Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 22nd issue of Pharma Web New letter April– June 2014. In this Newsletter the Training Programme conducted by Pharma Knowledge and Training Institute (Finishing School) is highlighted. The new training institute under the ageis of our Trust was inaugurated on 12th May 2014 and the objective of the Institute is to impart knowledge to the fresh pharmacy graduates on various subjects like Quality Control, Quality Assurance, Production Management, Regulatory Affairs etc., through a training programme. The first training programme on the subject of "Industrial Orientation Training for Quality Management Personnel" was conducted for a period of 4 weeks from 12th May 2014 to 9th June 2014. In this current newsletter the inauguration function, subjects taught by various faculties, practical training programme and placement interviews etc. are highlighted.

In this newsletter the articles on the subject of "Regulatory Requirement for Dugs & Pharmaceuticals Under Drugs & Cosmetics Act, 1940 and Rules there Under", a lecture delivered by Dr. B. R. Jagashetty, former Drugs Controller of Karnataka and the lecture delivered by Mr. J. Jayaseelan, Managing Director, M/s. Delvin Group of Companies on the subject of "Indian Pharm Industry – Overview" are published. We have published the Essay Competition Third prize article was awarded by our Trust on the subject of "Ethics in Pharmacy Practice and Pharmacist role in Safety of Medicine for Welfare of Common Man" by Ms. M. Anitha.

The important notifications issued by Ministry of Health and Family Welfare issued on the following subjects are illustrated in this newsletter.

a. Banning of conducting Clinical Trial on animals for cosmetics
b. Usage of Analgin for specific indication.
c. Exemption under Schedule D for import
d. Colours used in cosmetics and also standards are new cosmetics.

We have published various important news items pertaining to pharmacy profession appeared in various news papers. I hope the readers may be benefited by this issue with all articles as well as news items.

With Best Regards,
R. NARAYANASWAMY
Chief Editor

ARTICLES

REGULATORY REQUIREMENT FOR DUGS & PHARMACEUTICALS UNDER DRUGS & COSMETICS ACT, 1940 AND RULES THERE UNDER

By

Dr. B. R. Jagashetty

Former Drugs Controller for the State of Karnataka

(Lecture Delivered on 12th May 2014, during the Training Programme on Quality Control)

Quality Assurance & Quality Control in Pharma Industry

QA

It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use

GMP

Is that part of Quality Assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use

QC

Is that part of GMP concerned with sampling, specification & testing, documentation & release procedures which ensure that the necessary & relevant tests are performed & the product is released for use only after ascertaining it's quality

QA and QC

QA	QC
QA is the sum total of organized arrangements made with the object of ensuring that product will be of the Quality required by their intended use.	QC is that part of GMP which is concerned with sampling, specifications, testing and with in the organization, documentation, and release procedures which ensure that the necessary and relevant tests are carried out.
All those planned or systematic actions necessary to provide adequate confidence that a product will satisfy the requirements for quality.	Operational laboratory techniques and activities used to fulfill the requirement of Quality
QA is company based	QC is lab based

An Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics

Drugs and Cosmetics Act, 1940 - Aims

Aims:

An Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics. Whereas it is expedient to regulate the import, manufacture, distribution and sale of drugs and cosmetics

Drugs and Cosmetics Act, 1940 Objectives

- The Drugs and Cosmetics Act 1940 provides the central legislation, whic h regulates import, manufacture, distribution & sale of drugs & cosmetics in the country.
- The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious and the cosmetics marketed are safe for use.
- The D &C Act regulate the import of drugs into India so that no substandard or spurious drugs get imported in India.
- This Act regulates the manufacture of drugs so that no substandard or spurious drugs get manufactured in the country.
- This Act provides the regulation of sale and distribution of drugs and cosmetics
  whereby only qualified and trained persons can undertake their handling, compounding and distribution.

Drugs and Cosmetics Act, 1940 Objectives

- This Act also provides the regulation of manufacture and sale and distribution of Ayurveda, Siddha, Unani and Homeopathic drugs
- This Act enables to have regular inspection of licensed premises by Drug inspectors.
- This Act enables to have control over the standards over the drugs and cosmetics by taking samples and by getting them tested and analysed in the Drug Control Laboratories of State and Centre.
- To provide special provisions to regulate the preparations, standardizations and storage of biological and other special products.
- To prescribe the manner of labeling and packaging of various classes of drugs and cosmetics

Prohibition of manufacture and sale of certain drugs and cosmetics

18. Prohibition of manufacture and sale of certain drugs and cosmetics.—From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person

on his behalf—

(a) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale or distribute—

(i) **any drug which is not of a standard quality,** or is misbranded, adulterated or spurious;

(ii) **any cosmetic which is not of a standard quality** or is misbranded or spurious;

(iii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

Prohibition of manufacture and sale of certain drugs and cosmetics

(iv) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(v) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(vi) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(b) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

Prohibition of manufacture and sale of certain drugs and cosmetics

(c) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter :

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Central Government] may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality

Standards

CHAPTER IV MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

16. Standards of quality.— (1) For the purposes of this Chapter, the expression "standard quality" means—

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly

20.Government Analysts

(1) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the state and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(2) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(3) Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(4) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or sub-section (2) of this section.

Penalty

27. Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.—Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes, —

(a) ---

(b) ---

(c) ---

(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than twenty thousand rupees

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

29. Penalty for use of Government Analyst's report for advertising.—Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine, which may extend to five hundred rupees.

THE SECOND SCHEDULE

THE SECOND SCHEDULE (Sections 8 and 16)

STANDARDS TO BE COMPLIED WITH BY IMPORTED DRUGS AND BY DRUGS MANUFACTURED FOR SALE, SOLD, STOCKED OR EXHIBITED FOR SALE OR DISTRIBUTED

Good Laboratory Practice

- Good Laboratory Practices has been made as law by introducing it as Schedule L-1 which is a New Schedule under Drugs and Cosmetics Rules, 1945 vide Gazette notification no GSR 780 (E) 10-11-2008 with effect from 1-11-2010. Consequent to this amendment, Rule 74, 78 and Rule 150E of the Drugs and Cosmetics Rules, 1945 have been amended. It involves a number of good practices in the Quality Control laboratory which are to be undertaken to carry out an analysis with a defined degree of Accuracy & Precision.

Definition of GLP

- Good Laboratory Practices (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archi ved and reported.

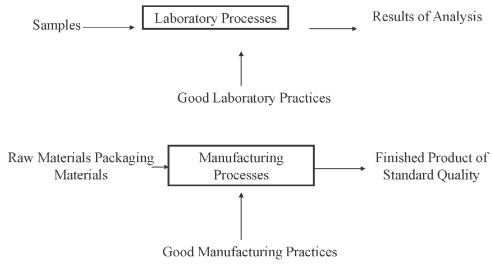
The purpose of GLP

The principle of Good laboratory practice (GLP): to promote the development of quality and validity of test data used for determining the safety of chemicals, Pharmaceuticals, etc.

Importance of G L P

Since raw materials, packaging materials, intermediates and finished products are ultimately released based on the analytical results generated in the Q.C. Laboratory, Accuracy, Precision and Reliability of these results are of paramount importance.

GMP vs. GLP



Schedule-L1 (GLP)

- General requirements-
  Legally authorized, Legally responsible, Responsibility of the management-Testing, calibration, Validation etc.
- Premises – Construction, Interior surfaces-Smooth, Space for utilities , Air ventilation, Drainage system, Space for stocking reference standards, Bio-medical waste, Bio burden, Animal House (CPCSEA) .
- Personal –Necessary qualification and experience, Training records, Head of lab- Control and maintenance of documents, Planning of audits, taking responsibility
- Equipment – Maintenance, Calibration, SOPs for operation, calibration, equipment records like name of the equipment, manufacturer's manual,
- Chemicals & Reagents – Identified with the labels, SOP for preparation and Standardization, Labels of Containers of stock solution and standard solutions
- Good House Keeping and Safety – Safety instructions to be displayed. SOP for safety, house keeping. Clothing, First aid kit, water showers, suction bulbs, protective precautions for violent and uncontrollable reactions.
- Maintenance , calibration, and validation of equipments - All equipments and instruments shall be calibratd and validated at regular intervals.

