



**Tamilnadu Pharmaceutical
Sciences Welfare Trust**

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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Jul. - Aug. - Sep. - 2013

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EDITORIAL

Dear Readers,

It's a great pleasure to publish and release 19th issue of our Pharma Web news letter Jul - Sep 2013.

In this issue the Ceiling Price of various Drug Formulations notified by NPPA are published for the benefit of consumer and industry. The issue also contains three articles namely, "Requirements for Pharm. D course" by Mrs. Archana Mudgal, Secretary, PCI, "The Road Ahead for Community and Hospital Pharmacy" by Dr. S. Sriram, of SRIPMS, Coimbatore and "Overview of Patent Law" by Shri S. Chandrasekaran, Former Controller of Patents, Chennai. We also published the article on Global Pharm Challenges - Are We Ready? by Ms. T. R. Ramcy, Swamy Vivekandha College of Pharmacy. Important Government notifications on banning of irrational combination along with important circulars by DCGI and NPPA are published. We also published various news items worth to read. We are happy to inform that our one of the important IPA (TN) EC member got Doctorate degree in Pharmaceutical Sciences from "The Tamil Nadu Dr. M.G.R. Medical University", Chennai. Mr. S. Abdul Kadhar, has taken charge of Director of Drugs Control of Tamilnadu in place of Shri G. Selvaraj, who retired from service.

I hope that readers may be benefited by this issue with all news items and technical information.

With Best Regards,
R. NARAYANASWAMY
Chief Editor



Editorial Policy and Disclaimer

The objective of this newsletter is to impart current news to the readers and the newsletter is circulated free of cost. Description or reference to any information or publication does not implement endorsement by us.

Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purpose.

This issue of Pharma Web is also available online at the Trust website www.pictrust.com

With best compliment from



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ARTICLES

PHARM.D. COURSE – REGULATIONS AND INFRASTRUCTURE REQUIREMENTS

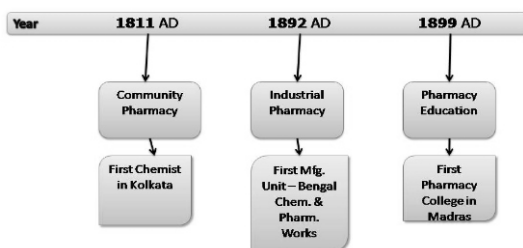
By

Archana Mudgal

Secretary, Pharmacy Council of India

Lecture delivered at 64th IPC, Chennai on 8th December 2012

Origin of Pharmacy In India



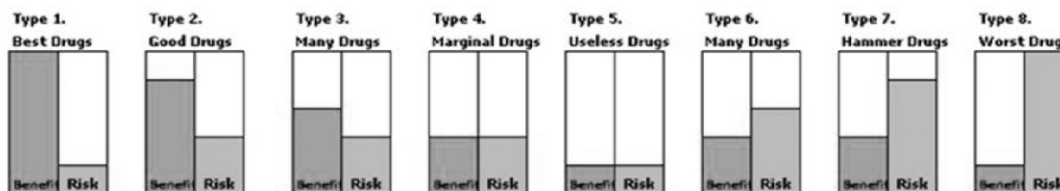
Regulation of Pharmacy

- Profession
 - Drugs and Cosmetics Act – 1940
- Education
 - Pharmacy Act - 1948

Why Pharm.D.

The Aubuchon Pharmaceutical Drug Classification System (PDCS)

Benefit/ Risk Ratios which describe most pharmaceutical medications -
(Effect vs. Side-Effects)

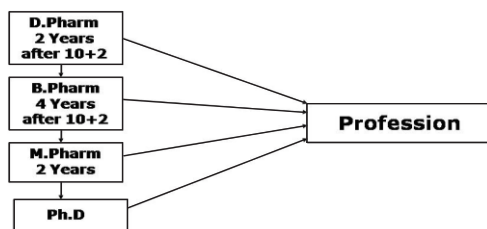


- Type 1 Drugs - These drugs have excellent benefits, and very low risk. They sell like candy. Some go OTC.
Type 2 Drugs - These drugs have very good benefits, and marginal risk.
Type 3 Drugs - These drugs have good benefits, and marginal risk.
Type 4 Drugs - These drugs have marginal benefit, and marginal risk.
Type 5 Drugs - These drugs have little benefits, and little risk. These drugs are the same as placebos.
Type 6 Drugs - These drugs have marginal benefits, but substantial risk.
Type 7 Drugs - These drugs have marginal benefits, but have high risk. ("Last resort" type of drugs.)
Type 8 Drugs - These drugs have little benefit, and very high risk. Many of these drugs are recalled.

MOST PHARMACEUTICAL PRESCRIPTION DRUGS are Types 3 and 6.

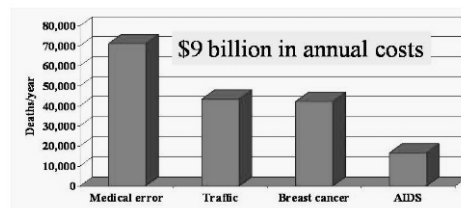
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Levels of Pharmacy Education in India before 2008



Why Pharm.D.

Causes of Death

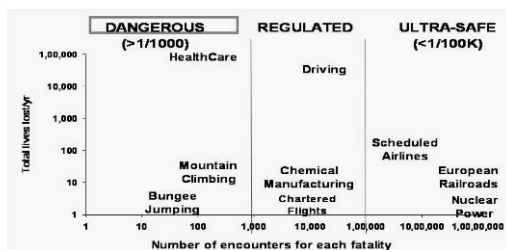


1999 Institute of Medicine Report

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Why Pharm.D.

Health Care Hazards



Lucian Leape, 2/2001

Why Pharm.D.

Frequent Medical Errors

Errors	Top Three Contributors (% of total)
Surgery (wrong site/wrong patient etc)	20
Medication Errors	16
Medical Errors	14.8

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Why Pharm.D.

WHO ESTIMATES



Why Pharm.D.

GAPS

Pharmacy education & licensing requirements

India	USA	UK	Australia
≈2 yrs. diploma or ≈4 yrs. degree	≈Minimum 2/3 yrs. approved pre-pharmacy course in pre-professional university ≈Pharm.D. (4 yrs.) ↓ Student has to obtain interim licence in the 1st year & -Perform function of registered pharmacist under the direct supervision of registered pharmacist.	≈4 yrs. + 1 yr. pre-registration training. or ≈5 yrs. practice integrated programme.	≈4 yrs. degree + ≈2000 hrs. practical training.

Contd...

Why Pharm.D.

GAPS
Pharmacy education & licensing requirement

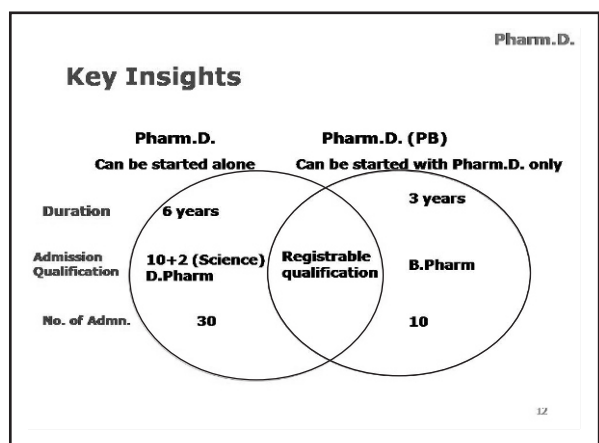
India	USA	UK	Australia
↓ No Exam. ↓ Registration as a pharmacist.	1500 hrs. experience in •dispensing •compounding •record keeping etc. ↓ Exam. by National Association of Boards of Pharmacy (NABP) ↓ Registration as a pharmacist.	↓ Exam. conducted by Royal Pharmaceutical Society of Great Britain ↓ Registration as a pharmacist.	↓ Registered Pharma-ceutical Chemist exam. ↓ Registration as a pharmacist.

Why Pharm.D.

GAPS

Country Parameter	India	U.S.	U.K.	Australia
Continuing education Programme	Not mandatory	Mandatory	Mandatory	Mandatory
Course Content hospital/ clinical pharmacy	Not well established	Well established	Well established	Well established
Patient counselling	Not mandatory	Part of dispensing	Part of dispensing	Part of dispensing

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- Pharm.D.
- Who can start the Pharm.D. ?**
1. Approved B.Pharm course u/s 12.
 2. Affiliation from an Examining Authority
format on www.pci.nic.in
 3. MOU with 300 bedded hospital
format on www.pci.nic.in

Pharm.D.

What type of 300 bedded Hospital ?

Own Hospital
Teaching hospital approved by MCI/ University.
Govt. Hospital
Corporate Hospital

Hospital shall provide
1. Pharmacy Practice Deptt. (30 sq.ft. per student)
2. Professional manpower.

Pharm.D.

Walk through "Mode of Study"

Ist, IInd, IIIrd & IVth year

Class Room Study

+ Laboratory Practicals

Pharm.D.

Walk through "Mode of Study"

Vth year



Class Room Seminars

+



Project work (6 months)

+



Clerkship (Ward rounds)

Output

- Data collection
- Interpretation skills
- Reporting

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Pharm.D.

Walk through "Mode of Study"

Vth year - Internship in 300 bedded hospital

6 Months General Medicines



2 Months in any of 3 Specialization (Total 6 months)

1. Surgery
2. Pediatrics
3. Gynecology and obstetrics
4. Psychiatry
5. Skin and VD
6. Orthopedics

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Ward Rounds

A. Refining Clinical Skills

- Exposure to different type of patient population.
- Various dosage forms and its administration.
- Detect ADR and Interactions.
- Medication errors monitoring.
- Learning about safe decision making – risk management.
- Poly pharmacy management.
- Drug and therapeutic information.

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Ward Rounds

B. Record Management

- How health care records are documented.
- Discharge planning of the patient etc.

C. Management skills

- How to work effectively in a team.
- Time management.
- Communications skills.

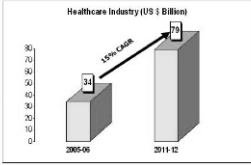
D. Responsibility towards patient

- How to maintain dignity of patient.
- Patient counselling.

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Healthcare Market Scenario

- The Indian Healthcare market was estimated at about US\$34 billion (FY 2006)
- Expected to grow at 15% p.a., to reach US\$79 billion by FY 2012



Source: CII/Investment Commission of India

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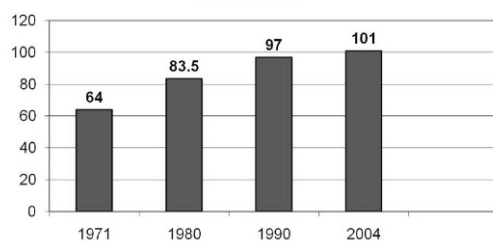
Growth in Domestic Market due to

- Healthcare delivery is one of the largest service sector industry in India
- World-class healthcare facilities are available in India
- Rapid growth in private sector companies owning and managing hospitals

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No. of Beds Per Hundred Thousand Population*

India No. of Beds Per Hundred Thousand Population



Source: www.indiastat.com

Increasing penetration of health insurance

- For BPL:
 - Rashtriya Swasthya Bima Yojna (RSBY): to cover more than 12 million families per year for next 5 years
 - To cover 300 million BPL ultimately
- Private Insurance market growing by 10% annually
- The medical insurance premium income is expected to grow to US\$3.8 billion by 2012

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Indian Healthcare Market

- The large domestic market complemented by the inflow of medical value travelers
 - Medical travelers have increased almost 20-fold from 10,000 in 2000 to about 1,80,000-2,00,000 in 2006
- High-growth in medical tourism: Cost of comparable treatment is on average 1/8th to 1/5th of those in western countries
- Medical tourism is expected to become a US\$2.2 billion industry by 2012

Source: CII/Investment Commission of India

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Doctor Patient Interaction

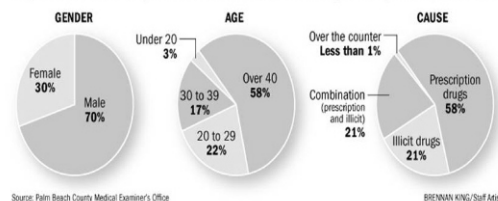
Doctor patient interaction	USA	Japan
Time spent	310-1418 s	150-738 s
Average time	668.7 s	505 s
Time distribution		
-Social Talk	12%	5%
-Verbal exam.	26%	26%
-Physical exam.	12%	29%
-Diagnosis	12%	15%
-Treatment	31%	16%

Good Pharmacy Practices

- Patient counselling ↔ Pharmacovigilance
- How & when to take medicine.
- What food/beverages etc. to avoid.
- Side-effects expected & how to manage.
- For how long to take medicine (Important)

Who dies of drug overdoses?

In Florida, prescription drug deaths outweigh illicit drug deaths 3-to-1, and Palm Beach County is no exception. Here, the average fatal drug overdose victim is 41 years old, more likely to be male, and is often abusing the drugs he is prescribed.



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Creating Job Opportunities for Pharm.D

1. approached UGC to include Pharm.D in UGC schedule u/s 22 (3) of the UGC Act as an approved qualification.
2. approached various recruiting agencies in Central/State Govt. to amend Recruitment Rules to include Pharm.D as an approved qualification
3. initiating action to amend statutory regulations (ER-91, Pharm.D. etc.) to include Pharm.D as an approved qualification for teaching.
4. initiating action for Mutual Recognition Agreement (MRA) with other countries.

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Pharmacy Practice Regulations

- Dispensing - by qualified registered pharmacist only.
- Panel provision for misconduct and defaulters.
- CEP - mandatory.
- Duties & Responsibilities of Pharmacist.
- Patient counselling.
- Pharmacist to charge counselling fee.

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REVISED TARIFF FOR ADVERTISEMENTS

The members of the Tamilnadu Pharmaceutical Science Welfare Trust desire to accept and publish important advertisements in Pharma Web, from Pharma and allied industries, Pharmacy colleges, etc. The following are the tariff :

Back Cover	Rs. 6,000/-
2 nd and 3 rd Cover	Rs. 4,000/-
Full Page	Rs. 3,000/-
Half Page	Rs. 2,000/-

Advertisement size

Page size : 24 cm x 18.5 cm

Print area : 20 cm x 16 cm

Advertisers may send the cheque in favour of 'Tamilnadu Pharmaceuticals Sciences Welfare Trust' to the address of the Trust along with the advertisement matter is soft copy.

Note: 20% discount on the above rates for four consecutive issues.

The above revised tariff are effective from next issue.

THE ROAD AHEAD FOR COMMUNITY & HOSPITAL PHARMACY

By

Dr. S. SRIRAM

Prof & Head, Dept of Pharmacy Practice,

College of Pharmacy, SRIPMS, Coimbatore.

Lecture delivered at 64th IPC, Chennai on 9th December 2012

TWENTY YEARS IN A ROW!

#1

Pharmacists are Voted

Gallup "Most Trusted Professionals" Poll

Percentage Ranked "Very High"



Gallup Poll is a Successful statistical method of survey sampling for measuring Public opinion on a wide range of Political, Social & economic issues. Americans rate the honesty and ethical standards of 28 occupations surveyed by the Gallup poll.



In Most Developed Countries...

PHARMACISTS

- Community Pharmacy } 80-90%
- Hospital Pharmacy }

OTHER AREAS } 10-20%

Direct Contact with patients/public

True Face of Profession

Provide Maximum Benefits to Patients

"Change is the constant thing in life"

Commercial Challenges

- Competition - Too many pharmacy licenses too close to one another
- Cut throat competition - pricing war
- Brands - >1.2 Lakh ??
- Drugs & FDCs - 5000 + ???

COMMERCIAL CHALLENGES..

- Expiry problems, Strip cutting
- Doctors dispensing
- Affordability to hire staff – Pharmacist salary?
- Retail chains



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PROFESSIONAL CHALLENGES.....

- Recognition of Pharmacist ??
- Professional atmosphere and inputs inappropriate
- No Continuing Professional Development
- Education inputs inappropriate
- Inadequate knowledge/ skills to handle patient queries
- Confidence??? Willingness????



