies in place to monitor the industry, officials admit that implementation is weak. As many accuse pharmacists of caring more about profits than customers' health, pharmacists say it's difficult to meet government standards. Meanwhile, the government is striving to strengthen monitoring and to increase consumer awareness.

Statistics on the number of people affected by expired or fake medicine in Nepal are unavailable. But lawyer Jyoti Baniya, chairman of the Forum of Protection of Consumer Rights, a nongovernmental organization that advocates for consumer rights, estimates that more than half of Nepal's population may be using and affected by expired and/or fake medicine.

Sanjib Acharya, office assistant at the Nepal Pharmacy Council, the autonomous professional and regulatory body for pharmacists created by Parliament in 2001, attributes the victims' susceptibility to fake and expired medicine to illiteracy and lack of awareness. Elaborating on the trend in Nepal, Acharya says that people don't visit hospitals here unless it's serious because of long lines at public hospitals and high bills at private ones. Instead, they usually go to their closest pharmacy when they think they require any medication.

Bodily damage from medicine can lead to fines and up to 10 years in prison for the seller, Baniya says. Selling potentially life-threatening expired medicines could result in life in prison. The Department of Drug Administration also has policies regarding marketing and guidelines for standards of quality. But Baniya says pharmacies are still cheating people and making them suffer because of the government's weak implementation of laws and policies and the strong position of manufacturers, distributors and sellers.

The court process is also long and tedious to charge pharmacists for selling fake or expired medicine, says Shyam Adhikari, one of the drugs inspectors at the Department of Drug Administration. Therefore, he says the department has appealed to the ministry to enable the inspectors to issue penalties on the spot.

Nepal Health Council, a body under Nepal government, recently partnered with WHO to monitor pharmacies in 22 of Nepal's 75 districts. It found that most of the pharmacies didn't have skilled professionals, says Dhana Prasad Poudel, registrar at the council.

Another problem is a lack of qualified staff available to prescribe medicine. In order to run a pharmacy, a person must pass a three-year course to obtain a diploma in pharmacy, as well as receive a license from the Department of Drug Administration.

- **Now send SMS to find if pill is genuine**
  The Times of India, September 23, 2012

Mumbai: Now before popping a pain-killer or having cough syrup, you can be sure that it's not fake or spurious, thanks to an innovation designed to curb the menace of spurious medicines. Strips of popular and commonly-used medicines like Combiflam, Dispirin, Crocin, Voveran and multi-vitamin Becosules will soon carry a unique code, which sent out through a SMS by a mobile phone of a consumer can help him verify the genuineness of the medicine.

While certain companies like Roche, Lupin and Unichem have started rolling out medicine packs with a new packaging including the unique code printed on it, many like Sanofi, Pfizer, GlaxoSmithKline are planning to follow suit. The tech innovation is being seen as a new weapon by pharma companies to combat the menace of spurious and fake drugs.

This is how it will work. Consumers will need to send the random alphaneumric code printed on the medicine strip through their mobile phone. Once they get a response that it is a genuine medicine, and not spurious or fake, it can be used. Not only that, the consumer will also get health tips and drug-refill reminders.

There is no uniform figure to determine the penetration of spurious, fake or misbranded medicines in the country, with the industry and government, offering varying estimates. Recently, the health ministry announced that of the over 48,000 drug samples tested by state drug controllers between 2011 and 2012, nearly 5% failed the quality test, while, almost one in three drugs (36%) were found to be "not of standard quality" from across the country. States like Maharashtra and Kerala have a huge issue of sub-standard drugs, with the incidence more in semi-urban and rural areas.

Mostly, the drug's quality suffers and so does its efficacy, while in certain cases, it may cause serious side-effects and even be fatal. There may also be instances when these ``fake" medicines offer no therapeutic benefits. It is virtually impossible to tell the difference between real and fake medicines unless a laboratory analysis is carried out. Since that's may not be a practical solution, drug companies along with regulators have been trying to counter the menace through measures like bar-coding, embedded holograms, RFID, but have met with little success. Industry sources say most frequently fake or spurious medicines are those which are of a high value (turnover) basically brands with Rs 100 crore plus, and those which are fast-moving from the retail counter.