Schedule-L1 (GLP)

- Reference materials- Traceability of working standards, Working standards , Register for reference and working standards
- Microbiological cultures – SOP for maintenance of microbial culture and sub-culture, non viable and mutant cultures to be destroyed. Not more than 5 passages.
- Quality system – Quality policy. Measurements and calibration conform with compendial standards , remedial actions on the audit reports.
- Internal quality system audits – Done to assure integrity of the analysis. Corrective measures on audit reports. Maintenance of all records.
- Management review – By top management at least once twelve months.
- Standard Operating Procedures – For various activities.
- Protocols and Specifications archive – Current versions of all specifications National pharmacopoeias.
- Raw data – of laboratory work sheet , note book, log book etc, to be maintained. Analyst making changes shall sign with date.
- Storage and Archival-

Factors influencing implementation & maintenance of GLP in Q.C. laboratory

- Laboratory infrastructure.
- Reference Standards & reference microbial cultures.
- Quality of analytical Reagents & Chemicals.
- Quality of Volumetric glass wares.
- Preparation of Standard solutions and reagent solutions.
- Calibration of Equipments / instruments & volumetric glass wares.
- Validation of Analytical methods specially non-pharmacopoeial methods.
- Proper documentation of analytical methods, specifications & protocol of tests.
- Training of analysts: formal & informal
- Good Safety practices.

Laboratory Infrastructure

✓ **General Chemical Laboratory**

The specific requirements are:

- ❖ Well ventilated, lighted and preferably air conditioned to maintain a temperature of 27 1^{0}C.
- ❖ Fitted with proper laboratory furnitures and fixtures .

✓ **Instrument Room:**

The specific requirements are:

- ❖ Temperature : 25 1^{0}C
- ❖ Relative humidity : 45 5%.
- ❖ Constant supply of Electricity
- ❖ No vibrational disturbances.
- ❖ Separate room for housing semi-micro & microbalances.

Laboratory Infrastructure (Contd)

✓ **Microbial Laboratory**:

- ❖ Air conditioned, preferably with AHU with suitable filter (5 micron or less).
- ❖ Fitted with proper laboratory furnitures & fixtures and a change room.
- ❖ For units having both sterile & non – sterile products there should be two aseptic zones having class 1000 area with LAF and entry through graded air zones, one for inoculation and cultures transfer and another for sterility testing. For units having only non-sterile products, one aseptic zone shall be there.

✓ **Hot Zone** :

For housing Hot Air Oven, Muffle Furnace, Fume Cupboard, Autoclaves etc. one Hot Zone is required. This zone should have proper ventilation system.

Laboratory Infrastructure (Contd)

✓ **Retained Sample Area** :

This is required for storage & preservation of retained samples of both finished products and active raw materials. The specific requirements are:

- ❖ Proper temperature control (wherever required)
- ❖ Proper demarcation for finished products and active raw materials.

✓ **Cleaning Area**:

The specific requirements are:

- ❖ Suitable size
- ❖ Provided with facilities like running hot and cold water, purified water, different cleaning agents for glass apparatus.

Laboratory Infrastructure (Contd)

✓**Storage Area for Lab Chemicals, Glass Apparatus & Miscellaneous Items:**

- There should be an adequate area with proper demarcation and proper temperature control wherever required for storage of laboratory chemicals, solvent, glass apparatus & miscellaneous items.
- In addition to these, there should be adequate arrangements for all types of services like vacuum, compressed air, nitrogen, potable water, purified water, ultra-pure water etc. in different sections of Q.C. Lab.

✓ **Package Material Testing Section** :

The specific requirements are:

- ❖ Adequate space,
- ❖ Required equipments and instrument.
- ❖ Furnitures & Fixtures.

Reference Standard

- Primary reference Standards for active & inactive bulk drugs of IP, BP, EP, USP grade
- Reference standards for impurities wherever applicable and available

❖ Procurement from respective authorities like Central Drugs Laboratory, Kolkata (Now from IPC); United States IP Commission, Pharmacopoeia Convention (USPC) etc.

❖ Proper Preservation (i.e. at controlled temperature and humidity etc.)

Reference Standard

❖ Development of suitable working Standard from available active raw materials with the help of these primary standards.

❖ Identification and Storage of working standards with expiry date, retest date and other appropriate information.

❖ Documentation of all information regarding these primary standards and working standards.

Reference Microbial Cultures

✓ **Reference microbial cultures**

❖ Procurement from Central Drugs Laboratory, Kolkata; National Collection of Type Culture (N.C.T.C.) U.K. and American Type Culture Collection (A.T.C.C.) U.S.A. Wherever required.

❖ Proper Maintenance in the microbial lab as per respective pharmacopoeia.

❖ Proper documentation.

Analytical Reagents & Chemicals

All analytical Reagents and Chemicals should be of analytical reagents grades of suitable manufacturer. These should comply with the specification for reagents given in different pharmacopoeia. The specification of the reagents required must be mentioned clearly in the test method.

Volumetric Glassware

Two grades of volumetric glassware are used in the laboratory

- Class A: with test certificate, as per specification laid down by B.I.S.
- Class B as B.I.S.

Class A are to be used for Work of the highest accuracy like standardization of volumetric solutions & Class B for routine work. Cleanliness of glassware should be ensured before use and periodic validation in this respect are to be done.

Preparation of Standard solutions and reagent

All standard solutions (reference standards and volumetric Standards) and reagents solution must have proper labels indicating name, strength, date of preparation, date of expiry and storage conditions. Proper documentation having details of preparation of these solution are to be maintained chronologically.

Validation of Analytical Procedure

All non Pharmacopoeial analytical methods having tests for identity, impurity / impurities & purity are to be validated properly before use in respect of –

1. Accuracy
2. Precision
3. Specificity
4. Linearity and Range
5. Limit of Detection
6. Limit of Quantitation
7. Robustness and
8. Ruggedness

(as applicable for each individual method).

For detailed methods of validation ICH guidelines may be referred.

Calibration of Equipments and instruments

Calibration is the comparison of the performance of a measuring equipment / instrument with that of standard equipment / instrument.

In a Quality Control lab, all equipments and instruments which are directly or indirectly used for measurement are to be calibrated periodically.

Types of Calibration

1. Calibration by external agency:

   Some measuring equipments / instruments like pressure gauge, thermo dials, glass thermometers, wet and dry bulb hygrometers, balances etc. can be calibrated with the help of an NABL accredited external agency.

2. Calibration in the laboratory :

   Some measuring instruments like UV VIS Spectrophotometer, Polarimeter etc can be calibrated internally using methods described in pharmacopoeia.

Types of Calibration

3. Calibration in the laboratory with the help of external agency Certain instruments like HPLC, gas chromatograph, particle counters etc. are to be calibrated with the help of procedures described in the operating manual and/ or service manual of these instruments.

4. Calibration by Validation of the respective procedure:
   Some equipments/ instrument may be calibrated indirectly by validation of the respective procedure. For example:

   ❖ Monitoring of the autoclaving process in an autoclave with the help of *Bacillus stearothermophyllus* spore strip .

Training

All laboratory personnel (managers, supervisory staffs, analysts, technicians, helpers and others) should have regular training and updation.

Training can be of two types –

1. Formal training : This may cover different topics like analytical chemistry, statistical techniques, microbial techniques, instrumental techniques, electronic data processing, documentation etc.

2. Informal training : Informal or on the job training involves laboratory skills .

Records of training must be kept.

Documentation & Records

Usual Document and records with which Q C Laboratory has to deal with are

- Specification
- Test Procedure
- Standard Operating Procedures
- Certificate of Analysis with relevant Test Protocols
- Sample Register
- Register for Reference Standards & Reference Cultures
- Calibration Records
- Validation Records
- Training Records
- Records for Retained samples (Both finished products & active raw materials)
- Records pertaining to the preparation of solutions of reference standards, volumetric solutions and other reagents.
- Log book for instruments & equipment.

All documents are to be reviewed periodically and updated whenever required. Records should be maintained in such a manner that these are always traceable. If required help of electronic data processing system may be taken.

Safety

In the Quality Control Laboratory, one has to handle a no of hazardous, poisonous and inflammable chemicals and also pathogenic organisms. Hence the adoption of proper safety measure and use of safety devices are of paramount importance.

The use of mask, gloves, face shields, aprons, gumboots etc. should be made compulsory in the handling of corrosive chemicals. There should be adequate fire fighting arrangements in the laboratory and personnel should be given proper training for fire fighting.

Training for other safety measures should be imparted regularly and records of these training should be maintained. Microbial residues should be regularly destroyed by autoclaving and records maintained.