STRONG RESISTANCE TO CHANGE

8

LEGAL CHALLENGES...

- Laws and regulations - not changed with times..
- Presence of a Pharmacist ????
- Sale of prescription medicines without a prescription and without a pharmacist.

**POOR IMPLEMENTATION
OF THE LAW**



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- There is need to increase the number of **TRAINED** pharmacists willing to work in community & hospital pharmacy.

IDENTITY ?

- If a PHARMACIST is not present while drugs are being dispensed, where does the question of IDENTITY come ?

On the contrary, the PHARMACIST becomes a **NON-ENTITY** in the eyes of the public !!!

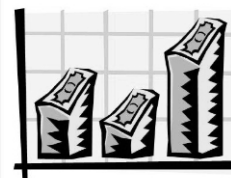


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REMUNERATION

The **BIG COMPLAINT** :

The PHARMACISTS' remuneration is not attractive !!!!



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PROVE FIRST OR PAY FIRST ?



- If we don't generate professional, knowledgeable pharmacists who exercise their role in the community, we cannot expect the employers, businesses, corporates to pay them well.

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- If we expect to be paid well FIRST..... and then become competent.....



- We may have to wait forever.....!!

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EARNING A BAD NAME

- Medicines are available without a prescription.
- Self Medication
- Medicine misuse
- Medicine abuse



GUARDIANS OF HEALTH ?



TIMES of INDIA Govt promises action against rogue chemists

TNN | Apr 23, 2011, 12.25am IST

MUMBAI: The state government will take stern action against chemists selling scheduled drugs without a doctor's prescription.

"The government will introduce stringent rules to tackle this issue," minister of state FDA told the legislative assembly on Friday in reply to a calling attention notice moved by Congress MLA Amin Patel.

The Indian government maintains a schedule of drugs based on their origin (biological, ayurvedic, etc). While some drugs can be bought over the counter, certain high-potency drugs (which evoke a larger response at low concentrations), which can be misused, can be bought only with a doctor's prescription.

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INDIA
PHARMACIST ?

OR....

SELLER OF MEDICINES...

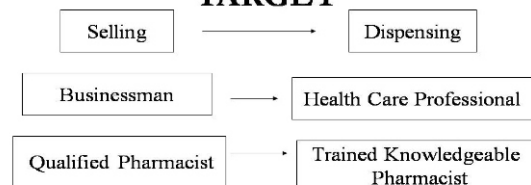


TRADER....

VENDOR..... ?????

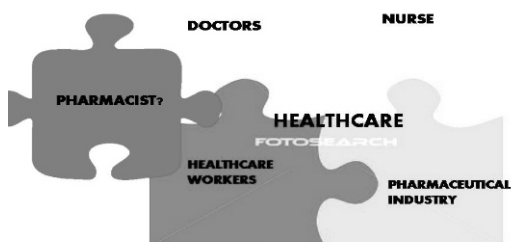
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TARGET

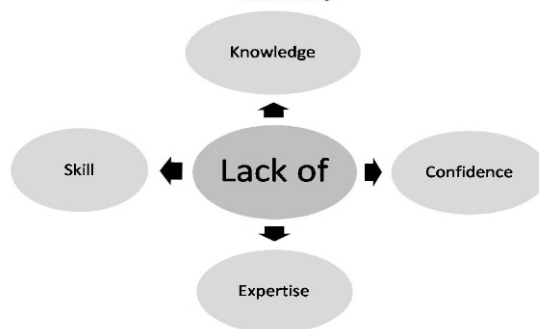


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FIT AS A HEALTH CARE PROFESSIONAL



BARRIERS



COMMUNITY PHARMACY PRACTICE - AROUND THE WORLD

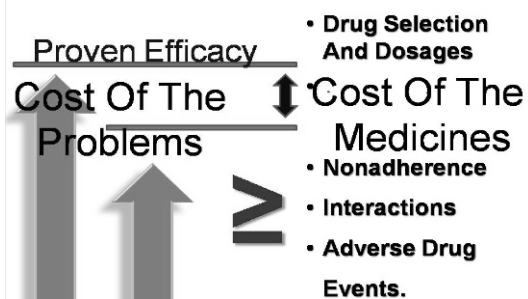
Country	Length of education	Ave Floor space in sq. mts	Pre. License training	Continuing Education requirements	Maintaining records	Dispensing with label/PIL	Interaction with physician
France	6 Yrs	80	N.A	Yes	Some	No	Good
Germany	4 Yrs	165	N.A	Yes	Some	Yes	Good
U.K	4 Yrs	*	1 Yr.	Yes	Yes	Yes	Good
Italy	5 Yrs	60	N.A	No	Some	Yes	Good
U.S.A	5.5 Yrs	400	N.A	Yes	All	Yes	Good
Canada	5 Yrs.	455	N.A	Yes	All	Yes	Good
Australia	3 Yrs	127	1 Yr	No	All	Yes	Good
Japan	4 Yrs	87	N.A	No	Most	Yes	Loose
Korea	4 Yrs	33	N.A	No	Some	Yes	Loose
India	2 Yrs	12	No	No	No	No	Loose

ROLES AND RESPONSIBILITIES OF A PHARMACIST RECOMMENDED BY WHO

- Processing of prescriptions
- Maintaining patient medication records
- Patient counseling
- Providing drug information
- Therapeutic consultation on rational prescribing
- Health screening services

DOCTOR- PATIENT RATIO

	Doctor : People
Current Ratio (Current)	1:1,953
Expected Ratio (2030)	1:1000
In Most Rural Areas	1:30000 Or More



Who can play an important role in improving access to health care and in closing the gap between the potential benefit of medicines and the actual value realized?

THE PHARMACIST

INDIA

- Very few Pharmacy graduates can be found in community pharmacy
- And patient oriented approach is just started in very small number of pharmacies

Community

Realize the duty to be performed.

Maintain patient data

Interaction with the Physician



Perform health screening services

Actively participate in CPE programmes

Change from traders to professional service providers

Collaborate with institutions

- Proper inventory control
- PTC
- TPN
- Sterile IV admixture
- Inter-relationship with other HCP
- Documentaion
- Pharmaco Economics

Hospital Pharmacy

- Sodium benzoate – for hyperammonia condition
- Neutral phosphate solution – for hypophosphatemia
- Inj. Vit K (for new born) – in hemolytic jaundice
- Antiseptics and disinfectants (sodium hypochlorite, benzalkonium chloride)
- Alum solution- for bladder irrigation
- Mandel's paint
- Lugols solution
- Potassium phosphate injection



Specialize in preparations not available in market.

Prescribing errors



Drug name confusion

Nootropil (Piracetam) & Nutrifil (Vitamins)
 Ocid (Omeprazole) & Ozid (Pimozide)
 Lasix (Furosemide) & Laxil (Lactulose)
 Dulcolax (Bisacodyl) & Duphalac (Lactulose)

A 5 year old boy fell down while playing and had mild dull aching back pain

He was prescribed *T.Serronak* [serratiopeptidase (10mg) + diclofenac sodium (50mg)] ½ Tab. t.i.d after food

Complaint of involuntary and frequent abnormal movements of right upper limb

Actually patient received *T.Serenace* 10mg (haloperidol)

Sound-alike Drugs

1 Celib	Celecoxib	8 Ciprid	Cefazolin
2 Celin	Vitamin C	9 Cipride	Ciprofloxacin
3 Clopreg	Clomifene	10 Daxid	Sertraline
4 Cloprez	Clopidogrel	11 Flunar	Desloratadine
5 Eltocin	Erythromycin	12 Flunat	Flunarizine
6 Eltroxin	Levathroxine	13 Fortum	Fluoxetine
7 Foracort	Budesonide	14 Fortwin	Ceftriaxime
	Foracet		Pentazocine
5 Gentin	Gabapentin	12 Lama	Amlodipine
6 Gentian	Gentamicin	13 Lamda	Lamivudine
7 Tibitol	Ethambutol	14 Clomine	Clomipramine
	Tenoxicam		Chlorpromazine
7 Xental-400	Pentoxifylline		Enalapril
Zental-400	Albendazole		Nimesulide

Sound-alike Drugs

15 Lori	Diazepam	20 Ocid	Omeprazole
Lorid	Loratadine	Ozid	Pimozide
16 Numol	Diclofenac + Paracetamol	21 Zidmin	Glipizide + Metformin
Numox	Amoxicillin+ Cloxacillin	Zidime	Ceftazidime
17 Zenotin	Ofloxacin+ Metronidazole	22 Pedicloryl	Chloral hydrate
Zanocin	Ofloxacin	Pedicloryl	Trichlofos
18 Fepra P	Paracetamol	23 Taxim	Cefotaxim
Espira	Esomeprazole	Tazin	Piperacillin
19 Berocin	Multivitamin	24 Lasix	Furosemide
Zanocin	Ofloxacin	Laxil	Lactulose

Ramipril

Dose	Prescribed Drug	Cost	Alternative Drug	Cost
1.25 mg	A	34.13	B	23.25
2.5 mg		65.40		42.25
5 mg		107.60		82.60
10 mg		149.00		105.25

Carvedilol

Dose	Prescribed drug	Cost	Alternative drug	Cost
3.125	A	30.00	B	9.00
6.25mg		42.00		16.00
12.5mg		47.50		30.00
25mg		82.00		52.00

Losartan

Dose	Prescribed drug	Cost	Alternative drug	Cost
25mg	A	36.96	B	18.90
50mg		69.30		37.44

Telmisartan

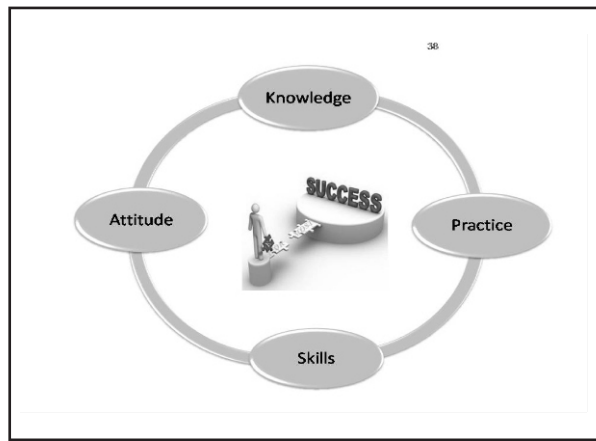
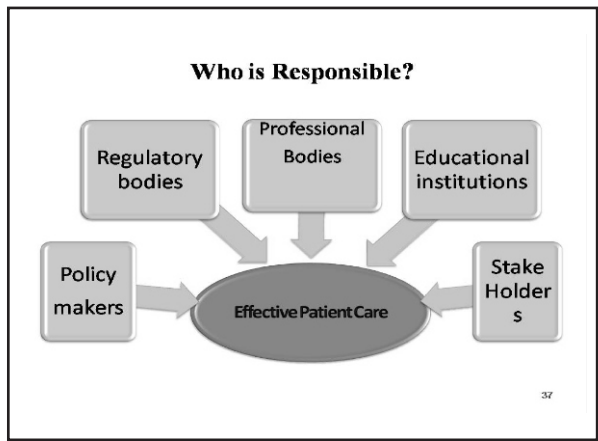
Dose	Prescribed drug	Cost	Alternative drug	Cost
20mg	A	38.90	B	30.00
40mg		71.00		63.00

Atorvastatin

Dose	Prescribed drug	Cost	Alternative drug	Cost
10mg	A	87.92	B	48.00
20mg		175.84		90.00

Clopidogrel + Aspirin

Prescribed Drug	Cost	Alternative Drug	Cost
A	75.00	B	26.47
A	80.00	B	26.70



— — — — —

**Doctorate Degree award to
Mr. S. Manivannan, Dy. Drugs Controller of India**



Dr. S. Manivannan, Deputy Drugs Controller (India), Central Drugs Standard Control Organisation (CDSCO), sub zone, Bangalore has received his degree in Doctorate in Philosophy in Pharmaceutical Science from "The Tamil Nadu Dr. M.G.R Medical University", Chennai. It was awarded by Honorable Minister for Health, Government of Tamil Nadu, Mr. K C Veeramani in the silver jubilee convocation celebration of "The Tamil Nadu Dr. M.G.R Medical University" which was held at Madras University, Cenetary hall on 20th August'13 .The function was presided by Honorable Chief minister of

Tamilnadu and honorable Governor of Tamilnadu. His PhD topic was Design, development of a novel Transdermal Drug Delivery System (TDDS) as wound dressing using herbal constituents. TDDS with herbal constituents for wound healing is a unique development even today in the market (both domestic and international). TDDS with herbal constituents is not available. It is a developing field wherein he has completed his PhD under the guidance of Dr. V. Ravichandran, Director, School of Pharmacy, Vel's University, Chennai. Dr. S. Manivannan is an active member of IPA TN Branch.



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Over View of 'Patent law'

By

Shri. S. Chandrasekaran

Former Controller General of Patents, Designs & Trademarks & GI and also the Former
Member (Technical) Intellectual Property Appellate Board, Chennai, India.

Lecture delivered at IPR Seminar conducted by IPA, TN on 27th July 2013



Over view of 'Patent law' – Study Material

WHAT IS A PATENT?

It is a form of contract between the true and first inventor (hereinafter referred to as 'inventor') and the State or the Country. Clearly stating, it is an exclusive monopoly right granted by the State to the Inventor for his invention, for a limited period of time. This exclusive monopoly right granted by the Government of the Country is valid only within the territory of the Country of Grant and not even in the territory of the neighboring country. To make it clear, the exclusive right granted to the patentee gives him the monopoly right to use his invention, to manufacture or to sell his patented device or even mortgage the same. If the patentee wants similar such monopoly right in other countries, he has to apply for similar such rights in the respective neighboring countries and consequently, if and when a patent is granted, he enjoys the same.

Thus this right can be exercised by the patentee only within the territory of the country of grant and the patentee enjoys for a limited period of time or term. For example, if it is an engineering invention, the patent can be kept in force for a period of 20 years from the date of the patent. Here, the date of the patent is the date of filing of the Application. Similarly, if the invention is regarding a food or pharmaceutical item, the term of the patent does not vary; the term is same 20 years. Here, it is very pertinent to note that at present, under the Patents Act, 1970, Product Patents are granted for the food, drugs and pharmaceutical and agro chemicals.

WHAT IS A COMPLETE SPECIFICATION?

While making an application for grant of patent, applicant files an application along with the specification, which contains the description of the invention and claims defining the monopoly, which the inventor seeks as an exclusive right. This specification is the complete specification.

WHAT IS MONOPOLY RIGHT?

The monopoly right obtained as a consequence of the grant of patent makes the patentee to use his invention exclusively by him to sell, use, manufacture, mortgage. Also the patentee can license the same to somebody to manufacture the patented item on getting certain amount of royalty. This exclusive right enjoyed by the patentee is called the “Monopoly Right”.

EXAMINATION OF APPLICATION AND GRANTING PROCEDURE

Numbering of Application : As soon as the application with the required documents and fees are received in the appropriate office of the Patent Office, the said office allots the number and date to the application. Thereafter, the filing of the application is published in the Patent office Journal on every Friday.

Publication:- The filing details as notified in the Patent Journal contain only application number, title of invention and name of applicant and the abstract. The best view or the drawing in which the invention is disclosed is published in the Journal. This is the first occasion when the invention is disclosed to the public by the Controller of Patents, after filing of the application for patent takes place.

Examination Process : Applications for patents are taken up for examination in the Patent Office in the order of their request for examination. Applications for patent accompanying with provisional specifications are taken up only after the complete specification in respect thereof are filed. If the complete specification is not filed within the prescribed period, the application will be treated as deemed to have been abandoned under section 9(1) of the Patents Act, 1970 and no further action can be taken thereon.

Issue of FER : First examination report, will be issued by the Patent Office after the technical examination of the patent application, communicating the defects, if any, found during the examination. The official requirements contained in the examination report are to be complied with, by the applicant within the period of 12 months termed as normal period from the date of issue of such First Examination Report (FER). This normal period of 12 months cannot be extended further.