Pfizer India has faced the issue of fake and substandard in its heritage and high-selling brands multivitamin Becosules, cough syrup Corex and Dolonex and Viagra, a company official said.
In the case of widely-used medicine Crocin, the company GlaxoSmithKline Consumer Healthcare rolls it out with a holographic strip, with a company and Crocin logo, while each tablet is embossed with the `CROCIN' lettering, as an anti-counterfeit measure.

MNCs like Roche have also made a small beginning in all their cancer drugs, and have engaged supply chain security experts Kezzler to provide encryption software that enables consumers to verify that their medicine is genuine.

Another company, PharmaSecure is working with over 10 leading pharmaceutical manufacturers and has coded over 300 million drug packages to fight the problem of counterfeit drugs. Certain companies are not rolling out the new packaging because of cost issues, and since many of these medicines are under price-control.

- **Chemists to become new drug busters**
  The Times of India, September 09, 2012

New Delhi: India's most ambitious " whistleblower policy" to handsomely reward those who help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices has failed miserably. Not a single reward has been given out till now even though Union health minister Ghulam Nabi Azad had announced the policy in Parliament in July, 2009.

Drug Controller General of India (DCGI) Dr G N Singh told TOI in an exclusive interview that "no credible information pin-pointing a place where manufacturing or supply of fake drugs was supplied by the public to the government." Now, Dr Singh has decided to rope in India's seven lakh chemist outlets to help government check the commercial sale of fake or spurious drugs. He is travelling to Chandigarh on Sunday to make an open plea to chemists during his address at the executive meeting of the All India Organization of Chemists and Druggists — an apex body of nearly 7.5 lakh members involved in wholesale and retail trade of pharmaceutical products.

According to Dr Singh, a vigilance cell is being set up in every state to monitor fake or spurious drugs. The ministry had earlier received tip-offs from states like Himachal Pradesh, Haryana and Rajasthan in the northern region and one from a southern state, but none produced concrete results.
The policy stipulates that the reward of a maximum of 20% of the total cost of consignments seized would be paid to the informer, which will not in any way exceed Rs 25 lakh in each case.

In respect to an officer in the government or the Central Drugs Standard Control Organization (CDSCO), the reward would not exceed Rs 5 lakh for one case and a maximum of Rs 30 lakh in h/his entire service. The reward would be given only when there would be confirmation of the seizure of spurious drugs, cosmetics and medical devices by the designated officers of CDSCO.

The policy said that once the fake drugs are seized, the government would engage senior advocates who have sufficient experience of cases relating to drugs to help punish the guilty. To ensure speedy trials, these cases will be filed before the designated/special courts set up for the purpose of drug-related issues, as per provisions of the Drugs and Cosmetics Act.
The health ministry estimates that 5% of drugs in India are counterfeit, while 0.3% are spurious.

A vision paper prepared by the CDSCO, quantifying how much funds are needed under the 12th Five Year Plan (2012-17), says that India would require Rs 3,256 crore to strengthen its drug regulatory system. This includes cost of upgrading state laboratories, improving manpower by 2,500, creation of additional labs, mobile drug testing labs and the CDSCO's pharmacovigilance programme.

- **War on bad medicine**
  The Times of India, July 05, 2012

Gandhinagar: When you buy a drug over the counter, there is no way to determine if it is substandard or spurious. From September 2009 till now, the Gujarat Food and Drugs control administration (FDCA) recalled 615 batches of tablets, injections, and capsules that did not meet pharmacological standards. Considering this problem, and following an Allahabad High Court ruling in October 2010, a special task force headed by Gujarat was formed for implementing the unique 'track-and-trace' system for every strip or bottle of medicine you buy off the counter anywhere in the country.