A General Checklist for GLP Implementation

1. Good house-keeping,
2. Quality Manual/Documentation,
3. Quality Policy,
4. Method Validation,
5. Instrumental Validation,
6. System Suitability Tests,
7. Calibration of Equipments / Instruments / Calibration Schedules / Traceability,
8. Equipment Log Books,
9. Standard Analytical Reference Samples and their Traceability(All related Certificates / Documentation),
10. Archives for Samples and Documents,
11. Specifications for the products investigated,

A General Checklist for GLP Implementation

12. Study Director for Projects,
13. Statistical Evaluations,
14. Staff proficiency, Health and Safety,
15. Procedures for Receiving, Dealing and Disposing Samples,
16. Environmental monitoring in working areas,
17. Effluent Treatment Monitoring and Control,
18. Participation in Proficiency Testing Programs,
19. Internal Audits/Checklists,
20. Management Review Meetings,
21. Official Audits/Surveillance Audits,
22. Customer Complaints—Procedures to deal with them and Finding Solutions,

A General Checklist for GLP Implementation

24. Validation of Computer Systems and Software,
25. Continuous Performance Assessment of QA Group,
26. Raw Data Collection/Traceability of Data
27. Continuous up gradation of knowledge of all Personnel through Systematic Training Programs,
28. Material Safety Data Sheets –Toxicity Information, Antidotes for all Dangerous/Hazardous Chemicals,
29. First Aid Facilities,
30. Assignment of Clear and Unambiguous Responsibilities to Various Officers/Personnel,
31. Standard Operating Procedures,
32. Sampling Procedures,

A set of highly qualified, experienced, dedicated and motivated persons to carry out the GLP program. Even if all the other conditions are satisfied, the GLP program will meet with failure, if adequate and competent Human Resources are not available.

INDIAN PHARMA INDUSTRY – OVERVIEW

By

Mr. J. Jayaseelan, B.Pharm., M.B.A.,

Managing Director, M/s. Delvin Group of Companies

(Lecture Delivered on 13th May 2014, during the Training Programme on Quality Control)

Indian Pharma Industry – Overview

Indian Pharma Industry Before 1970

- Depending on MNC from USA and Europe for supply of Medicines
- Hardly few Indian Companies in Top 25
- 1970 the Indian Patent Act removed the Product Patent and implemented Process Patent

Indian Pharma Industry 1970 - 2005

- Many Indian Companies emerged
- In 80's many Indian companies started launching the latest drugs in India at affordable price since there was no product patent
- In 90's India adopted liberalized economical policies and so,
  Indian pharma industry entered in to Exports aggressively

Indian Pharma Industry 1970 - 2005

- Due to the free liberal economy ,foreign companies partnered with Indian companies and taught the technology of US FDA and other global standards.
- Foreign Direct Investment was one of the main reason for making India as a leader in global exports.
- By 2000 more than 20 Indian companies reached the Top 25 slot

Indian Pharma Industry After - 2005

- We accepted for patent regime and so process patent changed into product patent
- No Indian companies could launch new molecules
- Many MNC entering back to Indian market and launching new drugs with unaffordable price
- Indian companies are forced to invest in R&D and launch value added old drugs

Indian Pharma Industry – Current Scenario

- India is the pharmacy for the world
- Every 3rd pill taken in the world is from India
- Domestic Pharma market value is around 70,000 crores ($11.5 billion) from 18000 crores ($3 billion) in 1995 with growing by 14% annually
- The exports of pharmaceuticals from India grew to 90,000 Crores ($14.6 billion) from nowhere in 1990 with growth rate of 25% .
- Total growth of the Pharma Market is around 22%.

Indian Pharma Industry – Current Scenario

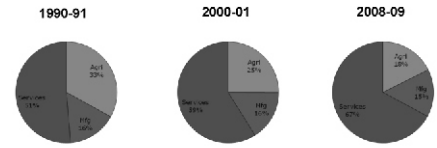
- Highest number of USFDA approved facility (550 Plants)
- Accounts for 40% of Generic drugs in USA
- India was recognized as global leader in supply of generic UNICEF
- India is the manufacturing hub for most of the countries
- Every 3rd ANDA and 3rd DMF filed in US is from India

Indian Pharma Industry –Current Scenario

- India's pharmaceutical sector will touch 270000 crores (US$ 45 billion) by 2020, according to a major study by global management and consulting firm, McKinsey & Company.
- Its steady growth is positively affecting the Indian economy.
- The country accounted for 8 percent of global production Most of the domestic pharmaceutical drug requirements are met by the domestic industry.
- Indian owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994

Along with growing economy, the composition of the economy is also under-going significant change

Composition of Indian Economy



Source:
1) RBI, Wikipedia, IMS Analysis

Indian Pharma Industry – Current Scenario

Inference – The most economical medicine provider in the World

Pharma Market

Regulated	Semi Regulated
USA, Europe, Australia & Japan	India, China and rest of the world
Products: Brand & Generics	No brand was available till 2005 Branded Generics Generics (small brands)
	After 2005 Brand Branded Generics Generics

Brand / Branded Generics / Generics

Brand – Patented

- This will motivate for New Innovation and Discovery
- 20 years monopoly
- High Price eg Nexavar (Bayer) Cost 2.84 Lakhs against NATCO Price Rs.8880/-

Branded Generics – Non Patented

- Dr. has belief on certain brand, perceiving quality and benefit of the same. Easy availability
- Easy dispensing and ensures the same company medicine for consumers
- Costlier than generics
- Cost depends on competition

Brand / Branded Generics / Generics

Generics – Non Patented

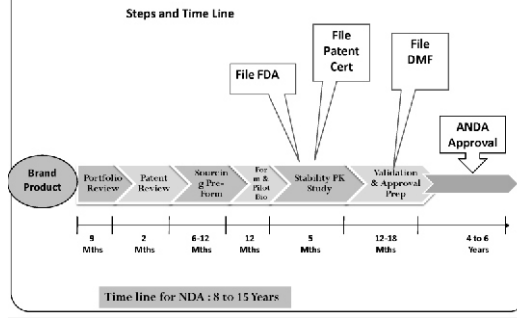
- Lowest Price (Govt. Hospital is giving free of cost)
- Availability of same company drugs
- Pharmacists role need to be upgraded

No MRP mentioned in most of the countries

NDA Vs ANDA Review Process

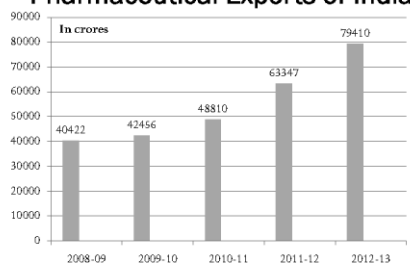
NDA (Branded Drug	ANDA (Generic Drug)
Chemistry	Chemistry
Manufacturing	Manufacturing
Control	Control
Labeling	Labeling
Testing	Testing
Animal Studies, Clinical and BA studies	BA alone
Cost : 13000 to 21000 Crores /NDA	Cost : 5 to 15 Crores /ANDA

Example of Application Process – ANDA - USFDA



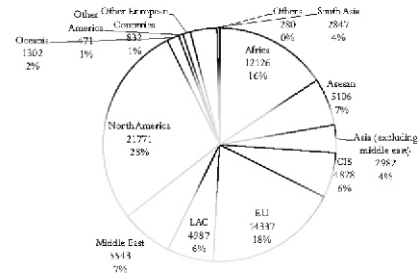
Time line for NDA : 8 to 15 Years

Pharmaceutical Exports of India



India is 5th Largest export country accounting to 4.83% and growth rate of 25%

Pharmaceutical Exports of India



India's Pharmaceutical exports region wise in 2012-13

Pharmaceutical Exports of India

Top 25 Destination Countries of India's Export Cog during 2012-13

Rank	Country	2012-13	Cr%	Cum%
1	USA	20139.13	25.31	25.49
2	RUSSIA	3090.68	3.88	3.89
3	UK	2786.13	3.51	3.61
4	GERMANY	2525.13	3.17	3.18
5	SOUTH AFRICA	2397.13	3.01	3.02
6	NIGERIA	1854.68	2.33	2.36
7	BRAZIL	1771.43	2.23	2.23
8	CANADA	1532.28	1.93	1.93
9	KENYA	1371.33	1.72	1.73
10	NETHERLANDS	1354.73	1.70	1.71
11	VIETNAM	1099.93	1.38	1.38
12	TURKEY	1072.13	1.35	1.35
13	AUSTRALIA	1016.38	1.28	1.28
14	SINGAPORE	1013.68	1.28	1.28
15	GHANA	1006.38	1.26	1.27
16	FRANCE	980.93	1.23	1.24
17	ISRAEL	974.88	1.23	1.23
18	JAPAN	964.98	1.21	1.22
19	SPAIN	943.53	1.18	1.19
20	IRAN	866.38	1.09	1.09
	TOTAL OF TOP 20	48855.93	61.42	61.66
	TOTAL EXPORTS	79450	38.08	100.00