If the application is not resubmitted within the normal period of 12 months period (i.e. normal period), meeting all the technical objections and if the application has not been placed in order for grant of patent within the said 12 months period, the application for patent will be treated as deemed to have been abandoned under section 21(1) of the Patents Act, 1970 and no further action can be taken thereon by the Patent Office. When the application is found in order for grant of patent, by the Controller of Patents, the complete specification is accepted for the grant of patent and is accorded a serial number (currently having six digits), which will be the patent number. The grant of patent is also notified in the Patent office journal.

Pre-grant opposition : From the date of this publication of the invention in the Journal, any person can obtain the copy of the specification and ascertain the details of the invention disclosed therein and oppose the grant of the patent.

This third party pre-grant opposition, against the grant of a patent on an application for patent can be filed by any person at the appropriate office of the Patent Office before the grant of patent from the date of publication of the invention on any of the grounds mentioned under Section 25(1) of the Patents Act, in the prescribed manner.

Post-grant Opposition to the Grant of a Patent : Though all care is taken by the Controller during the examination of the documents filed in respect of an application for patent so as to remove any defects in the documents, yet there may be some information regarding prior publication, use or other matters in respect of the invention disclosed in the application which may be of vital importance and which may be available to the people in research and trade and which might not be available in the records of the Patent Office and therefore the Controller of Patents might not have considered such documents / information at the time of examination.

By filing the opposition under Section 25(2) of the Patents Act 1970, in appropriate cases the grant of patent can either be refused or the scope of the protection claimed can be narrowed down by restricting the grant only to novel features of the invention.

This post-grant opposition can be filed by any interested person at the appropriate office of the Patent Office after the grant of patent but within one year from the date of grant of patent for the invention on any of the grounds mentioned under Section 25(2) of the Patents Act, in the prescribed manner.

An appeal lies against this post-grant opposition either way when it is decided or in a case where the Controller of Patent refuses to grant a patent under section 15 of the Patents Act, 1970.

DISCLOSURE OF THE INVENTION

Description :- The description shall be sufficiently clear to enable a person skilled in the art of work the invention. It may only contain such matter that will contribute to explain the invention. The description usually comprises a general part stating the field of use, the prior art and the purpose of the invention together with a solution to the problem. Then a special part follows with a description of certain embodiments of the invention. If drawings are included, there should be a list of them in the introduction to the special part of the description, stating what the different drawing represent.

Specification :-

Provisional Specification :-

It should be filed in triplicate and should contain (i) the title indicating the subject matter to which the invention relates; (ii) the name, address and nationality of the applicant(s); (iii) the prescribed preamble; (iv) Description of the invention; and (v) date and signature of the applicant.

It is permissible for the description of the invention to be in general term in the provisional specification; but it is in the applicant's interest to provide the fullest details of the invention. The provisional specification enables the applicant to show that the date of its filing is the priority date

to be accorded to those claims in the Complete Specification which are fairly based on the matter disclosed in the Provisional Specification (Section 11). As this is the purpose of a Provisional Specification, it is to be regarded as mere document of record.

Since provisional specification is regarded as a mere document of record no amendment that would add any fresh matter or extend the scope of the invention described in provisional specification is allowable without post-dating. Excision of part of the description in a provisional specification may be allowed at the applicant's request provided such excision does not in any way extend the scope of the invention as first disclosed. It may be noted that where an application accompanied by a provisional specification has been filed, the same will be examined under the provisions of the Act only after the complete specification in respect thereof has been filed.

Complete Specification :

It should be filed in triplicate on Form 2 and should contain (i) the title indicating the subject matter of the invention, (ii) name, address and nationality of the applicant(s), (iii) the prescribed preamble to the description of the invention (iv) full description of the invention and its operation or use and the best method by which it is to be performed, (v) a statement of claims preceded by the prescribed preamble 'I (We) Claim'.. and (vi) date and signature of the applicant.

The description should state in clear and intelligible language what the invention is, so that others may know what the monopoly is, that is granted to the patentee. The description should state in clear and intelligible language in what manner the patented invention is to be performed, so that others may learn from the specification how practically to avail themselves of the patented invention when the patent has expired; how they are to do what is necessary to carry out the new invention, the nature of which has been previously described.

The complete specification should end with a statement of claims defining the scope of the invention for which protection is claimed. The claims should relate to a single invention, should be clear, succinct and fairly based on the matter disclosed in the specification and provisional specification if any.

INFRINGEMENT OF PATENT

What constitute an infringement of a patent has not been defined in the Act. One has, therefore, to gather the meaning of infringement from the scope of monopoly rights conferred on the grantee because infringement means violation of those rights. In other words, infringement of a patent connotes a trespass upon the legal right of the patentee.

(a) Determination of Infringement

While deciding whether a person is infringing the rights conferred on a patent, the following criteria have to be considered :

- (I) the extent of monopoly rights conferred by the patent. This can be ascertained by the construction of the disclosure made in the Complete Specification;
- (ii) Whether the alleged act(s) amount to making, using, exercising, selling or distributing a product, or using or exercising a method or process in the case of patents granted covering the process;
- (iii) whether what the alleged infringer is doing amounts to an infringement of the monopoly conferred by the grant of the patent.

(b) Onus of Proof of Infringement

At present after the amendment of the law in line with the TRIPS agreement, in the case of infringement suits, the onus of proving the infringement is on the respondent i.e. on the person who is infringing the right of the patentee. This follows that the infringer has to clearly bring out the differences and prove as to how his process or method or the device he is manufacturing (which is being infringed) is totally different from that of the details of the patented invention.

(c) Suit for Infringement

An action for infringement of a patent must be instituted by way of a suit in any court not inferior to a District court having jurisdiction to try the suit. Accordingly, the suit must be filed either before the District Court or High Court.

The period of limitation for bringing suits for infringement of patent is governed by Section 40 of the Indian Limitation Act, which states “For compensation for infringing copyright or any other exclusive privilege - three years (from the date of infringement)”.

(d) **Reliefs :** The relief available for a successful plaintiff i.e. the person claiming infringement in an action for infringement include

- (i) an injunction;
- (ii) either damages or an account of profit.

The grant of these reliefs is discretionary. The power to grant relief is also subject to certain restrictions. If a defendant is able to prove that on the date of infringement, he was not aware and there existed no reasonable grounds for believing that the patent existed, he will not be liable for damages or account for profits. The onus is on the defendant to prove that he is innocent in this respect.

Provision for grant of a Licence :

There are two ways in which a patentee can exercise the rights accrued under a patent.

They are (i) he can deprive himself of the exclusive right to exercise those rights or part of them against particular persons (licensees) or (ii) he can transfer (assignment) to another person the whole or part of his right in the patent to prevent others from making, using, exercising or selling the invention concerned in the said patent.

(I) Licence

A patentee may, by a licence, prevent others from making, using or exercising the invention. A licensee has to be in possession of a licence embodying the terms and conditions of the licence.

(i) Licence

A patentee may, by a licence, prevent others from making, using or exercising the invention. A licensee has to be in possession of a licence embodying the terms and conditions of the licence. A licence may be expressed, implied or statutory. It may be exclusive, non-exclusive or limited. An exclusive licence excludes all other persons including the patentee from the right to use the invention. In a limited licence, the limitation may arise as to persons, time, place, manufacture use or sale. An expressed licence is one in which the permission to use the patent is provided in express terms. In an implied licence, the permission is not given in

express terms but in implied terms based on the circumstances. Such licence usually arises in connection with the purchase of patented articles purchased or sold with or without restrictions. For example, where a person buys a patented article, either directly or indirectly from the patentee or his licensee, there is an implied licence to use the article in any way and to resell it.

(ii) **Assignment**

The term assignment has not been defined in the Act. Under the patent law, assignment means an act of the patentee by which the rights in the patent are wholly or partly transferred to the assignee who acquires the right to prevent others from making using, exercising or vending the invention. The patentee may assign the whole or any share in the patent. The assignee includes the legal representative of a deceased person (i.e. a person who in law represent the estate of a deceased person). Since the rights in a patent are allowed on the patentee only after the grant of patent thereon, an agreement to assign an invention concerned in an application for patent, before the grant of patent does not amount to an assignment of the patent. An assignment of the patent rights before the grant of a patent on an application for patent is an equitable assignment, which can be enforced only after the grant of the patent.

Registration of Assignment / Licenses

All assignments, mortgage, licence or the creation of any other interest in a patent will not be valid unless it is in writing and is registered with the Controller. Validity of assignment, licence or interest created in the patent is essential for the enforcement of the right and obligation arising there from. Therefore, registration of such documents is compulsory under the Act.

The registration should be done under Section 68 of the Act, with the Controller of Patent at the Patent Office which has granted the patent within 6 months of the execution of the agreement. Thereafter, the interest allowed by the agreement should be entered in the Registrar of Patents as required under Section 69 of the Act. These two proceeding can also be effected simultaneously, if it is convenient. It is unlawful to include restrictional conditions such as prohibitions of the purchase of non-patented articles from person other than the patentee or his nominee, or of the use of any other articles which could be utilized for a purpose similar to that of a patented article or of the use of patent owned by the persons in any contract relating to sale or lease of a patented article or a licence to use the patent.

Compulsory Licence

Abuse of the monopoly rights granted under a patent is a common phenomenon. It may take various forms such as :

- (a) meeting the demand of the patented articles solely by importation from abroad and not by manufacturing the patented articles locally. The result of such an action may lead to the discouragement and prejudicing the establishment of new trade or industry and the development of an existing trade or industry in the country, which grants patents.
- (b) refusing the grant of licences to work the patent locally.
- (c) imposing unreasonable terms and conditions on licences discouraging thereby voluntary licensing.
- (d) imposing restrictive conditions on the use of the patented articles prolonging thereby the patent monopoly rights even after the term of patent has expired.

To prevent the above said abuse of the patent grant, a system of compulsory working of the patents in the country of grant by the grant of compulsory licences by a statutory authority has been adopted in many countries. The remedies adopted in India against abuses to patent rights consist of defining the purpose of patent grant and providing for a system of grant of compulsory licence by the Controller under specified circumstances.

The philosophy of the Act for the grant of patents is enumerated in Section 83 of the Act. The patent may be worked by the patentee himself or through licensees. Failure to meet the obligation of working the invention covered in a patent may result in the grant of compulsory license or the revocation of the patent itself.

The Act provides for the grant of compulsory licences in the following cases.

On making an application to the Controller by an interested person under Section 84 of the Act on the ground:

- (i) that the reasonable requirement of the public with respect to the patented invention has not been satisfied, or
- (ii) that the patented invention is not available to the public at a reasonable price.

The applicant making such request must make out a prima-facie case. The Controller can entertain application under this Section only after the expiry of 3 years from the date of sealing of the patent.

Failure to meet the reasonable requirements of the public may arise from any one of the following cases.

- (a) inadequate manufacture in India/failure to grant licences at reasonable terms resulting in
 - (i) Prejudice to the existing trade or industry or its development in India.
 - (ii) Prejudice to the establishment of a new trade or industry in India.
 - (iii) Prejudice to the trade or industry or any person or any classes of person trading or manufacturing in India.
 - (iv) Demand for the patented article not being met adequately by local manufacture.
 - (v) Failure to develop an export market for the patented articles in India.
 - (vi) Prejudice to the establishment or commercial activities in India.
- (b) prejudice to the establishment or development of trade or industry in India in goods not protected by the patent arising from the condition imposed by the patentee.
- (c) non-working of the patent in India on a commercial scale.
- (d) demand for the patented article being met by importation from abroad and
- (e) commercial working of the patented invention in India being hindered or prevented by the import of the patented article from abroad.

In case the patentee refuses to grant a licence or in case the terms and conditions are not acceptable to the person, he can approach the Controller to grant the licence. The term may be settled by the parties mutually or may be determined by the Controller if desired by either of the parties.

In the case of patents for inventions relating to substances used or capable of being used as food, drug or medicine, the royalty payable to the patentee under the licence should not exceed 4% of the net ex-factory sale price in bulk of the patented article. It is to be noted that this sealing of the royalty in such category of inventions is maximum, meaning that it can be less than 4% of the net ex-factory sale price in bulk of the patented article. This sealing is not applicable in the case of chemical patents other than food, drug and medicine. While granting licence under this category, the Controller need not require to look into the aspects of technical expertise and financial capacity of the applicants for licence. This is to avoid any delay in the grant of licence and setting up of the manufacture of the essential goods such as food, drug, medicine and chemical substances, which are vital for the society.

TERRITORIAL RIGHT

The patent right is purely territorial right and as said earlier, it is valid only in the country of grant. To have similar such rights in any other countries, one has to apply to the respective patent offices in the respective countries. Also this right is valid up to the territorial waters over which the state has the full jurisdiction of governance and right to administration.

POSITIVE RIGHT

To say that the patent monopoly right is a positive right is a misnomer. But in a certain angle if the same is looked at, then the same monopoly right fully works for the technological and scientific advancement in the country of grant, when the same is well exploited by the Patentee.

NEGATIVE RIGHT

It is very apt to say that this patent monopoly right is an exclusive monopoly right given only to the patentee to exclude all the others and the public at large from copying the same right; i.e., forbidden to use, sell or manufacture or mortgage in any form without the consent and permission of the patentee. Thus this right is called as a negative right.

(End of document)





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GLOBAL PHARMA CHALLENGES - ARE WE READY?

By

Ms. T. R. Ramcy,
Swamy Vivekanandha College of Pharmacy, Elayampalayam

Note: This article was awarded Third Prize in the Essay Competition conducted by our Trust

Our world is under lot of pressure due to the newly discovered diseases and also going on discovery of medicines for their treatment, from a long time. And for this purpose many type of medicines like ayurveda, siddha, allopathy is introduced. Among which allopathy got a worldwide success due to its fast healing process. This success made it to touch the industrial corners as well, now a day's preparing medicine is not at all a problem. Each successful medicine has its worldwide distribution by the company's by exporting it through trade. This is done for helping as well as for developing the economy. Pharmaceutical products have its place in every economy. Over 90% of the values of the world's pharmaceuticals are produced in high income countries. More than 70% is produced in just 5 countries and more than 45% by the top ten companies. The fraction of the pharmaceutical market in the hands of these top ten increased from 27.5% in the 1980's to 45.7% by the year 2000. It has been estimated that 15% of the world's population in these countries consume 90% of medication and the trend towards further market concentration continues. Global pharma has a lot of positive impact in INDIA as it supply a vast quantity of low cost, good - quality, generic medicines, which has saved or prolonged millions of life. In INDIA current pharma export of drugs, pharma and finechem amounted to Rs. 32051 crores during 2008-09. Biopharma export touched Rs. 3999 crores in 2007-08. Export to over 200 destination including small islands like "kiribati". Europe,

North America together account for half of exports. Share of dose exports 52%- a noteworthy achievement. World's no.1 pharma market, USA also India's top destination. Africa is biggest with 54 destinations. Global presents of India in the critical antiretroviral supply is now part of history. According to the global pharma industry's of 2008, global drug sales projected at \$773Bn with low growth of 48\$ in 2008, further slowdown expected in 2009. New products launch hurdles imposed by players on market access, world financial crisis are some reasons for reduced growth. According to the new condition of global pharma, the aggregate value of biotechnology drugs sale +\$75 Bn in 2007 are estimated to grow to \$169 Bn in 2014. Lipid Regulators (\$34Bn), Respiratory (\$31 Bn), Antidiabetic (\$27Bn), Antiulcer (\$26Bn), CVD (\$23Bn) are other top grade. US prescription drugs sales which grow 1.3% in 2008 to \$291 Bn is expected to decline by 1-2% in 2009. Highlights of global pharma are as follows. There are top 50 pharmaceutical companies accounted for prescription drug sale of \$558 Bn in 2008.

New drugs in development gone up to 9605(2009) from 5930(1998). Currently there are 100 blockbuster drugs, in which 22 biotech products are included. 32 NCE's launched in 2008 compared to 25 in 2007. There are benefits and risk in the early release of new medication, the new world of fully networked, clouded-based EHRs offers new tools to address the risk. Specifically EMRs with large data set up can harness the

power, speed and relatively low cost of this new technology to conduct formal U.S. testing prior to FDA approval.