This system has been planned to give every medicine a unique identity number and a possible bar code. Customers can simply SMS this identity number to a toll-free number to learn whether the drug is from an authentic manufacturer. If the drug happens to be low on efficacy, the licensed company can be hauled up for pumping in substandard products. The task force also proposed the use of non-clonable ID stickers, in place of barcodes, to carry the unique ID (UID) for medicines. The task force report was

submitted to the Union ministry of health recently. However, this proposed system has drawn fierce opposition from drug manufacturing companies.

"Few months back we had caught a licensed manufacturer, Hardik Drugs from Santej, printing duplicate labels of cough syrups made by Cipla. The labels were the exact copy of the original," says food and drugs commissioner H G Koshia, who is heading the task force. The department caught another manufacturer, Radhe Biotech, manufacturing fake syrups of a dubious Himachal-based company in Maninagar.

Drug manufacturers' organizations like the Confederation of Indian Pharmaceutical Industry (CIPI), Federation of Pharma Entrepreneurs (FOPE), Indian Drugs Manufacturers Associations (IDMA), and Organization of Pharmaceutical Producers in India (OPPI) had opposed the tracking system. They claimed that it will be a huge burden to small and medium enterprises. The associations in the report said that an SME with exports of around Rs 15-20 crore would need to invest Rs 2 crore on barcode machines (one for each blister machine and one each for syrups and injections).

The system is so designed that if a duplicate UID drug number or a number printed on spurious medicine is SMSed, the system immediately alerts the local drug inspector.

Highlights of the track and trace model
1. Drug manufacturers will have to label every medicine with a barcode which will have the details of a product including its batch number and date of manufacturing
2. Details, including the bar code used, will be uploaded in the manufacturer's portal
3. An SMS based authentication of drugs can be implemented for customers in this system.
4. Each time the product is invoiced or transferred to a subsequent whole-seller or retailer, the data will be updated in the manufacturer's portal.
5. More than 700 pharmaceutical companies, with approximately 8,000 export bar-coded products; resist introducing the system in India

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- **China-made fake drugs flooding Asian countries**
  ELEVEN Myanmar, August 15, 2012

Fake medicines made in China, including life-threatening anti-malaria drugs, are flooding Asian countries, especially Myanmar, Laos and Cambodia, according to experts.

IMS Health, a pharmaceutical company based in the US, has described China as the world's biggest counterfeit medicine producer. The company has its branches in Canada, Japan, China, Latin America, the Pacific, Europe, Africa and the Middle East.

Reports said that in China, an anti-fraud squad comprising more than 18,000 police had cracked down on at least 2,000 drug fraudsters. The confiscated counterfeit medicines are valued at 1.16 billion yuan (US$182 million).

Websites worldwide have stated that there are two kinds of fake drugs from the mainland – fake drugs and imitations of renowned brands. They said these drugs claim at least 700,000 lives every year. A study by IMS Health shows there has been an increase in production from 19 to 22 per cent since 2008. About 50 per cent of illicit drugs are mainly exported to Angola, |Burundi and Congo, whereas two-thirds of the rest make inroads in Myanmar, Laos and Cambodia, according to the website policynetwork.net. Reports said a haul of painkillers, cold drugs, and drugs for abdominal pain as well as counterfeit anti-malaria drugs have found their way into Myanmar through Chinese businessmen.

Dr. Win Si Thu, chairman of the Myanmar Drug Dealers Association, said the only way to raise public awareness about fake drugs was to launch organizational campaigns, adding that they report to the authorities like the Food and Drug Administration (FDA), calling on them to seize counterfeit drugs from the market. The FDA, in return, informs the association of the unsafe drugs and the association asks the dealers concerned to get the drugs out of the market, he said.