Source : DGCI&S, Kolkata

to 20,230 crore, growth of 21%

India in Global Arena

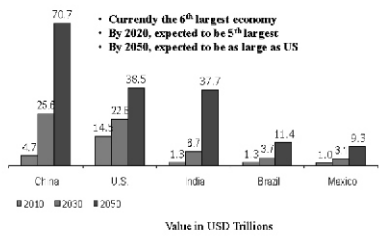
Authority	Name of Regulatory Agency	Nos
USA	DMF's filed with US FDA (Companies)	229
	No. of Sites (Bulk drugs + Formulations) Registered with US FDA (31st Jan 2012)	513
	Total no. of DMF's filed from India (30th March 2013)	8000
	ANDAs (30th Dec 2012)	2975
	Formulation companies with US FDA approvals	91
Europe	No. of CEPs received (30th Dec 2012)	997
	No. of companies with CEPs	157
	No. of Sites approved by EDQM in India (30th April 2013)	358
	UK MHRA, Market authorizations as Dec 2013	1061
Ethiopia	Drug Administration and Control Authority, Ethiopia (Companies)	50
Tanzania	Tanzania Food and Drugs Authority (Companies)	1373
India	WHO GMP Certified Plants (as per DCSI)	1257

- "India's Pharmaceutical industry is known as "Global Pharmacy of the World"
- India offers almost every product which has gone off patent and with a large vendor base
- India's filing of DMF's and USFDA as of March 2013 is 3000, the highest filed by any country in the world

Source : Pharmexcil

Projections indicate India will be the 3rd Largest economy by 2030

Real GDP – Long-term Projections[1]



Source:
1) Goldman Sachs, BRIC Report

SWOT Analysis of the Indian Pharmaceutical Industry

Strength

1. India is regarded as having an edge over china in terms of qualified, English-speaking manpower and fair protection of intellectual property rights supported by well-developed judicial system.
2. India has skilled scientists / technicians / management personnel at affordable cost leading to low cost of innovation / manufacturing / capex costs / expenditure to run cGMP compliance facilities and high quality documentation and process understanding
3. India is considered a desirable destination for off shoring of data management functions for clinical trials and also due to its rich biodiversity and strength in Chemistry which are essential for drug discovery.

SWOT Analysis of the Indian Pharmaceutical Industry

Weaknesses

1. Low investments in innovative R & D continue to be a major weakness of Indian Pharmaceutical Industry
2. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and Commercialization of molecules on a worldwide basis due to lack of resources.
3. Rapidly increasing costs of skilled manpower such as scientists / regulatory compliance personnel / pharmaceutical lawyers / International business development personnel is pushing up the cost of innovation

SWOT Analysis of the Indian Pharmaceutical Industry

Opportunities

1. India has significant export opportunities. US$40 billion worth of drugs in the USA and US$25 billion worth of drugs in Europe are expected to go off patent soon. Assocham estimates that Indian manufacturers may capture 30% of the market. This translates to an opportunity of additional export of US$19.5bn
2. Due to the cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage.
3. India has a very high potential for developing as a centre for international clinical trials due to rich diversity.
4. A rise in life expectancy generally, and increase in the population of the old, particularly in the development world is causing higher expenditure from respective national health budgets compelling them to move to cheaper APIs and formulations which are India's forte.

SWOT Analysis of the Indian Pharmaceutical Industry

Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.
2. Improper systems and issues complicates conducting clinical trials scope in India
3. MNCs play different strategies to pull down Indian companies
4. Drug Price Control Order puts unrealistic on product prices and profitability

Strategies and Challenges created by MNCs

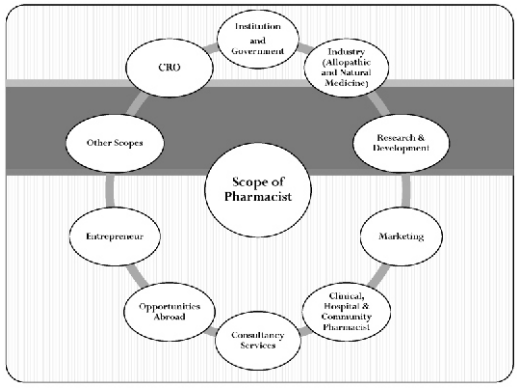
- Indian companies were innovating fixed dose combinations for better patient compliance in early 80's. Today MNCs are following the same route internationally. Recently more than 150 FDC was approved by USFDA
- MNCs intended to take over domestic companies. Now Govt. restricted this and notified that no non-competent class should be allowed in the take over process
- Since their growth in US and Europe is very less the MNCs is trying to penetrate other semi regulated market, where India is leader already. They use multiple strategies to reduce Indian export
- Politics in regulatory approvals. Eg. Ranbaxy, Wockhardt

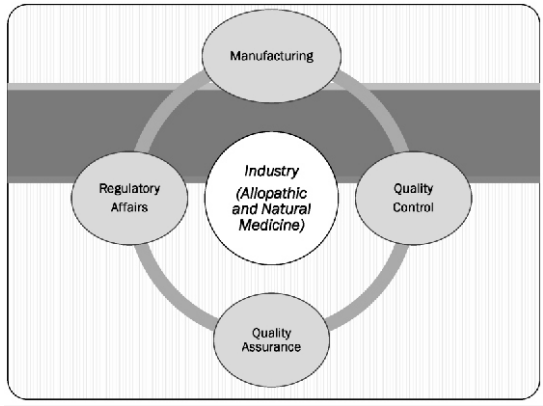
Reason for success of Indian Industries

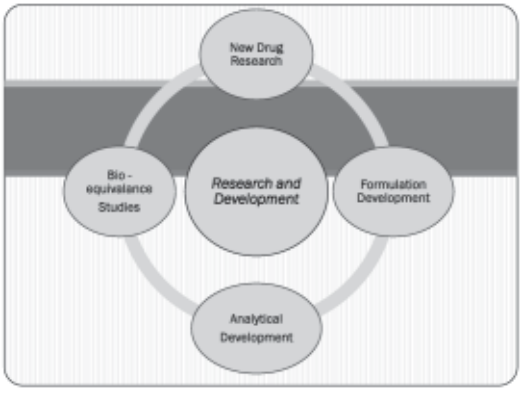
- 1970 Patent Act and liberation of economy
- Adherence to GMP helps it become a global out sourcing hub for Manufacturing
- Ability to meet global regulatory expectations
- Supplies of High Quality, Low Cost generic drugs
- Speed – Recruitment of patients & conducting clinical trials
- Also dependable outsourcing supplies
- India has strong IT skills for Clinical data Management

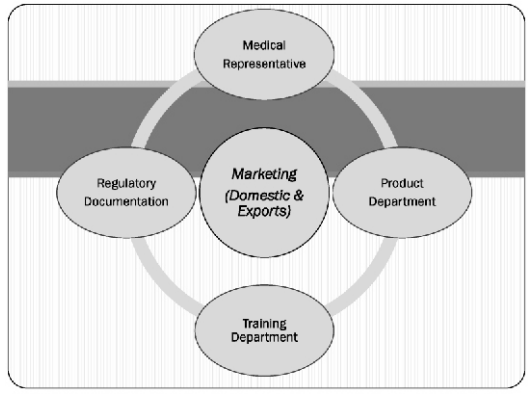
The Indian Pharma Advantage

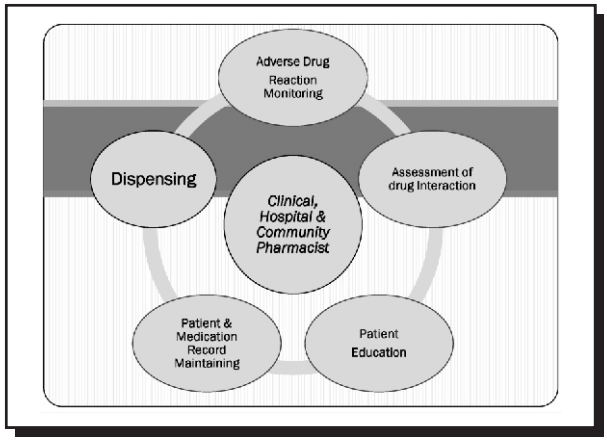
- ❖Core competence in bulk drugs, formulations and Clinical Research
- ❖ Highly skilled and motivated scientists
- ❖ Proven expertise in process chemistry and pharmaceutical sciences
- ❖ Growing experience with US FDA / and other international regulatory compliances
- ❖ High quality manufacturing facilities with significant capacity upside
- ❖ Cost effective and qualified, English-speaking manpower
- ❖ IT Skills