For a medication that has demonstrated safety and effectiveness worldwide but has not met the standard of proofs required for the U.S. market, a pharmaceutical company could be allowed or directed to arrange for additional testing to prove the required safety and effectiveness under controlled circumstances. The pharmaceutical company could be responsible for the design of the test subject to FDA approval of the design and oversight of its implementation.

The Human right to health is recognized in many international instruments, such as the founding documents of WHO, the Alma Ata Declaration and several treatments of human rights. Articles of the Universal Declaration of Human Rights (1948) states. Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.

Deep concerns about access to medications have appeared in the specialized literature since the 1990s. In 2001, the World Health Assembly endorsed a resolution calling for development of standardized methods for measuring and monitoring pharmaceutical

prices, resulting in the launch of the WHO's Health Action International Project on Medicine Prices and Availability. The first draft of its manual was published in 2003. Since then, more than 50 studies using the manual have been conducted on the affordability and availability of essential medications, and on the special and more complex case of medications for chronic diseases. In Addition to access the available medications there is a second dimension of the problem related to priority setting for scientific research on new pharmaceuticals. According to some estimates, less than 10% of the world's biomedical R&D funds are aimed at addressing the problems responsible for 90% of the global disease burden. This disparity has been termed the 10/90 gap.

In 2004, WHO created a Commission on Intellectual Property Rights, Innovation and Public Health, which in turn commissioned 22 studies to expand the knowledge base on the issue. These concluded that intellectual property does not provide effective incentive for innovation in developing countries.

Conclusion

By all the above news of health verses medication in accordance to global pharma we conclude that the medicines have got the first place in every human's life and the world is and will be competing for both human health and successful economy.



Drugs Donation by IPA TN Branch

The Indian Pharmaceutical Association (TN) is donated worth Rs. 87,000/- life saving drugs, like Antibiotics Cardiac, Diabetics and common Drugs like Antacid, Pain relieving, vitamins, cough syrup and other Drugs for common ailments to Uttarakhand Flood Relief. The drugs were donated M/s. Kammy Expo Links, M/s. Tanmed Pharmaceuticals, M/s.M.M. Pharma & M/s. Delvin Formulations Pvt. Ltd., donated the Drugs.

NOTIFICATIONS & CIRCULARS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd May, 2013

G.S.R.332 (E) – Whereas the Central Government is satisfied that the use of the drug Dextropropoxyphene and formulations containing Dextropropoxyphene for human use is likely to involve risk to human beings and whereas safer alternatives to the said drugs are available.

And whereas the Central Government is satisfied that it is necessary and expedient to regulate by way of suspension of manufacture, sale and distribution of the drugs in the country in public interest.

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby suspend the manufacture for sale, sale and distribution of the following drugs with immediate effect. 'Dextropropoxyphene and formulations containing Dextropropoxyphene for human use'.

[F.No.X.11014/1/2013-DFQC]

ARUN K. PANDA, Jt. Secy.



MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 18th June 2013

G.S.R.377 (E) - Whereas the Central Government is satisfied that the use of the drug Flupenthixol + Melitracen is likely to involve risk to human beings and whereas safer alternatives to the said drug are available.

And whereas the Central Government is satisfied that it is necessary and expedient to regulate by way of suspension of manufacture for sale, sale and distribution of the said drug in the country in public interest.

Now therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby suspends the manufacture for sale, sale and distribution of the following drug with immediate effect.

“Fixed dose combination of Flupenthixol + Melitracen for human use”.

[F.No. 4-01/2011-DC (Pt. Deanxit)]

ARUN K. PANDA, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 18th June, 2013

G.S.R. 378(E) - Whereas the Central Government is satisfied that the use of the drug Analgin and all formulations containing Analgin is likely to involve risk to human beings and whereas safer alternatives to the said drug are available.

And whereas the Central Government is satisfied that it is necessary and expedient to regulate by way of suspension of manufacture for sale, sale and distribution of the drug in the country in public interest;

Now therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby suspends the manufacture for sale, sale and distribution of the following drug with immediate effect:-

“Analgin and all formulations containing Analgin for human use”.

[F.No.4-01/2011-DC/Analgin]

ARUN K. PANDA, Jt. Secy.



MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th June 2013

G.S.R. 379 (E):- Whereas the Central Government is satisfied that the use of the drug Pioglitazone and all drug formulations containing Pioglitazone are likely to involve risk to human beings and whereas safer alternatives to the said drug are available.

And whereas, the Central Government is satisfied that it is necessary and expedient to regulate the way of suspension of manufacture for sale, sale and distribution of the said drug in the country in public interest.

Now therefore, in exercise of the powers conferred by Section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby suspends the manufacture for sale, sale and distribution of the following drug with immediate effect.

“Pioglitazone and all formulations containing Pioglitazone for human use”.

[F.No.4-01 2011-DC-Pioglitazone]

ARUN K. PANDA, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 31st July 2013

G.S.R 520(E).-- Whereas the Central Government was satisfied that the use of the drug Pioglitazone and all drug formulations containing Pioglitazone was likely to involve risk to human beings and whereas safer alternatives to the said drug are available;

Whereas, the Central Government was satisfied that it was necessary and expedient to regulate by way of suspension, the manufacture for sale, sale and distribution of the said drug in the country in public interest, and accordingly in exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940) the Central Government suspended the manufacture for sale, sale and distribution of Pioglitazone and all formulations containing Pioglitazone for human use through the notification number G.S.R. 379 (E) dated 18th June, 2013.

Whereas, the Drugs Technical Advisory Board has examined the issue of suspension of manufacture and sale of the said drug on 19th July 2013 and has recommended that the suspension of the drug should be revoked and allowed to be marketed subject to certain conditions the manufactures shall mention on their package insert and promotional literature of the drug;

Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board, the Central Government hereby revokes the notification G.S.R. 379 (E) dated 18th June, 2013 subject to the following conditions as recommended by the Drugs Technical Advisory Board:-

"Pioglitazone and all formulations containing Pioglitazone for human use is allowed to be manufacture for sale, sale and distribution subject to

the condition that the manufacturer shall mention the following on their package insert and promotional literature of the drug

1. The drug should not be used as first line of therapy for diabetes.
2. The manufacturer should clearly mention following box warning in bold red letters.

Advice for healthcare professionals;

- Patients with active bladder cancer or with a history of bladder cancer, and those with uninvestigated haematuria, should not receive pioglitazone
- Prescribers should review the safety and efficacy of pioglitazone in individuals after 3-6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (eg. Reduction in glycosylated haemoglobin HbA1c)
- Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals : age, current or past history of smoking, exposure to some occupational or chemotherapy agents such as cyclophosphamide, or previous irradiation of the pelvic region.
- Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone."

[F.No. 4-01/2011-DC/PiogI]

ARUN K. PANDA, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health)

NOTIFICATION

New Delhi, the 7th June 2013

G.S.R. 364(E).--- The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110 011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2013.
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, in Schedule Y,-
 - (i) in paragraph 2 on 'CLINICAL TRIAL', in sub-paragraph (4) relating to 'Informed Consent' after Clause (iii), the following shall be inserted namely:-
 - (iv) "An audio –video recording of the informed consent process of individual subject, including the procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record".
 - (ii) in APPENDIX V, under heading 1, in sub heading 1.1 relating to 'Essential Elements', the existing entry 14 shall be re-numbered as entry 16 and before entry 14 as so re-numbered, the following entries shall respectively be inserted, namely:-
 - "14. Statement that there is possibility of failure of investigational product to provide intended therapeutic effect.
 15. Statement that in the case of placebo controlled trail, the placebo administered to the Subjects shall not have therapeutic effect".

[F.No.X-11014/1/2012-DFQC]

ARUN K. PANDA Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No.F.28-10/45-H(1) dated 21st December 1945 and last amended vide notification number G.S.R. 72(E) dated 8th February, 2013.

No.DCG(I)/MISC/2013
Directorate General of Health Services
O/o Drugs Controller General India
FDA Bhawan, Kotla Road, New Delhi

Dated: 26th June, 2013.

To

All States/UTs Drugs Controller

**Subject: Re-labeling/Re-printing of revised prices as per NPPA's –
Notification regarding.**

Sir,

In pursuance to the National Pharmaceuticals Pricing Authority's (NPPA) recent Order/Notifications No.1542 (E) to 1692 (E) dated 14th June, 2013, and subsequent notifications in this regard which will follow for revising the ceiling price of the scheduled formulations, the NPPA is fixing the ceiling prices of scheduled formulations produced or available in the market. Accordingly, the manufacturers are required to ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

Consequent to the fixing of ceiling prices of the scheduled formulations by NPPA as per the above, the manufacturers may be required to re-print/re-label the revised prices of scheduled formulations produced or available in the market.

Accordingly, the office of DCG (I) does not have any objection for re-labeling/stickering of the drugs concerned under Rule 104A of Drugs & Cosmetics Rules for this purpose. Since the activity involved is large, it is necessary to take the practical approach to expedite re-printing of price, so that benefits of price reduction can be passed on to the consumers.

Yours faithfully,



(Dr. G.N. Singh)
Drugs Controller General (I)

Copy to:

1. Chairman, National Pharmaceuticals Pricing Authority's, New Delhi.
2. Secretary, Department of Pharmaceuticals, Shastri Bhawan, New Delhi.
3. Additional Secretary & DG (CGHS), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.

C.C. to:

IDMA/OPPI/IPA/BDMA/Others

PRODUCTS FROM READY STOCKS

- | | | |
|----------------------------|--------------------------|----------------------------|
| ➤ ALBENDAZOLE | ➤ DOMPERIDONE MALEATE | ➤ LUTEIN (NATURAL) |
| ➤ AMBROXOL HCL | ➤ ESCITALOPRAM OXALATE | ➤ LYCOPENE (NATURAL) |
| ➤ AMISULPIRIDE | ➤ ETHIONAMIDE | ➤ METHOXSALIN |
| ➤ AMLODIPINE BESYLATE | ➤ EZETIMIBE | ➤ METHYL SULPHONYL METHANE |
| ➤ AMPICILLIN TRIHYDRATE | ➤ FENBENDAZOLE | ➤ METOPROLOL SUCCINATE |
| ➤ ATENOLOL | ➤ FENUGREEK EXTRACT | ➤ MINOXIDIL |
| ➤ BACLOFEN | ➤ FERROUS ASCORBATE | ➤ MIZOLASTIN |
| ➤ BALOFLOXACIN | ➤ FERROUS BIS GLYCINATE | ➤ OXACILLIN SODIUM |
| ➤ BERGAPTEN | ➤ FEXOFENADINE | ➤ OXETACAIN |
| ➤ BETA CAROTENE (NATURAL) | ➤ FLUCONAZOLE | ➤ PANTOPRAZOLE |
| ➤ BROMELAIN | ➤ FLUNARIZINE HCL | ➤ PINE BARK EXTRACT |
| ➤ BROMOHXINE | ➤ FLUOXETINE HCL | ➤ PROTHIONAMIDE |
| ➤ CALCITROL (FARMOSA) | ➤ FLUVOXAMINE MALEATE | ➤ RABEPRAZOLE SODIUM |
| ➤ CAPSAICIN 95% | ➤ GLICLAZIDE | ➤ RANITIDINE INJ. GRADE |
| ➤ CARISOPRODOL | ➤ GLUCOSAMINE SULPHATE | ➤ RESPERIDONE |
| ➤ CEFIXIME | ➤ GRAPE SEED EXTRACT | ➤ RUTIN NF (RUTOSIDE) |
| ➤ CEFPODOXIME PROXETIL | ➤ GREEN TEA EXTRACT | ➤ S AMLODIPINE BESYLATE |
| ➤ CEPHALEXIN | ➤ GUAIFENESIN | ➤ SILYMARINE 70% (INDIAN) |
| ➤ CHLORPHENIRAMINE MALEATE | ➤ HYDROCHLORTHIAZIDE | ➤ SOY ISOFLAVONES 40% |
| ➤ CHONDROITIN SULPHATE | ➤ IRON DEXTRAN | ➤ TERBINAFIN |
| ➤ CINNARIZINE | ➤ IRON SUCROSE | ➤ TRIOXSALIN |
| ➤ CITRUS BIOFLAVONOIDS | ➤ ISOTRETINOIN | ➤ TROXERUTIN |
| ➤ COENZYME Q10 (INDIAN) | ➤ KETOPROFEN | ➤ UDCA |
| ➤ CYPROHEPTADINE | ➤ KETOROLAC TROMETHAMINE | ➤ ZINC ASCORBATE |
| ➤ DIOSMIN | ➤ LOPERAMIDE | ➤ ZINC BIS GLYCINATE |
| ➤ DOMPERIDONE | ➤ LORATIDINE | ➤ ZINC CARNOSINE |
| | ➤ LOSARTAN POTASSIUM | |

SPECIALITY OILS FOR COSMETICS & SOFTGEL

- | | |
|-----------------------------|------------------------|
| ➤ GRAPE SEED OIL | ➤ WHEAT GERM OIL |
| ➤ OLIVE OIL POMACE & VIRGIN | ➤ EVENING PRIMROSE OIL |
| ➤ SWEET ALMOND OIL | |



Shubham
Pharmachem Pvt. Ltd.

207, Laxmi Plaza, Laxmi Industrial Estate, Building No.9, New Link Road, Andheri (W), Mumbai - 400 053, India.
Tel.: 26344608 / 09 / 10, 66914797 • Fax: 66923929 / 26318808
Email: shubham@shubham.co.in • Website: www.shubham.co.in

**F. No. 4-01/2013-DC (Misc13-PSC)
Directorate of General of Health Services
Central Drugs Standard Control Organization
(FDC DIVISION)**

**FDA Bhawan,
Kotla Road, New Delhi**

Dated: 05 JUL 2013

**To
All State/UT Drug Controllers**

Subject: - Approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Sir,

This is in continuation to this office letter No. 4-01/2013-DC (Misc13-PSC) dated 15.1.2013 on the subject cited above.

The issue related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term 'new drug' in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India) had been raised in many forums from time to time. The Parliamentary Standing Committee of the Ministry of Health and Family Welfare in its 59th report on the functioning of CDSCO have also observed that the some of the State Licensing Authorities have issued manufacturing licenses for a very large number of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been tested for efficacy and safety. This can put patients at risk.

It may be mentioned that Rule 122A, 122B, 122D, 122E and Schedule Y prescribing the requirements and guidelines for import, manufacture of New drugs including FDCs was introduced in the Drugs and Cosmetics Rules 1945 vide GSR No. 944E dated 21.9.1988. Requirements with respect to the approval of various categories of FDCs are specified in the Appendix VI of Schedule Y.

Earlier, in 2007, direction was issued to the State Drugs Controllers to withdraw 294 FDCs which were licensed without approval of DCG (I). However, the manufacturers Association got stay order from the Madras High Court. The matter is still sub-judice. Action in respect of the aforesaid 294 FDCs will be taken after the outcome of the court case in Madras High Court.

Accordingly, this office vide letter no. 4-01/2013-DC (Misc13-PSC) dated 15.1.2013 has requested all state/UT Drug Controllers to ask the concerned manufacturers in their State to prove the safety and efficacy of such FDCs as mentioned above before the office of DCG (I) within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

However so far hardly any such manufacturers have approached to CDSCO to prove the safety and efficacy of such FDCs.

In view of above, it has been decided that applications for such FDCs should be submitted to the office of DCG(I) latest by 30th August 2013 so that these applications may be processed in a timely manner. The following procedure should be followed for filing the application for assessing the safety and efficacy of such FDCs:-

1. The concerned manufacturer(s) shall apply in Form 44 alongwith requisite Treasury Challan and supporting documents supporting the safety and efficacy of the FDC.
2. The applications will be examined in consultation with Expert committee. If considered necessary, the applicant may be asked to present their case before the committee.
3. In case of requirement of clinical trial, protocols etc. should be submitted by the firm for approval by DCG(I).
4. In case of multiple applications for the same FDC, all such applicants will have option to conduct one such study (wherever necessary) sponsored by the firm(s), if required.

You are therefore requested to ask the concerned manufacturers that applications for such FDCs should be submitted to this Directorate latest by 30th August, 2013 so that these applications may be processed in a timely manner.