Myanmar is cooperating with related international organizations to address the issue of fake medicines. Some cases were found to have been linked mainly to Chinese businessmen. An FDA official said: “The problem does not concern China alone. We conduct regular inspections in the market. In some cases, fake medicines are found to have been produced domestically. But we are solving the problem of fake medicines from other countries in collaboration with Interpol, WHO [World Health Organisation] and WCO [World Customs Organisation].” “Among China-made fake medicines is an anti-malaria drug, whose ingredients are life-threatening. This is why we are carrying out inspections across the country. Officials from international malaria-related organisations visited us last week for inspection,” he said. Myanmar needs to take more systematic steps to clamp down on illegal imports of fake medicines. It also should release a statement on the possible spread of China-made fake medicine brands by seeking bilateral cooperation between the two governments, officials from Myanmar Medical Association said.

- **One-third of malaria drugs in SE Asia are fake**
  The Myanmar Times, Volume 32, No. 628, May 28 - June 3, 2012

Paris: More than a third of malaria drugs examined by scientists in Southeast Asia were fake, and a similar proportion analysed in Africa were below standard, doctors warned last week.

“These findings are a wake-up call demanding a series of interventions to better define and eliminate both criminal production and poor manufacturing

of antimalarial drugs," Joel Breman of the Fogarty International Center at the US National Institutes of Health (NIH) said on May 22. Trawling through surveys and published literature, the researchers found that in seven Southeast Asian countries, 36 percent of 1437 samples from five categories of drugs were counterfeit. Additionally, 30pc of the samples failed a test of their pharmaceutical ingredients.

Sub-standard medications are a major problem in the fight against malaria, a disease which killed 655,000 people in 2010, according to the UN's World Health Organisation (WHO). Many of the drugs that are being faked or poorly manufactured are artemisin derivatives, the study said. This is especially worrying as artemisinins are the frontline treatment for malaria, replacing drugs to which the malaria parasite has become resistant. Last month, studies published in The Lancet and Science journals reported that artemisin-resistant malaria, which was first spotted in Cambodia in 2006, has since been detected 800 kilometres (500 miles) westward on the Thailand-Myanmar border.

- **Dangerous Malaria Drug**
  Bangkok Post, December 07, 2011

In South-East Asia, the malaria parasite is acquiring new resistance to once-effective drugs used against it. Indian, Chinese and Vietnamese pharmaceutical companies are believed to be contributing to the phenomenon in a big way.

The malaria parasite's resistance to artemisinin, a once effective drug used against it, is spreading along the Cambodia-Thai border, where it was first detected in 2009, and possibly is making inroads into Myanmar as well, according to the World Health Organisation. Resistance to artemisinin now threatens the most effective treatment around for malaria, namely, artemisinin-based combination therapy.

Part of the problem of the malaria parasite acquiring resistance to drugs can be attributed to the use monotherapies, that is, pharmaceuticals that contain just one active agent. Combination therapies, in which more than one agent works in tandem, are believed to hold out longer. Monotherapies, still being manufactured in India, China and Vietnam, not only contribute to antimicrobial resistance in a big way, they also hampers new drug formulations.

Anti-microbial resistance (resistance by microbes to drug formulations) is caused also by the use of sub-standard pharmaceuticals. Notably, of the anti-malaria drugs that were found to be sub-standard, as much as half contained artemisinin, which was a contributory factor in the malaria parasite's resistance to the drug, Bate told the panel. Not only is the use of poor quality medicines in the affected region (the Thai-Cambodia-Burmese border) by no means negligible, the poor grade pharmaceuticals in question are not illegal there either, he went on to add.

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"SEARPharm Forum is FIP forum of National Pharmaceutical Associations in collaboration with WHO Regional Office of South East Asia. Its Secretariat is based in Delhi. The focus within the SEARPharm Forum is to establish working relations with WHO-SEARO and implementation of FIPs strategic plan by marking better use of pharmacists to improve health and quality of life of citizens in South-East Asia Region."