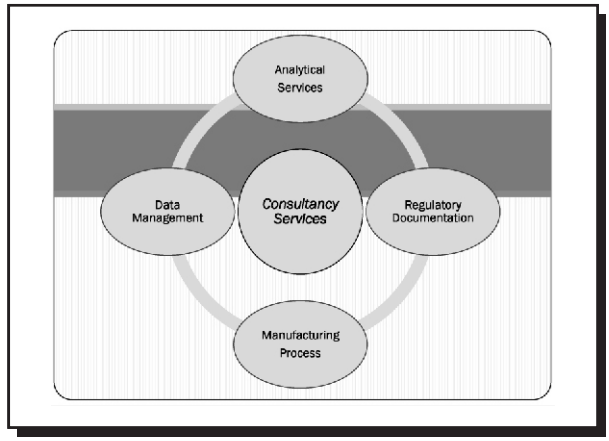


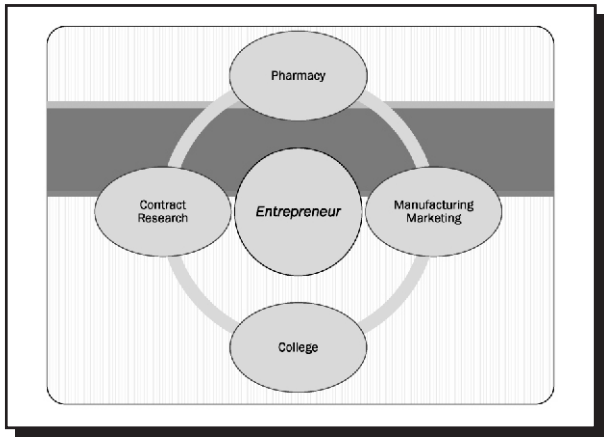


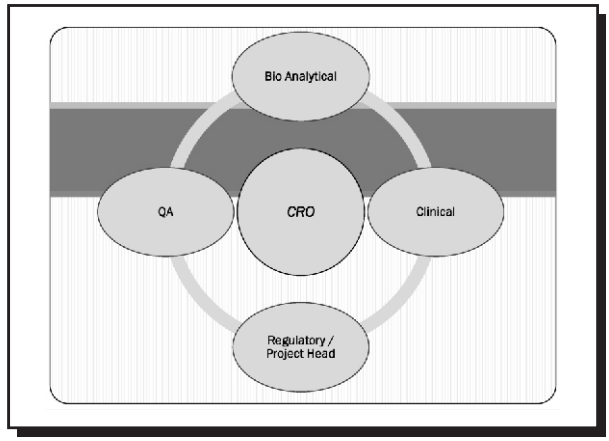


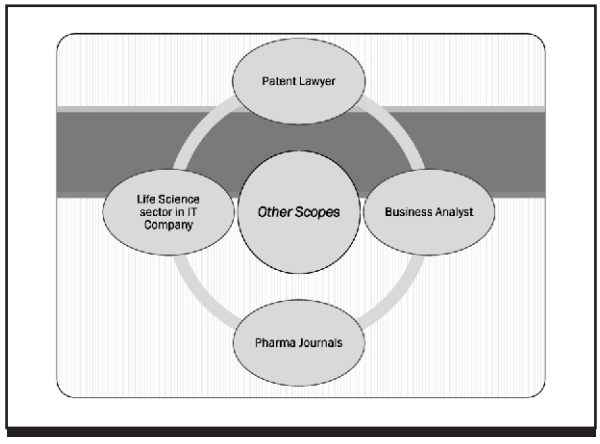



Adverse Drug Reaction Monitoring
Dispensing
Clinical, Hospital & Community Pharmacist
Assessment of drug Interaction
Patient & Medication Record Maintaining
Patient Education


Analytical Services
Data Management
Consultancy Services
Regulatory Documentation
Manufacturing Process


Pharmacy
Contract Research
Entrepreneur
Manufacturing Marketing
College


Bio Analytical
QA
CRO
Clinical
Regulatory / Project Head


Patent Lawyer
Life Science sector in IT Company
Other Scopes
Business Analyst
Pharma Journals

Ethics in Pharmacy Practice and Pharmacist role in Safety of Medicine for Welfare of Common Man

By

Ms. M. Anitha, Mother Theresa Post Graduate & Research Institute of Health Sciences, Pondicherry

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

Content

Introduction

Ethics originates from the Greek word "**ethikos"** meaning **custom or characters**. Ethics means the **"code of moral principles"** or it may defined as the science or philosophy of moral values. It is mainly emphasized on the determination of right or wrong while doing one's duty. In short it is mainly concerned with the right way of conducting in daily life which should be governed by moral behavior.

Code of ethics in pharmacy practice

. Profession of pharmacy is a noble profession as it is indirectly healing the persons to get well with the help of medical practitioners and other co-professionals. So it has the responsibility of safeguarding the people's health**. Pharmacy Council of India** has formulated the code of pharmaceutical ethics to set general guidelines for the Indian pharmacist. These codes are an appeal to the conscience and do guide many to tread on right paths. **Hippocrates** or **charaka** formulated oaths for the medical practitioners they were trying to morally bind them to always act in good faith and to keep their patients welfare as the only guiding principle.

Law abiding citizen

A pharmacist, who is engaged in profession of pharmacy has to be an enlightened citizen with a fair knowledge of the laws of the land and he should be especially conversant with the enactments pretaining to food, drug, pharmacy, health, sanitation and the like and should abide by them in every phase of life. A pharmacist life be is a unit whole and his cannot divided into compartments.

Pharmacist in relation to his job

Supply of emergency medicines at all times according to the need of the public and also supplying commonly required medicine without undue delay. Error of accidental contamination in the preparation, dispensing and supply of medicine should be checked in a pharmacy. A pharmacist should receive a prescription and dispensing it without any discussion. Careful handling is needed in answering any questions on a prescription. The pharmacist should neither add, omit nor substitute any ingredient without consent of the prescriber. The prescription should always be referred back to the prescriber for correction. The patient should be advised by the pharmacist to use medicines. Only drugs and medical preparation of standard quality should be used. If any drug required for abusive purpose, these should not be supplied to anyone.

Pharmacist role in safety of medicine

In our vision, pharmacists as guardians of patients safety and welfare maximizing the benefits of medicine and minimizing the risk of adverse effects. While taking **sulphonamides** it may cause **Crystalluria** and **haematuira** because it is poorly soluble in acidic urine. This may be avoided by taking plenty of water. Other adverse effects are hypersensitivity reaction including skin rashes, itching and fever. Pharmacist should take care of our patient to prevent them such risk of adverse effects.

On daily basis, pharmacist undertake clinical checks of prescription to confirm safe and appropriate prescribing and identify potential or actual side effects. Pharmacist should give information on patient medication at the point of transfer of care and the use of medicines in high risk settings such as care homes and hospitals. Accurate dispensing of prescribed medicine against prescription and providing sound advice on responsible self medication.

Role in safety of dispensing drugs

The temperature of the drug should be maintained. Storage conditions include protection from heat, light, moisture, freezing and excessive heat. For eg: capsules, oral powders, tablet inhalation powders are protected from light, microbial contamination and water vapour. Pharmacist should not dispense controlled (scheduled) drug without prescription because they are potentially harmful if not used under the supervision of licensed health care practitioner. For eg: **schedule1 -drugs** with high abuse risk. These drugs have no safe, accepted medical use **eg: heroin**.