Yours faithfully,


(Dr. G. N. Singh)

Drugs Controller General (India)

Copy to

1. UŠ(D), Ministry Of Health and Family Welfare, Nirman Bhawan, New Delhi
2. All Zonal/Sub-Zonal offices of CDSCO

No. 31011/17/2012-PI-II
Government of India
Ministry of Chemical and Fertilizers
Department of Pharmaceuticals

New Delhi, the 08th August, 2013

CIRCULAR

Subject: Notification no. 22/2013-Central Excise, dated 29.07.2013 issued by
The Department of Revenue, Ministry of Revenue... regarding

This is in reference to aforesaid notification, where in the Central Government, on being satisfied that it is necessary in the public interest so to do, hereby exempts the scheduled formulations as defined under the Drugs Price Control Order (DPCO), 2013 published vide S.O. 1221 (E) dated the 15th May, 2013, falling under Chapter 30 of the First Schedule to the Central Excise Tariff Act, 1985 (5 of 1986) and which are subjected to re-printing, re-labeling, re-packing or stickering, in a premises which is not registered under the Central Excise Act, 1944 (1 of 1944) or the rules made thereunder, in pursuance of the provisions contained in the said Drugs Price Control Order (DPCO), 2013 from whole of the duty of excise leviable thereon under the said Central Excise Act subject to the conditions as stipulated therein.

In pursuance of aforesaid notification, I am directed to say that the Department of Pharmaceuticals, on being satisfied that, it its necessary in the public interest to do so, hereby extends the period of exemption, as stated in paragraph above, for a period of thirty days from 29.07.13 in respect of ceiling price notification dated 14.6.2013 issued by the National Pharmaceutical Pricing Authority (NPPA). Similarly, in respect of ceiling price notifications dated 21.06.2013, 28.06.2013 and 05.07.2013 issued by the NPPA, the period of validity of exemption is extended for a period not exceeding thirty days from the date when the period of forty five days will expire, as granted by Department of Revenue, for the above said purpose.

The aforesaid extension of exemption shall be applicable only for the purpose of exemption from the provisions of Central Excise Act regarding whole of the duty of excise leviable in case of re-printing, re-labeling, re-packing or stickering, in a premises which is not registered under the Central Excise, 1944 (1 of 1944) or the rules made thereunder.

The above is without prejudice to the provisions of DPCO, 2013 in respect of compliance and implementation of revised ceiling price as per price notifications issued by the NPPA.

(Raj Kumar)

Under Secretary to the Government of India

Tele: 23071162

Telefax: 23385765

To;

- (i) Shri Malay Samir, Under Secretary, Department of Revenue, North Block, New Delhi with the request to circulate the above among the concerned officers and for putting the same on their website.
- (ii) Chairman, Central Board of Direct Taxes, New Delhi with the request to circulate the above among the concerned officers and for putting the same on their website.
- (iii) Chairman, NPPA, New Delhi.
- (iv) All Pharma / Chemists and Druggists Associations
- (v) Director (NIC), with the request to put the same on the DoP's website

(Raj Kumar)

Under Secretary to the Government of India



**Fees Proposed by Tamilnadu Drugs Control Department for
various Certificates to be issued by them**

S. No	Name of the Certificate	Fees Suggested
1.	Quality and Capacity Certificate	Rs. 300/-
2.	Validity Certificate	Rs. 100/-
3.	GMP Certificate	Rs. 300/-
4.	Market Standing Certificate subject to mandatory inspection	Rs. 300/-
5.	Free Sale Certificate Quality	Rs. 100/-
6.	Non Conviction Certificate	Rs. 300/-
7.	Manufacturing and Marketing Certificate, subject to Mandatory inspection.	Rs. 300/-
8.	Performance Certificate, subject to mandatory inspection	Rs. 300/-
9.	No. of Products for which WHO GMP Certificate for each product	Rs. 1000/-
10.	No. of Products for COPP is issued for each drug	Rs. 300/-
11.	Other Certificates (Approval of Technical Staff, change of Brand Names and etc.)	Rs.500/- each

List of NLEM drugs with Ceiling Prices

S. No	S.O.No	Date	Name of the Schedule Formulation	Strength	Unit	Ceiling Price (Rs.)	Equivalent MRP (Inclusive of all Taxes) (Rs.)
1	1540(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	40 IU	10ml vial	135.12	140.52
2	1540(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	100 IU	10ml Vial	318.52	331.26
3	1540(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	100 IU	3ml Cartridge	144.8	150.59
4	1541(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	40 IU	10ml vial	160.26	166.67
5	1541(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	100 IU	10ml Vial	369.34	384.11
6	1541(E)	6/14/2013	Insulin Human (recombinant DNA Origin)	100 IU	3ml Cartridge	200.01	208.01
7	1542(E)	6/14/2013	Halothane Vaporizer Inhalation	-	1 ml	5.87	
8	1543(E)	6/14/2013	Ketamine Hydrochloride Injection	50mg/ml	1 ml	10.46	
9	1544(E)	6/14/2013	Thiopentone Sodium Injection	0.5gm/pack	Each Pack	41.67	
10	1545(E)	6/14/2013	Propofol Injection	1% Oil Suspension	1 ml	7.94	
11	1546(E)	6/14/2013	Lignocaine Hydrochloride+ Adrenaline Injection	1%+1: 200,000/pack	Each Pack	0.68	
12	1547(E)	6/14/2013	EMLA Cream		1gm	20.08	
13	1548(E)	6/14/2013	Atropine Sulphate Injection	0.6mg / ml	1 ml	4.01	
14	1549(E)	6/14/2013	Diazepam Injection	5mg/ml	1 ml	5.59	
15	1550(E)	6/14/2013	Midazolam Injection	1mg/ml	1ml	5.79	
16	1551(E)	6/14/2013	Midazolam Injection	5mg/ml	1ml	24.78	
17	1552(E)	6/14/2013	Promethazine Syrup	5mg/5ml	1ml	0.21	
18	1553(E)	6/14/2013	Paracetamol Injection	150mg/ml	1ml	3.29	
19	1554(E)	6/14/2013	Paracetamol Syrup	125mg/5ml	1ml	0.33	
20	1555(E)	6/14/2013	Paracetamol Tablets	500mg	1 Tab.	0.94	
21	1556(E)	6/14/2013	Paracetamol Suppository	80mg	1 Suppository	4.88	
22	1557(E)	6/14/2013	Paracetamol Suppository	170mg	1 Suppository	5.99	
23	1558(E)	6/14/2013	Fentanyl Injection	50mcg/ml	1 ml	20.26	
24	1559(E)	6/14/2013	Colchicine Tablets	0.5mg	1 Tab.	2.88	
25	1560(E)	6/14/2013	Azathioprine Tablets	50mg	1 Tab.	9.89	

26	1561(E)	6/14/2013	Methotrexate Tablets	5mg	1 Tab.	7.60
27	1562(E)	6/14/2013	Methotrexate Tablets	7.5mg	1 Tab.	11.27
28	1563(E)	6/14/2013	Hydroxychloroquine Phosphate/Sulphate Tablet	200mg	1 Tab.	5.64
29	1564(E)	6/14/2013	Leflunomide Tablets	20mg	1 Tab.	28.63
30	1565(E)	6/14/2013	Adrenaline Bitartrate Injection	1mg/ml	1 ml	37.24
31	1566(E)	6/14/2013	Promethazine Tablets	25mg	1 Tab.	2.49
32	1567(E)	6/14/2013	Penicillamine Capsules	250mg	1 Capsule	13.12
33	1568(E)	6/14/2013	N-acetylcysteine Injection	200mg/ml	1 ml	22.52
34	1569(E)	6/14/2013	Phenobarbitone Tablets	60mg	1 Tab.	1.69
35	1570(E)	6/14/2013	Phenytoin Sodium Tablets	50mg	1 Tablet	0.77
36	1571(E)	6/14/2013	Sodium Valproate Tablets	200mg	1 Tab.	3.07
37	1572(E)	6/14/2013	Sodium Valproate Syrup	200mg/5ml	1 ml	0.58
38	1573(E)	6/14/2013	Lorazepam Injection	2mg/ml	1 ml	7.39
39	1574(E)	6/14/2013	Diethylcarbamazine Citrate Tablets	50mg	1 Tab.	0.47
40	1575(E)	6/14/2013	Ampicillin Powder for Suspension	125mg/5ml	1 ml	0.63
41	1576(E)	6/14/2013	Ceftazidime Injection	250mg	Each Pack	63.40
42	1577(E)	6/14/2013	Azithromycin Tablets	500mg	1 Tab.	19.86
43	1578(E)	6/14/2013	Azithromycin Injection	500mg	Each Pack	182.27
44	1579(E)	6/14/2013	Vancomycin Hydrochloride Injection	500mg	Each Pack	330.60
45	1580(E)	6/14/2013	Vancomycin Hydrochloride Injection	1gm	Each Pack	514.44
46	1581(E)	6/14/2013	Clofazimine Capsules	50mg	1 Capsule	1.28
47	1582(E)	6/14/2013	Clofazimine Capsules	100mg	1 Capsule	2.22
48	1583(E)	6/14/2013	Ethambutol Tablets	400mg	1 Tablet	2.17
49	1584(E)	6/14/2013	Ethambutol Tablets	600mg	1 Tablet	3.15
50	1585(E)	6/14/2013	Ethambutol Tablets	800mg	1 Tablet	3.74
51	1586(E)	6/14/2013	Ofloxacin Syrup	50mg/5ml	1 ml	0.67
52	1587(E)	6/14/2013	Pyrazinamide Tablets	500mg	1 Tablet	3.77
53	1588(E)	6/14/2013	Pyrazinamide Tablets	750mg	1 Tablet	6.91

54	1589(E)	6/14/2013	Pyrazinamide Tablets	1000mg	1 Tablet	8.30
55	1590(E)	6/14/2013	Acyclovir Tablets	200mg	1 Tablet	7.30
56	1591(E)	6/14/2013	Lamivudine+Nevirapine+Stavudine Tablets	150mg + 200mg + 30mg	1 Tablet	17.29
57	1592(E)	6/14/2013	Lamivudine+Zidovudine Tablets	150mg+300mg	1 Tablet	19.63
58	1593(E)	6/14/2013	Stavudine+Lamivudine Tablets	30mg+150mg	1 Tablet	9.20
59	1594(E)	6/14/2013	Zidovudine+Lamivudine+Nevirapine Tablets	300mg + 150mg + 200mg	1 Tablet	19.05
60	1595(E)	6/14/2013	Nevirapine Suspension	50mg/5ml	1 ml	0.98
61	1596(E)	6/14/2013	Indinavir Capsules	400mg	1 Capsule	19.41
62	1597(E)	6/14/2013	Primaquine Tablets	7.5mg	1 Tablet	1.98
63	1598(E)	6/14/2013	Quinine Sulphate Tablets	300mg	1 Tablet	5.10
64	1599(E)	6/14/2013	Quinine Sulphate Injection	300mg/ml	1ml	9.07
65	1600(E)	6/14/2013	Mefloquine Tablets	250mg base	1 Tablet	50.06
66	1601(E)	6/14/2013	Dihydroergotamine Tablets	1mg	1 Tablet	16.71
67	1602(E)	6/14/2013	Cyclosporine Capsules	25mg	1 Capsule	24.75
68	1603(E)	6/14/2013	Cyclosporine Capsules	50mg	1 Capsule	48.26
69	1604(E)	6/14/2013	Alpha Interferon Injection	3 million IU	Each Pack	759.70
70	1605(E)	6/14/2013	Bleomycin Injection	15mg	1 ml	616.06
71	1606(E)	6/14/2013	Cyclophosphamide Tablets	50mg	1 Tablet	3.75
72	1607(E)	6/14/2013	Danazol Capsules	50mg	1 Capsule	9.37
73	1608(E)	6/14/2013	Danazol Capsules	100mg	1 Capsule	20.33
74	1609(E)	6/14/2013	Doxorubicin Injection	50mg	Each Pack	1145.20
75	1610(E)	6/14/2013	Gemcitabine Hydrochloride Injection	200mg	Each Pack	1304.86
76	1611(E)	6/14/2013	Gemcitabine Hydrochloride Injection	1 gm	Each Pack	5969.16
77	1612(E)	6/14/2013	Methotrexate Tablets	2.5mg	1 Tablet	4.72
78	1613(E)	6/14/2013	Vincristine Injection	1mg / ml	Each Pack	50.60
79	1614(E)	6/14/2013	Dacarbazine Injection	500mg	Each Pack	1029.09
80	1615(E)	6/14/2013	Imatinib Tablets	400mg	1 Tablet	268.33
81	1616(E)	6/14/2013	Raloxifene Tablets	60mg	1 Tablet	9.89

82	1617(E)	6/14/2013	Tamoxifen Citrate Tablets	20mg	1 Tablet	2.77
83	1618(E)	6/14/2013	Ondansetron Tablets	8mg	1 Tablet	11.07
84	1619(E)	6/14/2013	Trihexyphenidyl Hydrochloride Tablets	2mg	1 Tablet	1.36
85	1620(E)	6/14/2013	Folic Acid Tablets	5mg	1 Tablet	1.15
86	1621(E)	6/14/2013	Warfarin Sodium Tablets	5mg	1 Tablet	2.24
87	1622(E)	6/14/2013	Diltiazem Tablets	30mg	1 Tablet	2.27
88	1623(E)	6/14/2013	Glyceryl Trinitrate Sublingual Tablets	0.5mg	1 Tablet	1.85
89	1624(E)	6/14/2013	Glyceryl Trinitrate Injection	5mg/ml	1 ml	7.53
90	1625(E)	6/14/2013	Isosorbide 5 Mononitrate Tablets	10mg	1 Tablet	1.92
91	1626(E)	6/14/2013	Isosorbide 5 Mononitrate Tablets	20mg	1 Tablet	3.29
92	1627(E)	6/14/2013	Adenosine Injection	3mg/ml	1 ml	114.55
93	1628(E)	6/14/2013	Amiodarone Tablets	100mg	1 Tablet	6.52
94	1629(E)	6/14/2013	Amiodarone Tablets	200mg	1 Tablet	11.67
95	1630(E)	6/14/2013	Amiodarone Injection	50mg/ml	1 ml	20.76
96	1631(E)	6/14/2013	Esmolol Injection	10mg/ml	1 ml	20.51
97	1632(E)	6/14/2013	Atenolol Tablets	100mg	1 Tablet	3.72
98	1633(E)	6/14/2013	Enalapril Maleate Tablets	2.5mg	1 Tablet	1.78
99	1634(E)	6/14/2013	Enalapril Maleate Tablets	5mg	1 Tablet	2.96
100	1635(E)	6/14/2013	Losartan Potassium Tablets	25mg	1 Tablet	2.50
101	1636(E)	6/14/2013	Losartan Potassium Tablets	50mg	1 Tablet	4.30
102	1637(E)	6/14/2013	Nifedipine Capsules	10mg	1 Capsule	1.18
103	1638(E)	6/14/2013	Nifedipine Tablets	10mg	1 Tablet	1.13
104	1639(E)	6/14/2013	Hydrochlorthiazide Tablets	12.5mg	1 Tablet	0.97
105	1640(E)	6/14/2013	Hydrochlorthiazide Tablets	25mg	1 Tablet	1.66
106	1641(E)	6/14/2013	Digoxin Tablets	0.25mg	1 Tablet	1.26
107	1642(E)	6/14/2013	Dobutamine Injection	50mg/ml	Each Pack	65.42
108	1643(E)	6/14/2013	Dopamine Hydrochloride Injection	40mg/ml	1 ml	5.53
109	1644(E)	6/14/2013	Streptokinase Injection	750,000 IU	Each Pack	1087.43