Pharmacist should prescribe some drugs only in accordance with age limit. For eg: **combined oral contraceptive pills** have high efficacy and thus suitable to be used in women less than 35 years and **minipill** is used for women aged more than 35 years. Pharmacist should play a role in preventing drug abuse by providing clear information about the adverse effects of medication. Drug abuse may arise due to one of the following reason wrong diagnosis, inappropriate drug selection, poly pharmacy, drug interaction, unwarranted prophylactic use, self

medication with prescription drug, misuse of new amphetamine, transquillizers, diazepam and phensidyl cough syrup etc is found to be common among drug addicts.

Safeguarding children

Misuse of drugs and mental problems are strongly associated with significant harm to children. Especially when concerned with other circumstances, such as domestic violence. The pharmacy team may be the first to observe problems. For eg: when a patient visits the pharmacy regularly to collect the supply of **methadone**. It is particularly important that information be shared between the health professionals involved and that appropriate support be provided to lessen the potential adverse effects for children.

Conclusion

As a pharmacist, I promise to do all I can protect and improve the physical and moral well-being of society, holding the health and safety of my community above other consideration and I shall uphold the laws and standards governing my profession and I shall safeguard the distribution of medical and potent substances. **"I am proud to be a pharmacist".**

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

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and family welfare)

NOTIFICATION

New Delhi, the 13th February 2014

G.S.R 86 (E) – Whereas the Central Government was satisfied that the use of the drug Analgin and all drug formulations containing Analgin for human use 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 drugs 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 Analgin and all formulations containing Analgin for human use through the notification number G.S.R 378 (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 25th November 2013, in its 65th meeting and recommended that the suspension of the drug should be revoked and allowed to be marketed subject to certain conditions which the manufacturers 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. 378(E) dated 18th June 2013 subject to the condition that manufacturers shall mention the following on their package insert and promotional literature of the drug.

"The drug is indicated for Severe pain or pain due to tumor and also for bringing down temperature in refractory cases when other antipyretics fail to do so".

[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 5th May, 2014

G.S.R. 310(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- 110 001.

Draft rules

1. These rules may be called the Drugs and Cosmetics (Seventh Amendment) Rules, 2014.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, against serial number 35, under the heading “Extent and conditions of exemption”, the words, figures and letter “in Form 20-C” shall be omitted:-

[F.No.X.11014/9/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (I), dated the 21st December, 1945 and last amended vide notification number G.S.R. 153(E), dated the 5th March 2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th May, 2014

G.S.R 311(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 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 Official Gazette containing these draft rules are made available to the public;

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.

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

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Fourth Amendment) Rules, 2014
   (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, after rule 135-A, the following rule shall be inserted
   Namely:-

   "135-B, *Import of cosmetics tested on animals prohibited* – No cosmetic tested on animals shall be imported".

[No.X-11014/11/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification No. F.28-10/45-H (I) dated the 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R 153 (E) dated the 5th March, 2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi the 5th May, 2014

G.S.R 312(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 will 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 Official Gazette of India in which this notification is published, are made available to the public;

Any person interested in making any objection or suggestion on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110 011.

Draft rules

1. These rules may be called the Drugs and Cosmetics (Sixth Amendment) Rules, 2014.

2. In the Drugs and Cosmetics Rules, 1945, in rule 3A, for sub-rule (8), the following sub-rule shall be substituted namely:-

"(8) The functions of the Laboratory in respect of the following kits or class of drugs shall be carried out at the National Institute of Biologicals, Noida and the functions of the Director in respect of the said drugs or class of drugs shall be exercised by the Director of the said institute, namely:-

(1) Blood grouping reagents

(2) Diagnostic kits for human immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus

(3) Blood products:-

(i) Human Albumin,

(ii) Human Normal Immunoglobulin (intramuscular & intravenous)

(iii) Human Coagulation Factor VIII

(iv) Human Coagulation Factor IX

(v) Plasma Protein Fractionation,

(vi) Fibrin Sealant Kit

(vii) Anti Inhibitor Coagulation complex

(4) Recombinant products:-

(i) Recombinant Insulin and Insulin analogues

(ii) r-erythropoietin (EPO)

(iii) r-Granulocyte Colony Stimulating Factor (G-CSF)

(5) Biochemical kits:-

(i) Glucose Test Strips

(ii) Fully automated analyser based glucose reagents

[F.No.A.11018/6/2011-DFQC]

ARUN K. PANDA, Jt. Secy.

Note: The principal rules were published in the Gazette of India, vide notification No F.28-10/45-H (1) dated the 21st December 1945 and last amended vide notification number G.S.R 153 (E) dated 5th March 2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 21st May, 2014

G.S.R. 346(E) – Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health & Family Welfare) number G.S.R 16(E) dated the 13th January, 2014 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) dated the 13th January 2014, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 16th January, 2014;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred under section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945 namely-

1 (1) These rules may be called the Drugs and Cosmetics (2nd Amendment) Rules 2014.

(2) They shall come into force on the date of their publication in the Official Gazette.

2 In the Drugs and Cosmetics Rules, 1945, after rule 148-B, the following rule shall be inserted namely:-

"148-C *prohibition of testing of cosmetics on animals – No person shall use any animal for testing of cosmetics"*

[F.No.X-11014/7/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

Note:- The principal rules were published in the Gazette of India vide notification No F.28-10/45-H (I) dated the 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G S R 153(E) dated the 5th March ,2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd May, 2014

G.S.R. 350 (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. The rules may be called the Drugs and Cosmetics (Fifth Amendment) Rules, 2014.
2. In the Drugs and Cosmetics Rules, 1945,-

(a) in Schedule Q, in Part I,-

(i) the entry, "Resorcin Brown" and the entries relating thereto occurring in columns (2) and (3) shall be omitted.

(ii) the entry, "Solvent Red 1" and the entries relating thereto occurring in column (2) shall be omitted.

(b) in Schedule S, after serial number 30 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely :-

"31. Liquid foundation make-up IS 14318:1996

32. Cold Wax-Hair remover IS 15152:2002

33. Face Pack IS 15153:2002

34. Kajal IS 15154:2002

35. Oxidation Hair Dyes (Emulsion type) IS 15205:2005

36. Cream Bleach IS 15608:2005"

[F.No.X-11014/06/2013-DFQC]

ARUN K. PANDA, Jt.Secy.

Note: The principal rules were published in the Gazette of India *vide* Notification No. F. 28-10/45-H (1) dated 21st December, 1945 and was last amended by notification number G.S.R. 153(E), dated the 5th March, 2014.

INFORMATIONS

M.Pharm & Pharm D Scholarship 2013-14 awarded by TNPSWT

Profile of Second Rank Projects

PHARMACEUTICS

Name: Mr. Uday Krishna Baruah
Project Title: Design & Evaluation of Nanoparticles for intra cellular targeting and improved material therapy
College: J S S College of Pharmacy, Ooty
Guide's Name: Mr. N. Jawahar

PHARMACEUTICAL CHEMISTRY

Name: Mr. S. Vengatesh
Project Title: Drug Design, Synthesis, Characterisation & Biological Studies of some novel heterocyclic compounds as anti tubercular agents
College: Madras Medical College, Chennai
Guide's Name: Dr. A. Jerald Suresh

PHARMACEUTICAL ANALYSIS

Name: Mr. Bandarupalli Chiranjeevi
Project Title: Development & Validation of Oral sustained release dosage form of Rivastigmine and its pharmacokinetic evaluation in rabbit plasma.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. D. N. Venkatesh

PHARMACOLOGY

Name: Mr. Gonala Vijay Kumar
Project Title: To evaluate the cardio protective role of leaf extract of Tridax procumbens in isoproterenol induced mycocardial ischemia.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. R. Vadivelan

PHARMACOGNOSY

Name: Ms. T. Muthu Lakshmi
Project Title: Pharmacognostical, preliminary phytochemical & antileucodermic studies of bark of Dalbergia sissoo Roxb
College : Madras Medical College, Chennai
Guide's Name : Dr.R.Radha

PHARMACY PRACTICE

Name: Ms. Sheril Elsa Baby
Project Title: A study on safety analysis of cardiac drugs in neonatal & pediatric age group in a tertiary care teaching centre
College: Sri Ramachandra University, Chennai
Guide's Name: Mr. P. Thennarasu

PHARM D- PHARMACY PRACTICE

Name: Mr. Prathap PPJ, Sabella Thanmayee, Salagha Merin Gigy, Sure Pradeep Kumar
Project Title: Monitoring phenytoin levels after loading dose of phenytoin and fosphenytoin
College : Sri Ramachandra University, Chennai
Guide's Name : Dr. G. Kannan

PHARM D- CLINCIAL PHARMACY

Name: Mr. Gokul Gummadapu
Project Title: Clinical outcome of drugs and physiotherapy of osteoporotic population in the nilgiris district
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. P. R. Anand Vijaya kumar

INDUSTRIAL ORIENTATION TRAINING

for

QUALITY MANAGEMENT PERSONNEL

During July 2013, in one of the Governing Council meetings of Tamilnadu Pharmaceutical Sciences Welfare Trust, Chairman Mr. S. V. Veerramani felt the need for organising a **"Finishing school"** for B. Pharm students aspiring to build their career in Pharmaceutical industry on the line of Pharma Training Institute, Bangalore. Accordingly an Institute in the name of **"Pharma Knowledge and Training Institute" (Finishing School)**, under the control of TNPSWT may conduct the training programme for fresh pharmacy graduates on continuous basis. Mr. R. Narayanaswamy, Mr. K. Prafulla Chandra, Dr. V. Ravichandran and Mrs. Pratima Mathur visited Bangalore in the month of September 2013 to understand and obtain the details.