110	1645(E)	6/14/2013	Streptokinase Injection	15,00,000 IU	Each Pack	2034.04
111	1646(E)	6/14/2013	Urokinase Injection	500,000 IU/ml	Each Pack	2028.57
112	1647(E)	6/14/2013	Atorvastatin Tablets	5mg	1 Tablet	3.82
113	1648(E)	6/14/2013	Permethrin Cream	5%	1 gm	1.77
114	1649(E)	6/14/2013	Permethrin Lotion	5%	1 ml	1.07
115	1650(E)	6/14/2013	Tropicamide Eye Drops	1%	1 ml	9.60
116	1651(E)	6/14/2013	Povidone Iodine Solution	5%	1 ml	0.39
117	1652(E)	6/14/2013	Povidone Iodine Solution	10%	1 ml	0.91
118	1653(E)	6/14/2013	Pantoprazole Injection	40mg	Each Pack	47.93
119	1654(E)	6/14/2013	Domperidone Syrup	1mg/ml	1 ml	1.03
120	1655(E)	6/14/2013	Metoclopramide Tablets	10mg	1 Tablet	1.04
121	1656(E)	6/14/2013	Metoclopramide Syrup	5mg/5ml	1 ml	0.47
122	1657(E)	6/14/2013	Metoclopramide Injection	5mg/ml	1 ml	2.09
123	1658(E)	6/14/2013	Hyoscine Butyl Bromide Injection	20mg/ml	1 ml	9.84
124	1659(E)	6/14/2013	Testosterone Capsules	40mg (as undecanoate)	1 Capsule	10.96
125	1660(E)	6/14/2013	Ethinylestradiol Tablets	0.01mg	1 Tablet	2.12
126	1661(E)	6/14/2013	Glibenclamide Tablets	2.5mg	1 Tablet	0.48
127	1662(E)	6/14/2013	Glibenclamide Tablets	5mg	1 Tablet	0.96
128	1663(E)	6/14/2013	Glucagon Injection	1mg/ml	Each Pack	788.33
129	1664(E)	6/14/2013	Clomiphene Citrate Tablets	100mg	1 Tablet	12.18
130	1665(E)	6/14/2013	Medroxy Progesterone Acetate Tablets	5mg	1 Tablet	2.59
131	1666(E)	6/14/2013	Medroxy Progesterone Acetate Tablets	10mg	1 Tablet	5.24
132	1667(E)	6/14/2013	Norethisterone Tablets	5mg	1 Tablet	5.07
133	1668(E)	6/14/2013	Carbimazole Tablets	5mg	1 Tablet	1.77
134	1669(E)	6/14/2013	Carbimazole Tablets	10mg	1 Tablet	3.43
135	1670(E)	6/14/2013	Anti-D Immunoglobulin (human) Injection	300mcg	Each Pack	2209.80
136	1671(E)	6/14/2013	D.P.T. Vaccine Injection	-	1 Vial	232.86
137	1672(E)	6/14/2013	Rabies Vaccine Injection	-	Each Pack	302.39

138	1673(E)	6/14/2013	Tetanus Toxoid Injection	-	Each Pack	10.29
139	1674(E)	6/14/2013	Atracurium Besylate Injection	10mg /ml	Each Pack	45.28
140	1675(E)	6/14/2013	Neostigmine Injection	0.5mg /ml	1 ml	4.04
141	1676(E)	6/14/2013	Sulphacetamide Sodium Drops	20%	Each Pack	1.73
142	1677(E)	6/14/2013	Betaxolol Hydrochloride Drops	0.50%	1 ml	6.59
143	1678(E)	6/14/2013	Homatropine Drops	2%	1 ml	5.00
144	1679(E)	6/14/2013	Methyl Ergometrine Tablets	0.125mg	1 Tablet	7.14
145	1680(E)	6/14/2013	Oxytocin Injection	10IU/ml	1 ml	37.70
146	1681(E)	6/14/2013	Misoprostol Tablets	100mcg	1 Tablet	9.43
147	1682(E)	6/14/2013	Terbutaline Sulphate Tablets	2.5mg	1 Tablet	0.98
148	1683(E)	6/14/2013	Haloperidol Injection	5mg/ml	1 ml	5.63
149	1684(E)	6/14/2013	Olanzapine Tablets	5mg	1 Tablet	2.90
150	1685(E)	6/14/2013	Olanzapine Tablets	10mg	1 Tablet	5.32
151	1686(E)	6/14/2013	Amitriptyline Tablets	25mg	1 Tablet	2.12
152	1687(E)	6/14/2013	Imipramine Tablets	25mg	1 Tablet	0.75
153	1688(E)	6/14/2013	Imipramine Tablets	75mg	1 Tablet	2.00
154	1689(E)	6/14/2013	Lithium Carbonate Tablets	300mg	1 Tablet	1.41
155	1690(E)	6/14/2013	Beclomethasone Dipropionate Inhalation	250mcg/ MT Dose	Each MT Dose	1.52
156	1691(E)	6/14/2013	Hydrocortisone Sodium Succinate Injection	400mg	Each Pack	135.70
157	1692(E)	6/14/2013	Oral Rehydration Salts Powder for Solution	As per IP	1 gm	0.58
158	1793(E)	6/21/2013	Albendazole Tablets	400mg	1 Tablet	9.12
159	1794(E)	6/21/2013	Albendazole Suspension	200 mg/ 5 ml	1 ml	1.48
160	1795(E)	6/21/2013	Amoxicillin Powder for suspension	125 mg / 5 ml	1 ml	0.57
161	1796(E)	6/21/2013	Amoxicillin Capsules	500 mg	1 Capsule	6.09
162	1797(E)	6/21/2013	Ampicillin Capsule	500 mg	1 Capsule	4.75
163	1798(E)	6/21/2013	Ampicillin Injection	500 mg	Each Pack	13.40
164	1799(E)	6/21/2013	Ceftazidime Injection	1 gm	Each Pack	229.19
165	1800(E)	6/21/2013	Ceftriaxone Injection	250 mg	Each Pack	24.60

166	1801(E)	6/21/2013	Amikacin Injection	250mg/2ml	1 ml	13.96
167	1802(E)	6/21/2013	Artesunate Tablets (To be used only in combination with Sulfadoxine +Pyrimethamine)	50mg	1 Tablet	20.04
168	1803(E)	6/21/2013	Ondansetron Injections	2mg/ml	1 ml	7.37
169	1804(E)	6/21/2013	Ondansetron Syrup	2mg/5ml	1 ml	1.04
170	1805(E)	6/21/2013	Bromocriptine Mesylate Tablet	1.25mg	1 Tablet	7.58
171	1806(E)	6/21/2013	Bromocriptine Mesylate Tablet	2.5mg	1 Tablet	13.60
172	1807(E)	6/21/2013	Albumin Injection	20%	1 ml	36.66
173	1808(E)	6/21/2013	Amlodipine Tablets	2.5mg	1 Tablet	2.03
174	1809(E)	6/21/2013	Amlodipine Tablets	5mg	1 Tablet	3.06
175	1810(E)	6/21/2013	Atenolol Tablets	50mg	1 Tablet	2.07
176	1811(E)	6/21/2013	Atorvastatin Tablets	10mg	1 Tablet	5.91
177	1812(E)	6/21/2013	Acyclovir Cream	5%	1 gm	8.88
178	1813(E)	6/21/2013	Ispaghula Granules	-	1 gm	0.76
179	1814(E)	6/21/2013	Metformin Tablets	500mg	1 Tablet	1.56
180	1815(E)	6/21/2013	Levothyroxine Tablets	100mcg	1 Tablet	1.11
181	1816(E)	6/21/2013	Acetazolamide Tablets	250mg	1 Tablet	3.69
182	1817(E)	6/21/2013	Alprazolam Tablets	0.25mg	1 Tablet	0.96
183	1818(E)	6/21/2013	Glucose Injection	5% isotonic	1 ml	0.03
184	1819(E)	6/21/2013	Glucose Injection	10%	1 ml	0.05
185	1820(E)	6/21/2013	Cefixime Tablets	100mg	1 Tablet	7.69
186	1821(E)	6/21/2013	Primaquine Tablets	2.5mg	1 Tablet	1.55
187	1822(E)	6/21/2013	Fluconazole Capsule	50mg	1 Capsule	10.16
188	1823(E)	6/21/2013	Fluconazole Tablets	50mg	1 Tablet	7.83
189	1824(E)	6/21/2013	Fluconazole Tablets	100mg	1 Tablet	14.16
190	1825(E)	6/21/2013	Fluconazole Capsules	200mg	1 Capsule	38.91
191	1826(E)	6/21/2013	Fluconazole Tablets	200mg	1 Tablet	25.86
192	1827(E)	6/21/2013	Imatinib Tablets	100mg	1 Tablet	87.59
193	1828(E)	6/21/2013	Omeprazole Capsules	10mg	1 Capsule	2.76

194	1829(E)	6/21/2013	Omeprazole Capsules	20mg	1 Capsule	3.02
195	1830(E)	6/21/2013	Atropine Sulphate Drops	1%	1 ml	2.91
196	1831(E)	6/21/2013	Atropine Sulphate Ointment	1%	1 gm	3.24
197	1832(E)	6/21/2013	Diazepam Tablets	5mg	1 Tablet	1.32
198	1872(E)	6/28/2013	Tramadol Capsules	50mg	1 Capsule	6.12
199	1873(E)	6/28/2013	Methotrexate Tablets	10mg	1 Tablet	13.95
200	1874(E)	6/28/2013	Leflunomide Tablets	10mg	1 Tablet	15.10
201	1875(E)	6/28/2013	Cetirizine Tablets	10mg	1 Tablet	1.81
202	1876(E)	6/28/2013	Cetirizine Syrup	5mg/ml	1 ml	0.54
203	1877(E)	6/28/2013	Phenobarbitone Tablets	30mg	1 Tablet	0.93
204	1878(E)	6/28/2013	Phenytoin Sodium Capsules	100mg	1 Capsule	1.51
205	1879(E)	6/28/2013	Phenytoin Sodium Tablets	100mg	1 Tablet	1.42
206	1880(E)	6/28/2013	Sodium Valproate Injection	100mg/ml	1 ml	5.39
207	1881(E)	6/28/2013	Amoxicillin+Clavulinic acid Tablets	625mg	1 Tablet	22.46
208	1882(E)	6/28/2013	Amoxicillin+Clavulinic acid Powder for suspension	228.5mg/5ml	1 ml	1.87
209	1883(E)	6/28/2013	Amoxicillin+Clavulinic acid Injection	600mg/vial pack	Each Pack	85.96
210	1884(E)	6/28/2013	Amoxicillin+Clavulinic acid Injection	1.2gm/vial pack	Each Pack	127.37
211	1885(E)	6/28/2013	Nitrofurantoin Tablets	100mg	1 Tablet	6.88
212	1886(E)	6/28/2013	Clotrimazole Gel	2%	1 gm	2.07
213	1887(E)	6/28/2013	Acyclovir Tablets	400mg	1 Tablet	11.64
214	1888(E)	6/28/2013	Lamivudine Tablets	150 mg	1 Tablet	9.40
215	1889(E)	6/28/2013	Cyclosporine Capsules	100 mg	1 Capsule	106.29
216	1890(E)	6/28/2013	Cisplatin Injection	50 mg/vial pack	Each Pack	301.26
217	1891(E)	6/28/2013	Cytosine Arabinoside Injection	500 mg/vial pack	Each Pack	515.53
218	1892(E)	6/28/2013	Cytosine Arabinoside Injection	1000 mg/vial pack	Each Pack	1170.62
219	1893(E)	6/28/2013	Doxorubicin Injection	10 mg/vial pack	Each Pack	196.48
220	1894(E)	6/28/2013	Flutamide Tablets	250 mg	1 Tablet	8.62
221	1895(E)	6/28/2013	Carboplatin Injection	150 mg/vial pack	Each Pack	789.01

222	1896(E)	6/28/2013	Tamoxifen Citrate Tablets	10 mg	1 Tablet	4.35
223	1897(E)	6/28/2013	Filgrastim Injection	-	1ml	2142.79
224	1898(E)	6/28/2013	Protamine Sulphate Injection	10mg/ml	1ml	8.92
225	1899(E)	6/28/2013	Diltiazem Tablets	60mg	1 Tablet	4.79
226	1900(E)	6/28/2013	Nifedipine Capsules	5mg	1 Capsule	0.86
227	1901(E)	6/28/2013	Nifedipine Sustained Release Tablets	10mg	1 Tablet	1.42
228	1902(E)	6/28/2013	Sodium Nitroprusside Injections	50mg/5ml	Each Pack	129.98
229	1903(E)	6/28/2013	Miconazole Ointment	2%	1gm	2.19
230	1904(E)	6/28/2013	Miconazole Cream	2%	1gm	1.39
231	1905(E)	6/28/2013	Povidone Iodine Ointment	5%	1gm	1.64
232	1906(E)	6/28/2013	Clomiphene Citrate Tablets	50mg	1 Tablet	7.93
233	1907(E)	6/28/2013	Methyl Ergometrine Injection	0.2mg/ml	1 ml	12.89
234	1908(E)	6/28/2013	Alprazolam Tablets	0.5mg	1 Tablet	2.01
235	1909(E)	6/28/2013	Diclofenac Tablets	50 mg	1 Tablet	1.95
236	1910(E)	6/28/2013	Diclofenac Injection	25 mg / ml	1 ml	1.53
237	1911(E)	6/28/2013	Sodium Valproate Tablets	500 mg	1 Tablet	7.18
238	1912(E)	6/28/2013	Amphotericin B Injection	50mg/vial pack	Each Pack	4245.32
239	1913(E)	6/28/2013	Zidovudine Tablets	300 mg	1 Tablet	14.97
240	1914(E)	6/28/2013	Cytosine Arabinoside Injection	100 mg/vial	Each Pack	238.44
241	1915(E)	6/28/2013	Etoposide Injection	100mg/5ml vial	Each Pack	192.39
242	1916(E)	6/28/2013	Carboplatin Injection	450 mg/ vial	Each Pack	2424.93
243	1917(E)	6/28/2013	Enoxaparin Injection	60mg/pack	Each Pack	530.98
244	1918(E)	6/28/2013	Promethazine Injection	25mg/ml	1ml	2.66
245	1919(E)	6/28/2013	Pyridostigmine Tablets	60 mg	1 Tablet	12.69
246	1920(E)	6/28/2013	Vecuronium Injections	2 mg/ml	Each Pack	74.58
247	1921(E)	6/28/2013	Oxytocin Injections	5 IU/ ml	1ml	16.23
248	1922(E)	6/28/2013	Fluoxetine Hydrochloride Capsules	20 mg	1 Capsule	3.47
249	2046(E)	7/5/2013	Amoxicillin Capsules	250mg	1 Capsule	2.76

250	2047(E)	7/5/2013	Ampicillin Capsules	250mg	1 Capsule	2.50
251	2048(E)	7/5/2013	Cephalexin Capsules	250mg	1 Capsule	5.25
252	2049(E)	7/5/2013	Cephalexin Capsules	500mg	1 Capsule	11.65
253	2050(E)	7/5/2013	Cephalexin Syrup	125mg/5ml	1 ml	0.91
254	2051(E)	7/5/2013	Azithromycin Tablets	100mg	1 Tablet	5.13
255	2052(E)	7/5/2013	Azithromycin Tablets	250mg	1 Tablet	10.26
256	2053(E)	7/5/2013	Ofloxacin Tablets	100mg	1 Tablet	3.30
257	2054(E)	7/5/2013	Fluconazole Capsules	150mg	1 Capsule	23.59
258	2055(E)	7/5/2013	Fluconazole Tablets	150mg	1 Tablet	14.45
259	2056(E)	7/5/2013	Acyclovir Injection	250mg/pack	Each Pack	460.05
260	2057(E)	7/5/2013	Isosorbide Dinitrate Tablets	10mg	1 Tablet	0.69
261	2058(E)	7/5/2013	Metoprolol Tablets	25mg	1 Tablet	3.73
262	2059(E)	7/5/2013	Metoprolol Tablets	50mg	1 Tablet	5.30
263	2060(E)	7/5/2013	Clopidogrel Tablets	75mg	1 Tablet	10.03
264	2061(E)	7/5/2013	Nifedipine Sustained Release Tablets	20mg	1 Tablet	1.90
265	2062(E)	7/5/2013	Mannitol Injection	20%	1 ml	0.35
266	2063(E)	7/5/2013	Domperidone Tablets	10mg	1 Tablet	2.26
267	2064(E)	7/5/2013	Dicyclomine Hydrochloride Injection	10mg/ml	1 ml	2.95
268	2065(E)	7/5/2013	Bisacodyl Tablets	5mg	1 Tablet	0.97
269	2066(E)	7/5/2013	Methyl Prednisolone Injection	40mg/ml	1ml	62.54
270	2067(E)	7/5/2013	Ethinylestradiol+Levonorgesterol Tablets	0.03mg +0.15mg	1 Tablet	3.05
271	2068(E)	7/5/2013	25% Dextrose Injection	100ml	1 ml	0.16
272	2069(E)	7/5/2013	Levothyroxine Tablets	50 mcg	1 Tablet	1.01
273	2070(E)	7/5/2013	Chloramphenicol Ointment	1%	1 gm	4.26
274	2230(E)	7/22/2013	Isoflurane Inhalation	-	1 ml	10.73
275	2231(E)	7/22/2013	Tramadol Injection	50mg/ml	1 ml	11.73
276	2232(E)	7/22/2013	Chlorpheniramine Maleate Tablets	4mg	1 Tablet	0.10
277	2233(E)	7/22/2013	Hydrocortisone Sodium Succinate Injection	100mg	Each Pack	37.13