The members had a detailed discussion with Mr. R. Anandarajashekar, Dean of the Pharma Training Institute and Dr. B. R. Jagashetty, Drugs Controller for the State of Karnataka and submitted a report to the Governing Council. On the basis of suggestions from industries, it was decided to organise first training programme for Quality Management Personnel for four weeks which includes theory & practical training in industry. The committee, after interacting with the industry personnel and understanding their exact requirements, prepared the syllabus for the training programme. Senior Quality Control Managers of various industries agreed to be part of this programme as resource persons. M/s. Fourrts (India) Laboratories Pvt. Ltd., M/s. Tablets (India) Ltd., M/s. Saimerra Innopharm Pvt. Ltd. M/s. Medopharm and M/s. Apex Pharmaceuticals Pvt. Ltd agreed to send their senior technical persons in their Quality Control department as faculty for this training programme and also to give practical training. M/s. Spinco Biotech, Chennai also agreed to provide faculties and practical training to the trainees. It was decided to conduct the training programme on 12th May 2014, with the maximum intake of 20 nos. of trainees. However, about 15 Final year B. Pharm students, mostly from Madras Medical College, Chennai and Jaya College of Pharmacy, Chennai, PSG College of Pharmacy, Coimbatore and EGS Pillay College of Pharmacy, Nagapattinam enrolled their names for the training programme. It was decided to have an inaugural function on 12th May 2014 of the new training institute followed by the training programme.

The Inaugural function of the "Pharma Knowledge and Training Institute" (Finishing School) was held on 12th May 2014 at Hotel Hablis, Chennai. Mr. R. Anandarajashekar, Dean of the Pharm Training Institute, Bangalore and Dr. B. R. Jagashetty, former Drugs Controller for the State of Karnataka were invited as Guests of Honour.

Many dignitaries from pharmaceutical industries, educational institutions, regulatory departments and professional associations as well as students were present in good number. Mr. S. V. Veerramani, Chairman of TNPSWT inaugurated the function and emphasized the need for training to the fresh pharmacy graduates from Tamilnadu Pharmacy colleges for their future carrier. Mr. J. Jayaseelan, Managing Director of M/s. Delvin Formulations group of companies, Mr. R. Thiruvengadam, Joint Managing Director, M/s. Tablets (India) Ltd., Dr. Manivannan, DDC, South Zone, CDSCO, Chennai, Mr. R. Srinivasan, Vice Chairman, C. L. Baid Metha College of Pharmacy, Chennai, Mr. S. Thiyagarajan,

Chairman, M/s. Spinco Biotech Pvt. Ltd. Chennai, Dr. Jerald Suresh, Madras Medical College, Chennai offered their felicitations for the success of the programme. Mr. R. Narayanaswamy, Coordinator of the programme addressed the gathering on the various modules of the training. The theoretical training commenced from the afternoon of 12th May at our Trust office.

Theoretical Training Prgramme (12th May to 23rd May 2014)

- **Drug Testing under Drugs & Cosmetics Act** – Dr. B.R. Jagashetty - Drugs Controller, Karnataka (Retd.)
- **CDSCO Role on Approval of Drug Testing Lab & Import of Reference standards** - Dr. S. Manivannan - Deputy Drugs Controller (India) CDSCO, South Zone
- **Regulatory Requirements of QC for Drugs & Cosmetics** – Mr. A. Arunachalam – Deputy Drugs Controller (Retd.), Tamilnadu
- **Regulatory Requirements of Quality Control for Medical Devices & Import of Reference Standards** – Mr. R. Narayana Swamy, Deputy Drugs Controller , India (Retd.)
- **Overview of Pharmaceutical Industry** – Mr. J. Jayaseelan, MD, M/s. Delvin Formulations P. Ltd
- **What is Quality, Why is Quality essential in Pharmaceutical industry, Quality Control and its Relationship with Quality Assurance, Production, R&D, and Regulatory Divisions of Pharma Industry. What Are The Various Divisions of a Quality Control Lab, Explanation of Different Equipments Used in Q.C. Lab** – Mr. P.R. Abdul Hameed, Exe. Director, Technical, Medopharm
- **Good Laboratory Practices**
- **Good Laboratory Practices SCHEDULE L**
- **G.M.P. Pertaining to Quality Control**
- **Standard Operating Procedures** & **ICH Guidelines**
- **Change Control, Deviation Control and their Importance, Market Complaints, CAPA, Oos, OOT etc. GMP Guide Lines for MHRA & FDA Approved Units** – Mr. Sanjay Kumar DasMohopatra, Medopharm
- **What is Pharmacoepoea, Pharmacoepoeas of Different Countries, How to use pharmacoepoea, Monographs and their explanation** - Dr. N. Murugesan, Chief Analyst CDTL, Chennai.
- **Basic Calculations in Quality Control, Dilutions, Impurity profile and calculation, LOD and Moisture Content and Statistical Analysis**
- **Qualitative Analysis, Quantitative Analysis & Elemental Analysis**
- **Air Systems, Water Systems, Their sampling & Testing**
- **Basic Problems Faced In Analysis and How to Correlate Them With Manufacturing Processes-**
- **IQ, OQ, PQ etc of different equipments used in Q.C**. – Mr. JayaKumar, Apex Labs.
- **Microbiological Testing, Laminar Flow, Sterility testing, Environmental Monitoring, Plate Exposures,Airsamplingetc.**-Mr.R.Thiruvengadam,Jt.MD,M/s.TabletsIndiaPvt.Ltd.
- **Calibration of Q.C. Equipments** - Mrs. Ajitha Saraswathi, Tablets India

Inaugural Function of Pharma Knowledge and Training Institute (Finishing School)

Inaugural address by Chairman of our Trust

Audience during Inaugural Function

Audience during Inaugural Function

Audience during Inaugural Function

Address by Dr. B. R. Jagashetty

Felicitation to Mr. S. Thyagarajan of M/s. Spinco Biotech

Felicitation to Dr. A. Jerald Suresh, Principal, MMC (Pharmacy)

Students attended the Training Programme

Lecture by Dr. N. Murugesan, Director, CTDL, Chennai

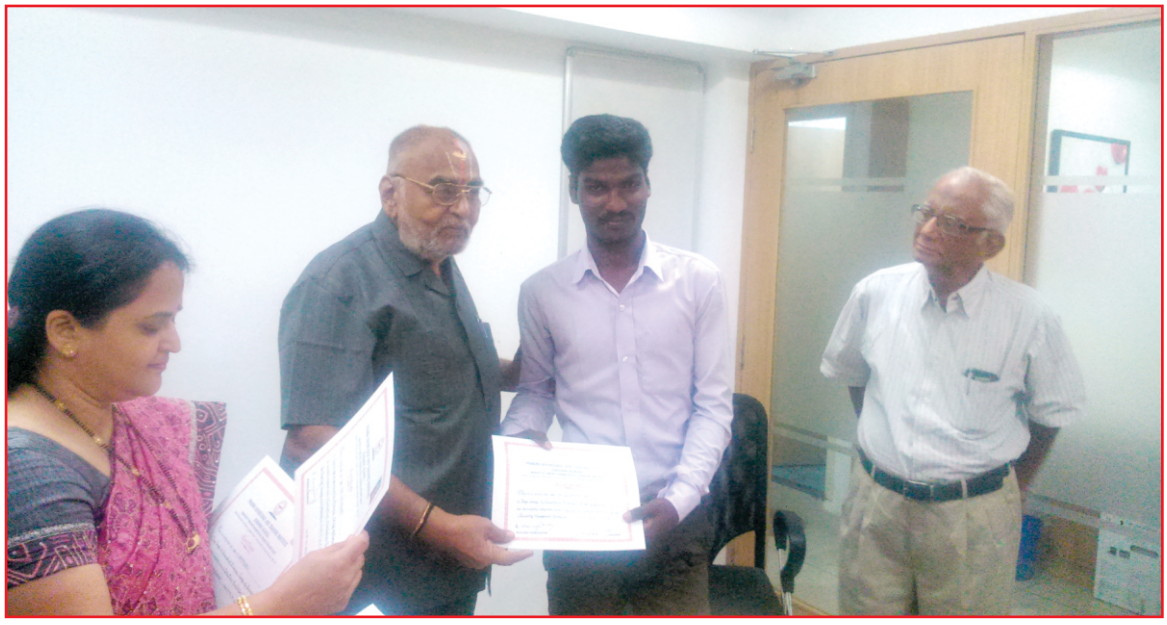
Lecture by Mr. S. Jayakumar of M/s. Apex Laboratories