278	2234(E)	7/22/2013	Naloxone Injection	0.4mg/ml	1 ml	91.51	
279	2235(E)	7/22/2013	Ceftriaxone Injection	1 gm	Each Pack	55.44	
280	2236(E)	7/22/2013	Cefixime Tablets	200mg	1 Tablet	11.25	
281	2237(E)	7/22/2013	Azithromycin Suspension	100mg/5ml	1 ml	1.55	
282	2238(E)	7/22/2013	Isoniazid Tablets	300mg	1 Tablet	1.27	
283	2239(E)	7/22/2013	Ofloxacin Tablets	200mg	1 Tablet	4.9	
284	2240(E)	7/22/2013	Propranolol Hydrochloride Tablets	10mg	1 Tablet	1.09	
285	2241(E)	7/22/2013	Cisplatin Injection	10mg	Each Pack	84.84	
286	2242(E)	7/22/2013	Methotrexate Injection	50mg/ml	1 ml	33.18	
287	2243(E)	7/22/2013	Mesna Injection	200mg	1 ml	24.57	
288	2244(E)	7/22/2013	Ondansetron Tablets	4mg	1 Tablet	4.7	
289	2245(E)	7/22/2013	Iron Dextran Injection	50mg iron/ml	1 ml	28.71	
290	2246(E)	7/22/2013	Enoxaparin Injection	40mg	Each Pack	439.39	
291	2247(E)	7/22/2013	Metoprolol Injection	1mg/ml	1 ml	2.61	
292	2248(E)	7/22/2013	Lignocaine Hydrochloride Injection	2%	1 ml	1.00	
293	2249(E)	7/22/2013	Cetrimide Solution	20% (Conc. For dilution)	1 ml	0.43	
294	2250(E)	7/22/2013	Mannitol Injection	10%	1 ml	0.69	
295	2251(E)	7/22/2013	Polyvalent Antisnake Venom Injection	10 ml	Each Pack	410.56	
296	2252(E)	7/22/2013	Timolol Maleate Drops	0.25%	1 ml	4.46	
297	2253(E)	7/22/2013	Timolol Maleate Drops	0.50%	1 ml	12.07	
298	2254(E)	7/22/2013	Mifepristone Tablets	200mg	1 Tablet	357.13	
299	2255(E)	7/22/2013	Calcium Carbonate Tablets	500mg	1 Tablet	1.67	
300	2258(E)	7/22/2013	Pyrantel Pamoate Suspension	Pyrantel Pamoate eq to Pyrantel-250mg	10ml Glass Bottle with M. Cup & Carton	11.68	12.67
301	2259(E)	7/22/2013	Metronidazole + Norfloxacin Suspension	Metronidazole Benzoate eq. to Metronidazole -100mg Norfloxacin -100mg	30ml Pet Bottle with M. Cup	11.56	12.54

302	2526(E)	8/21/2013	Phenobarbitone Injection	200 mg/ml	1 ml	18.75	
303	2527(E)	8/21/2013	Pyrazinamide Tablets	1500 mg	1 Tablet	9.78	
304	2528(E)	8/21/2013	Propranolol Hydrochloride Tablets	40 mg	1 Tablet	2.56	
305	2529(E)	8/21/2013	Cyclophosphamide Injections	500 mg	1 Injectable	72.71	
306	2530(E)	8/21/2013	Oxaliplatin Injection	50 mg	1 Injectable	2993.26	
307	2531(E)	8/21/2013	Oral Rehydration Salts Powder for solution	As per I.P	1 Gram	0.84	
308	2532(E)	8/21/2013	Oral Poliomyelitis vaccine (LA) Solution	--	1 ml	52.52	
309	2533(E)	8/21/2013	Diazepam Tablets	2 mg	1 Tablet	1.44	
310	2264(E)	8/21/2013	Cefixime Trihydrate + Ofloxacin Tablets	Each tablet contains Cefixime Trihydrate eq. to Anhydrous Cefixime-100 mg Ofloxacin 100mg	1 Tablet	5.73	

Note: * Ceiling means prices exclusive of excise duty and local tax, if any,

* Equivalent MRP means inclusive of excise duty and education cess, sales tax/VAT of each of the Scheduled formulations

* 2256(E) & 2257(E) Withdrawal Notifications



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- ★ Ayurvedic Proprietary Medicines
- ★ Dietary/Nutritional Supplements
- ★ Cosmeceuticals

Please contact :

Dr.D.Natarajan, M.Pharm, Ph.D, MBA
Formulation Development Scientist
&
Pharmaceutical Consultant



TO SOLVE PROBLEMS IN EXISTING PRODUCTS

- ★ DT and Dissolution related issues
- ★ To ensure physical and chemical stability
- ★ To optimize Release profiles for Extended Release (SR) Formulations
- ★ To solve any other existing problems

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Consultation Available from October 2013

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INFORMATION

M.Pharm Scholarship 2012-13 awarded by TNPSWT

Profile of Illrd Rank Projects

PHARMACEUTICS

Name: Ms. Prathyusha Maguluri

Project Title: “Design and evaluation of quercetin loaded solid lipid nanoparticles incorporated into a hydrogel for its photoprotective activity”.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. D. Nagasamy Venkatesh

Name: Mr. M. Nazeer Ahamed

Project Title: “Niosome Embedded Adhesive Transdermal Patch of Nifedipine”

College: Periyar College of Pharmaceutical Sciences, Trichy

Guide's Name: Dr. T. N. K. Suriyaprakash

PHARMACEUTICAL CHEMISTRY

Name: Mr. Sagun Kumar Sharma

Project Title: “Design, synthesis and anti-diabetic evaluation of some novel DPP - IV inhibitors”.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. M. J. N. Chandrasekar

PHARMACEUTICAL ANALYSIS

Name: Ms. V. Dhathri Menon

Project Title: “Validation of stability indicating RP HPLC and HPTLC methods for the determination of stability of meropenem injection in peritoneal dialysis solutions”.

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Mrs. A. S. Manjuladevi

PHARMACOLOGY

Name: Ms. Lavisha Goel

Project Title: “Mimosine in Dimethylhydrazine induced colorectal cancer in wistar rats: a mechanism based approach”

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. M. N. Sathish Kumar

PHARMACOGNOSY

Name: Ms. F. Anna Pushpa Jeyarani

Project Title: “Anti - Aging Activity of Some Indian medicinal plants using *Caenorhabditis elegans* model, *Drosophila melanogaster* and SIRT1 activation assay”.

College: Madurai Medical College, Madurai

Guide's Name: Dr. Ajithadas Aruna

PHARMACY PRACTICE

Name: Ms. Gisha Mary George

Project Title: “Study on bacterial spectrum and antibiotic resistance of pathogens at a private corporate Hospital”.

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. S. Sriram

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EVENTS

Seminar on Intellectual Property Rights by Indian Pharmaceutical Association, TN Branch,



IPA TN Branch in association with IDMA TN Branch conducted one day seminar on Intellectual Property Rights for Pharmaceutical companies on 27th July 2013 at Hotel Savera, Chennai – 600004.

The President of IPA (TN) Branch Shri. M. M. Yousuf welcomed the participants as well as the speakers and stressed need of such seminar to protect new invented drug by the Pharmacy professionals. Shri. J. Jayaseelan, Secretary IPA (TN) explained the status of Patent Law and its usefulness for the Pharmacy professionals as well as Pharmaceutical manufacturers. Shri M. Radhakrishnan, IDMA conducted the proceedings. Shri. S. Chandrasekaran Former controller General - Patents Designs & Trade Marks, Former Member of Intellectual Property Appellate board. Explained about the over view of

patents Law. Shri T. C. James Former Director – Department of Industrial Policy & Promotion Ministry of commerce & Industry Govt. of India gave a lecture on the subject of “Copy Rights and Related Rights.” Shri. V. Natarajan, Deputy Registrar - Trade Mark & GI, spoke on the subject of Trade Mark & its Relevance, Shri M. K. Rao Senior Advocate and Shri. Soundrapandiayan, Former District & Session Judge and Shri. Tippule Venkatesh Adviser Govt. of India on Quality spoke on the subject of drafting of specification and claims for patent application, general principles of law and its application on patents and Quality accreditation respectively.

The seminar was sponsored by Tamilnadu Pharmaceutical Sciences Welfare Trust, Tamilnadu Indian Pharmaceutical Association Trust and Co-sponsored by M/s. Apex Laboratories Ltd, Chennai.

Anti-Narcotics Day at MMC, Chennai



To commemorate the Anti-Narcotics day a meet was arranged by the College Of Pharmacy, Madras Medical College on 26th June 2013 (Wednesday) at 9.30 a.m. The Welcome address was given by Dr. A. Jerald Suresh, Principal, College of Pharmacy, Madras Medical College. The introductory lecture was given by Dr. R. Nandhini, Vice Principal, Madras Medical College, Dr. V. Kanagasabai, M.D, Dean, Madras Medical College, presided over the function and counselled the students on how "A Sound Mind in a Sound Body" is very much essential in life.

Dr. V. Kanagasabai, said that today students have set up very high ambitions in their lives. This many times leads to failures, causing Psychological depressions in life. Taking drugs seems an easy way out for the students to boost up their spirits. And in many cases, on the contrary, many fun -loving students also become addicted to drugs under peer

pressure and for the sake of excitement. Finally he emphasised on the importance of exercises, yoga and meditation to keep our mind and body fit and healthy. On this day many B. Pharm and M.Pharm students around 250 students enrolled themselves as active members of the Anti-Narcotics club and filled up the membership form.

At the end of the programme, students undertook an oath, highlighting the points, "Not to consume any narcotic drug"

"Not to encourage people taking drugs". "Not to involve oneself in any form of illegal drug trafficking".

"To actively campaign against drug abuse".

The vote of Thanks was given by Dr. N. Jayashree Professor and Head of the Department, College Of Pharmacy, Madras Medical College. The College of Pharmacy, Madras Medical College will continue to focus on other social issues apart from excellence in academics and research.

Madras Medical College Alumni Meeting



Donation by "Tamilnadu Pharmacy Scientific Trust"



The Alumni meeting of Madras Medical Pharmacy Graduates held on 15th August 2013.

About 100 - 150 graduates assembled in the Pharmacy campus at Madras Medical college. Dr. Kanagasabai, Dean of Madras Medical College presided over the function. The meeting was conducted by Dr. K. Chinnaswamy retired professor of Madras Medical College and Mr.

J. Jayaseelan of Delvin Formulations Pvt Ltd. and Dr. Jerad Suresh, Principal, College of Pharmacy Madras Medical College.

Many graduates who were / are in top position in our profession attended the meeting. Many graduates voluntarily agreed to help the

pharmacy department of MMC by way of donation. The dean of Madras Medical College agreed to start the course of Pharm. D in Madras Medical College. He also requested the Alumni of Pharmacy to give their valuable advice to the pharmacy department in order to improve the pharmacy education. During this meeting trustees of "Tamilnadu Pharmacy Scientific Trust" Mr. R. Sabapathy, Mr. R.Narayana swamy, Mr. R.S. Anbu Ilango and Dr. K. Chinnaswamy donated Two nos of Lab working benches as well as sophisticated lab equipments to the pharmacy department costing about Rs. 2.2 lacs. The meeting was sponsored by Mr. M. D. Varadharajan, M/s. Kniss Laboratories (P) Ltd., Chennai.

வாழ்த்துகிறோம்



தமிழ்நாடு மருந்துக் கட்டுப்பாட்டுத் துறையின் இயக்குனராக பணிபுரிந்த திரு. **G. செல்வராஜ்** B.Pharm., அவர்கள் 31-5-2013 வுடன் பணி நிறைவு பெற்று ஓய்வு பெற்றுள்ளார்கள். அவர்களுக்குப் பதிலாக திரு. **S. அப்துல் காதர்** B.Pharm., அவர்கள் இயக்குனர் (பொறுப்பு) பொறுப்பேற்று உள்ளார்கள். பழக இனிமையானவரும், இறை பக்தி உள்ளவரும், மனித நேயம் மிக்க மாமனிதராக விளங்கும், நமது இயக்குனர் அவர்களை நமது மாநில சங்கம் மனதார பாராட்டி நமது பதவியில் மேன்மேலும் சிறப்புகள் பெற வாழ்த்துகிறோம்.

NEWS

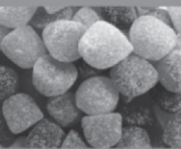
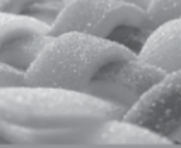
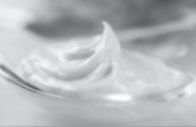
IPM Grows at 9.9 per cent in May 2013

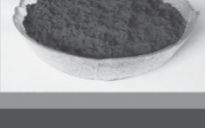
The Indian Pharma Market (IPM) has been valued at Rs 6100 crores in May 2013. It has seen a growth of 9.9 per cent during May. For the month of May 2013, amongst the top 10 corporates, Zydus has seen a growth of 24.3 per cent, followed by Sun Pharma at 21.2 per cent and Ranbaxy at 20.2 per cent. 23 corporates have crossed the growth of IPM for the month of May amongst the top 50.

	With Bonus Units at Full Value							
Val in Crs	Rank		MAT May -13			May-13		
COMPANY	MAT	MTH	Val (Cr)	MS%	GR%	GR%	MS%	GR%
IPM			71774	100.00	10.6	6069	100.00	9.8
Sun Pharma	1	1	3608	5.03	20.9	327	5.39	21.2
Cipla	2	2	3576	4.98	6.0	307	5.06	12.1
Glaxo	3	5	3201	4.46	6.7	248	4.08	-5.1
Ranbaxy	4	3	2983	4.16	7.9	256	4.21	20.2
Zydus Cadila	5	4	2961	4.13	23.3	253	4.17	25.3
Abbott HC	6	6	2732	3.81	7.6	222	3.66	11.0
Mankind	7	7	2597	3.62	20.2	215	3.55	8.2
Lupin	8	8	2210	3.08	14.2	189	3.11	14.4
Alkem	9	9	2190	3.05	11.8	185	3.05	15.8
Macleods	10	10	1846	2.57	18.1	156	2.57	12.8
Intas	11	11	1781	2.48	18.8	154	2.54	15.7
Pfizer	12	13	1714	2.39	12.1	136	2.25	-0.3
Aristo	13	12	1651	2.30	9.8	139	2.28	7.4
Dr. Reddys	14	14	1583	2.20	12.1	136	2.24	13.0
Sanofi-Aventis	15	15	1436	2.00	9.0	120	1.98	4.0
Glenmark	16	18	1430	1.99	17.0	116	1.91	14.5
Abbott	17	16	1418	1.98	6.9	117	1.93	1.7
IPCA	18	19	1298	1.81	15.8	112	1.84	15.8
USV	19	17	1284	1.79	20.9	116	1.91	18.8
Micro Lab	20	21	1271	1.77	5.7	106	1.74	9.0

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Amongst the top 50 corporates, Bharat Serums has the highest growth of 52.8 per cent followed by AstraZeneca at 39.9 per cent and Eris at 28.5 per cent. Amongst the 11-20 ranked companies USV has shown high growth at 18.8 per cent followed by Ipca at 15.8 per cent and Intas at 15.7 per cent. Akumentis breaks into top 50 amongst the corporates. Amongst the upcoming corporates Corona Remedies has seen a growth of 171.6 per cent, Eris at 28.5 per cent and Akumentis at 24.2 per cent. Astra comes to positive growth during May with 39.9 per cent. Centaur has entered the `200 crores club and Micro has crossed Rs 1300 crores on MAT basis.

Val in Crs	RANK MAT			With Bonus in Crs			
Super Group	SV	AV	BV	MAT May13	GR%	Mth May13	GR%
IPM				71774	10.6	6069	9.8
ANTI-INFECTIVES	1	1	1	12666	8.5	996	8.7
CARDIAC	2	2	10	8839	13.1	776	12.9
GASTRO INTESTINAL	3	3	3	8178	11.8	756	9.0
VITAMINS/MINERALS/NUTRIENTS	4	4	7	6344	11.2	554	7.1
RESPIRATORY	5	5	4	5429	7.5	382	9.7
PAIN/ANALGESICS	6	6	5	5309	7.9	440	6.8
ANTI DIABETIC	7	7	16	4671	14.6	414	12.5
GYNAECOLOGICAL	8	9	2	4658	8.0	400	5.1
NEURO/CNS	9	8	12	4383	11.4	382	13.2
DERMA	10	10	9	3770	11.5	322	11.7
OPHTHAL/OTOLOGICALS	11	11	15	1286	11.3	114	5.8
HORMONES	12	12	14	1242	16.3	104	12.2

From therapy perspective nine therapies have outgrown the IPM growth. The anti-infective market has a growth of 8.7 per cent whereas respiratory market is at 10.4 per cent growth. The anti-diabetic market has seen a growth at 12.5 per cent and Cardiac at 12.9 per cent in chronic business. Amongst the top 10 therapies, Neuro/ CNS market has shown the highest growth at 13.2 per cent.

About PharmaTrac

PharmaTrac is a the secondary sales data audit conducted by AIOCD Pharmasofttech AWACS, a

pharmaceutical market research company formed by All Indian Origin Chemists & Distributors (AIOCD) in a joint venture with Trikaal Mediinfotech.

AWACS in AIOCD AWACS stands for Advanced Working, Action & Correction System - reflecting the underlying philosophy behind AIOCD AWACS' research tools to reduce time to information by 50 per cent or more and to significantly improve on accuracy of information. Accurate and faster information flows from the market will help clients grow topline and bottom-line.

Terminologies used**MAT** - Moving Annual Total**MTH** - Month**Val(Cr)** - Value in Crores**MS per cent** - Market Share in Percentage**GR per cent** - Growth in percentageFor more information, visit <http://www.aiocd.net>**Source:** *Express Pharma*, 1-15th July 2013**SC Rejects Plea Against Ranbaxy on Substandard Drugs**

Citing want of material evidence, the Bench says orders can't be passed on the basis of newspaper reports

The Supreme Court, on Tuesday, declined to entertain a public interest writ petition seeking a probe against Ranbaxy Laboratories for allegedly manufacturing and selling substandard medicines in the domestic market for want of materials.

A vacation Bench of Justices A. K. Patnaik and Ranjan Gogoi made it clear to the petitioner advocate M. L. Sharma that the court could not pass orders on the basis of newspaper reports in the absence of materials to show that the drugs manufactured by Ranbaxy were harmful to the public.

Justice Patnaik observed "we are here to protect and enforce the fundamental rights if there is any breach. We can't entertain a petition for publicity in the absence of materials." The Bench, however, allowed the petitioner to file a fresh petition if he found some evidence against the company in support of his allegation that it was engaged in

manufacturing and selling substandard drugs. The Bench said it could not decide the plea against the company on the basis of a U.S. court judgment against Ranbaxy.

Justice Patnaik said: "Your entire argument is based on the proceedings in the U.S. We have no jurisdiction over it. Show us material that things are happening in India and they adversely affects right to life of people here. What are the drugs produced by Ranbaxy that are found to be harmful... you produce evidence... we will consider your case. Where is the material against Ranbaxy? No material has been placed to show that drugs manufactured by any unit of Ranbaxy are substandard, adulterated, spurious or misbranded and that such drugs are prohibited under the law. In the absence of such material, we cannot entertain this petition."

The PIL, comes in the wake of the pharma major being fined \$500 million by the USFDA for making and selling "adulterated" drugs.

Source: *The Hindu*, 26th June 2013**India Bans Testing of Cosmetics on Animals**

India is the first country in South Asia to ban the testing of cosmetics and its ingredients on animals.

Alokparna Sengupta, Humane Society International (HSI)/India's Be Cruelty-Free campaign manager, said: "This is a major victory for countless animals who will no longer be made to suffer, and it is a proud moment for India as it becomes the first country in South Asia to end cosmetics cruelty."

The decision was taken at a meeting of the Bureau of Indian Standards (BIS) Cosmetics Sectional Committee, chaired by the Drugs Controller General of India and is in line with the European Union's stand.

The decision follows appeals from various quarters, including that from the National Advisory Council Chairperson Sonia Gandhi and campaigner for animal rights Maneka Gandhi, to prevent cruelty to animals.

The People for the Ethical Treatment of Animals, India, has also been campaigning to end the testing of household products and their ingredients on animals.

Any cosmetic product which carries out animal testing will face action as per provisions of the Drugs and Cosmetics Act and the Animal Cruelty Act. Violation of the Drugs and Cosmetics Act by any person or corporate manager or owner is liable for punishment for a term which may extend from 3-10 years and shall also be liable to fine which could be Rs.500 to Rs.10,000, or with both.

The use of modern non-animal alternative tests also becomes mandatory, replacing invasive tests on animals. This means that any manufacturer interested in testing new cosmetic ingredients or finished products must first seek the approval from India's regulator Central Drug Standards Control Organisation. A manufacturer will be given approval to test only after complying with the BIS non-animal standards.

More than 1,200 companies around the world have banned all animal tests in favour of effective, modern non-animal tests, but many still choose to subject animals to painful tests.

Member of Parliament Baijayant 'Jay' Panda said, "This is a great day for India and for the thousands of animals who will no longer suffer, yet more work must be done. Our government must go a step further by banning cosmetics products that are tested on animals abroad and then imported and sold here in India. Only then will India demonstrate its commitment to compassion and modern, non-animal research methods and truly be cruelty free."

Israel and the 27 countries that make up the European Union have implemented both testing and sales bans to bring an end to cosmetics animal suffering in their respective jurisdictions, and HSI is leading the campaign to persuade India to become the next fully cruelty-free cosmetics zone. A sales ban will prevent companies from outsourcing testing and importing animal-tested beauty products back into India for sale.

Source: *The Hindu* 29th June 2013

Drug Failure May Not Bring Compensation for Trial Participants

A person undergoing clinical trial wouldn't become eligible for financial compensation just because a new investigational potential drug fails to deliver the desired results, the Drug Technical Advisory Board, the apex decision-making body on drugs safety has recommended in a recent meeting.

It has also suggested, that if the subject is put under a placebo in a clinical trial, but is not taken off his standard medical regimen, he cannot claim financial compensation for an adverse event.

For instance, if a hypertensive patient is on a cholesterol-lowering drug, but is undergoing a clinical trial for a new skincare molecule, during which the doctor asks him to continue taking his prescribed medication but administers placebo for the trial, he would not be eligible for compensation for an adverse effect.

But the patient must be explained in detail about the lack of therapeutic effect, at the time when informed consent is taken from him, before the trial starts.

However, if the patient has been directed to stop his regular medication during the placebo trials, and he or she suffers an adverse event, the volunteer can claim compensation for the same.

The technical board has also clarified that the pharma companies or other sponsor of the clinical trial would have to pay for the free medical management of a subject, only if the injury in question is related or caused by the trial.

"Medical management should be provided in case the injury is due to clinical trial related activities only, as the free medical management may create undue influence for patient to enroll in a clinical trial," the board said. The contract research organisations

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and clinical research industry has welcomed the changes.

"This clarification was important as a clinical trial sponsor should not have to provide for medical management of a non-related injury suffered by a subject, for instance, a road accident. Also, free

medical management itself shouldn't become an inducement for any person to be part of any trial," said Saurendra Das, executive director, Excel Life Sciences, a US-headquartered clinical trial management service provider.

Source: *The Economic Times*, 6th July 2013

US Bans 'Natural' Diabetes Drugs, Indian Cos on List

The US Food and Drug administration has cracked down on what are widely considered alternative or natural treatment for diabetes, including ayurvedic and homeopathic remedies. Fifteen companies in the US, including some that procure alternative diabetes medications from India, have been served warning letters by the FDA, asking them to stop sale in the US of products claiming to treat, cure, and prevent diabetes.

Separately, in a case unrelated to diabetes crackdown, the Indian pharma major Wockhardt was also issued a notice for a range of violations, from manufacturing defects and poor training of personnel to inadequate toilet facilities.

"Until all corrections have been completed and FDA has confirmed corrections of the violations and your firm's compliance, FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer," the July 18 letter warned Wockhardt chairman Habil Khorakiwala, accusing the company of impeding FDA inspectors at its Aurangabad plant.

Wockhardt joins Ranbaxy, Sun Pharma, RPG Life Sciences among Indian drug companies that have come under FDA scrutiny for violations that range from poorly trained personnel, to dodgy record keeping, to stinky toilets.

But it was the diabetes medication crackdown that sent shock waves through the industry, because the market for alternative diabetes remedies has grown hugely in the past decade. Sales of diabetes medication has increased 60 per cent â€" from \$14 billion to \$22 billion â€" in the last four years alone, as the world, from developed countries such as U.S

to developing nations like India, have gotten sucked into a sugar-starch overdose.

Adverse Effects of Iron Folic Tablets Were Expected: NRHM

schools and three lakh in anganwadi centres. "The side effects are self-limiting and would be reduced on regular consumption of tablets," Dr. Ramji explained.

Calling for more sensitisation of teachers and those involved with administering tablets, Ms. Anuradha Gupta said they had been trained and sensitised about the possible effects but would be further counselled. "The benefits of the tablets outweigh the transitory adverse impacts," she said.

India has a very high prevalence of adolescent anaemia. About 56 per cent girls and 30 per cent boys suffer from anaemia, occurring primarily due to deficiency of essential micronutrients. As high as 50 per cent of nutritional deficiency is related to iron deficiency anaemia. It results in poor physical growth, reduced school performance, diminished concentration in daily tasks thus impacting work capacity.

Source: *The Hindu*, July 23, 2013

Rubbishing reports that Government had revoked Swiss pharmaceutical major Roche Holding's patent, the Commerce and Industry Ministry, on Monday, said that it (Roche) lost the Indian patent

for breast cancer drug 'Herceptin' as it did not comply with local norms after facing a post-grant challenge.

In a statement issued here, the Ministry said Roche filed for patent of Herceptin on October 11, 2000 and was granted a patent on April 6, 2007, but faced a post-grant challenge. Following that, the Controllers of the Patent Office gave the company an opportunity, under three applications filed by it, to be heard before the final disposition of these cases.

"The patent had lapsed due to the procedural delays on part of the Swiss company. Before the Controllers issued their decisions, the applicants were given due opportunity of being heard but the applicants have chosen not to attend. It is submitted that in the instant cases, the Patent Office has followed the due course of principle of natural justice, gave the applicant the opportunity of being heard, and then only finally disposed of the matter," the Ministry's statement said.

The statement said in the instant cases, it was found that proper steps for filing request or filing divisional applications were not followed by the applicants.

The Ministry statement said that if the requests were not filed within time, they were treated as

Roche Did Not Comply With Local Patent Norms: Govt

withdrawn under section IIB(4) of the (Indian Patents) Act.

Prescribed period

Giving details on how the company had failed to adhere to deadlines, the statement said the Patent Controller found that the Request for Examination had been filed on March 7, 2006, i.e., beyond the prescribed period (which was due on February 16, 2006) as per the Indian patent norms.

"Two separate dates were given to the company

this year by the Controller to hear its case but the agent of the applicant did not appear in the hearing and even did not submit any notes of argument. Under these circumstances, the Controller ordered that the application should be treated as withdrawn," the statement added.

Source: *The Hindu*, 6th August 2013

Many Indian drugmakers will soon have to bear higher costs for sale of products in American markets, as the US health regulator FDA is hiking

the fees for generic drugmakers by up to 48 percent from October.

India is the second largest drug exporter to the US, according to the Food and Drug Administration (FDA).

Indian drugmakers mostly specialise in manufacturing of generic versions of innovative drugs at a fraction of cost after their patent expiry and are estimated to command 10 per cent share in the \$30-million US generic drug market.

Getty Images

The US regulations require the companies to pay

user fees to supplement the costs of reviewing generic drug applications and inspecting facilities.

However, the FDA's proposed hike in fees for generic drugmakers is expected to push up the overall costs for companies from India and other countries, including US itself.

The FDA said it is aware that industry is adjusting to the new requirements and fees, and it has minimised the increase in fees "as much as possible".

The increased fees have been published in the Federal Register - the official journal of the US government - and would be effective from October

US To Hike Fees for Generic Drugmakers; Indian Cos To Be Hit

1, 2013. The fees would be reviewed after a year.

The new Abbreviated New Drug Application (ANDA) fee has been fixed at \$63,860, which is around 24 per cent higher than the existing \$51,520.

An ANDA contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product.

Similarly, the Prior Approval Supplement (PAS) fees for fiscal year 2014 (from October 1, 2013 to September 30, 2014) has been hiked by 24 per cent to \$31,930. The PAS application includes change to be made to approved products.

The steepest increase has been made in Drug Master File (DMF) fees, which has been hiked by 48 per cent to \$31,460.

Source: *The Economic Times*, 12th August 2013

Notwithstanding strong warnings by the parliamentary standing committee on health, new drugs continue to be approved for marketing in the country without holding any clinical trials on Indian patients to test their safety and efficacy.

Sources in the health ministry admit that as many as 26 new drug molecules have been approved since 2010 without testing them through drug trials on local populations.

While eight new drug molecules of biologicals and non biologicals were approved by the country's apex drug regulator, the Central Drugs Standard Control Organisation (CDSCO), last year, two have already been allowed for sale so far this year.

As many as 13 such new drugs were approved in 2010 and three more were approved in 2011.

Officials of the health ministry say that new drugs have been approved without clinical trials after taking adequate caution.

They said such drugs are the ones used in medical emergencies and where trials are not possible in the country due to less number of patients and in cases where diseases are rare.

They said that it is only after expert opinion that such drugs are being approved.

Source: *The Times of India*, 19th August 2013



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26 New Drugs Permitted for Sale Without Trials in India

Biocon Launches Drug for Treating Psoriasis

Indian biotech major Biocon announced on Saturday that it had launched its first biologic drug for psoriasis, which affects about 10-20 million Indians. The drug against the disease, which attacks the immune system, will be about half the price of similar drugs offered by multi-nationals in the country, said Chairman and Managing Director Kiran Mazumdar-Shaw.

ALZUMAb, which took the company 10 years to develop, is available in India at Rs.7,950 a vial. She claimed the drug was the world's first "novel" anti-CD6 antibody to treat psoriasis. Ms. Shaw said the cheaper biologic would enable poorer patients to access a cure for psoriasis. "Currently, the Indian market for biologics is very small, but the availability of a cheaper option would expand the size of the market," she said.

The company was in talks with foreign companies for "partnerships" to reach out to global markets. "The value of the global market for biologics to address psoriasis is valued at more than \$30 billion," she said. "We will start trials in these markets soon," she said.

Ms. Shaw said the success of the company, which she attributed to a large R&D budget, encouraged it to seek remedies for other autoimmune diseases such as lupus, rheumatoid arthritis and Sjogren's disease. Biocon earned revenues of over Rs.2,500 crore in 2012-13. It spent 10 per cent of overall revenues on R&D, Ms. Shaw said

Source: *The Hindu*, 11th August 2013



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