Lecture by Dr. D. Natarajan of M/s. Cavinkare

Lecture by Mr. V. Manikandan of M/s. Spinco Biotech

Participants during Training Programme.

Visit to M/s. Spinco Biotech



Awarding the Certificates by Dr. K. Chinnaswamy

- **Introduction to Theory of Chromatography**
- **Hyphenated Techniques – LC-DAD-MS-NMR- A 'bird's eye' View** - – Dr. V. Manohar, Indian Institute of Chromatography & Mass Spectrometry (IICMS), Guindy, Chennai - 32
- **Gas Chromatography(GC) – Instrumentation & Applications**
- **Detectors in HPLC, Method Development & A case study analysis** - Mr. V. Manikandan, Indian Institute of Chromatography & Mass Spectrometry (IICMS), Guindy, Chennai - 32
- **High Performance Liquid Chromatography(HPLC) – Instrumentation & Columns Spectroscopic Techniques – UV & IR instrumentation & Applications** - Mr. S. Saravanan, Indian Institute of Chromatography & Mass Spectrometry (ICMS),Guindy, Chennai – 32
- **Quality tests for various Drug Dosage forms from consumer, regulatory and performance point of view**. Dr. D. Natarajan, Senior Consultant Scientist, Pharmaceutical Formulations Development,
- **Dissolution & its Importance, Methods used in Dissolution Testing**
- **Storage and accounting of Narcotic Substances, Reference Standards, Working Standards and Control Samples** – Mr. K.M. Sridhar, Manager, Q.C, Fourrts India
- **Scrap Books, Documentation & report writing, Maintenance of records**
- **Sampling of Raw Materials, In- process Materials, Finished materials, Various Methods used in Sampling of Products** - Mr. Saravana Kumar, Sr. GM Corporate Q.A., Fourrts India
- **Analytical Method Validation, Validation of Equipment Etc** – Mr. G. T. Arularasu, Manager Q.C., Fourrts India
- **Stability Testing, Accelerated and Real Time Studies**
- **Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability .**
- **Control Sample Storage and Their Analysis** – Mr. M. Ramalingam, Fourrts India
- **Soft Skills Program**- Full Day - Mr. B. Shivakumar, Director Marketing, Simple & Smart Solutions, Chennai

There was a daily written assessment on topics covered during the day. During the training programme, heads of Pharmacy Colleges like Madras Medical College, Jaya college of Pharmacy, SRM College of Pharmacy and Sri Ramachandra College of Pharmacy, visited to our Trust office as observers. They gave suggestions for further improvement of the training programme.

Practical Training (26th May to 7th June 2014)

The practical training in the Quality Control Department of the industries was held from 26th May 2014 to 7th June 2014. Sai Mirra Innopharm Pvt. Ltd., Ambattur, Tablets (India) Pvt. Ltd., Tondiarpet, Chennai, Apex Laboratories Pvt. Ltd., Alathur, Chennai, Fourrts India Laboratories Pvt. Ltd., Thorappakam and Medopharm, Guduvanchery, Chennai offered their facilities for training the participants. The candidates were sent for training in a group of 2 - 4. During the industrial training, they were assessed on common parameters by the Heads of Quality Control department of the respective industries.

On the 9th of June 2015, all the participants went to Indian Institute of Chromatography & Mass Spectrometry (ICMS), Guindy, Chennai for a demonstration of various analytical instruments used in Quality Control.

The final written evaluation was held on 9th June 2014.

During the Practical training programme, the trainees were exposed to the following subjects

- Introduction to various QC department and S.O.P.s used in the Lab
- Introduction to various documents & Pharmacopoeias used by the Laboratory
- Good Laboratory Practices particularly DQ. IQ, PQ and OQ
- Sampling of Active Ingredients, Diluents, In-process and Finished Materials:
- Use of Analytical equipments like Weighing Balance, pH meter, Melting Point Apparatus &Use of Vacuum Desiccator and its calibration
- **Introduction to Wet Lab/ Preparatory Lab Activity:**
- Volumetric solution preparation & standardization, Dilution of concentrated solutions
- Acid / base / Non – aqueous / Complexometric titrations
- Introduction to various Limit tests analysis like - Heavy metals, Arsenic, Chloride & Sulphate, Sulphated Ash etc.
- Introduction to Distillation analysis like Kjeldal, Sopanification value, etc.
- LOD & Moisture Content determination
- Determination of Water Content by KFR
- Handling of Reference Standards, method of preparation of Working Standards & their shelf-life
- Handling of various simple instruments such as Bulk Density apparatus, Karl Fischer Titrator, Friability apparatus, Viscometer, Sieve Shakers, Refractometer, D.T. machine, etc.
- Water Systems, Water Sampling & Air sampling & Analysis
- Packaging Material Sampling & Analysis
- **Operation & calibration of certain sophisticated Instrumentation like:**

  FTIR , Dissolution Apparatus, TLC,HPLC - involving Isocratic, normal phase, Reverse Phase & gradient analysis , GC, UV spectrophotometer , Polari meter,
- Introduction to microbiological testing and its methodology

On 10th June 2014, all the participants were awarded course completion certificates by Dr. K. Chinnaswamy, Professor (Retd.), Madras Medical College and Trustee, Tamilnadu Pharmaceutical Sciences Welfare Trust.

Following this, placement interviews were conducted. Technical and HR Department personnel from Sai Mirra Innopharm Pvt. Ltd., Tablets (India) Pvt. Ltd., Apex Laboratories Pvt. Ltd., and Fourrts India Laboratories Pvt. Ltd. interviewed all the 15 candidates. Selected candidates were given offer letters.

The programme was very much appreciated by the industries and also by the participants. The industries participating in the placement interview expressed that the candidates trained by the Trust are much superior in knowledge than the untrained graduates.

In the future, the Trust proposes to conduct similar training programmes on Production, QA and Regulatory Affairs.

NEWS

Pharmacists Oppose Sales Record Rule

Chemists and pharmacists have threatened to launch a nationwide agitation against a government order making it mandatory for them to maintain a separate sale register for sleeping pills, antibiotics and anti-tuberculosis drugs. They will sit in dharna in the capital on March 24. The March 1 order comes even as the Health Ministry has allowed chemists to sell antibiotics listed under Schedule H1, but manufactured before February 28, without the new labelling requirements.

However, they have been asked to follow other instructions for sale of these antibiotics with regard to prescription and maintenance of sale records as per the amended rule under Schedule H1, according to official sources.

The pharmacists claimed it was “impractical” to maintain the register and implement the order in all 6,00,000 retail shops all over the country.

As per the order, retail shop owners have to maintain a new register while selling several hundred drugs containing one of the 46 molecules identified by the government. These drugs were categorised under the new schedule, H1. The register will have the names and addresses of doctors, names of patients and of the drugs and quantities supplied.

“This is impractical because of patient pressure at the shops. We receive 300-400 prescriptions every day and maintaining a manual register would be cumbersome and time-consuming,” said Kailash Gupta, president, All India Chemists and Distributors Federation. The pharmacists say maintaining a register will mean duplication as a large number of shops in big cities use software for billing prescription drugs, and the order would be a new tool for harassment at the hands of drug inspectors.

As for the relaxation of labelling requirements, it came following representations by the trade bodies, which citied difficulties in re-labelling products manufactured earlier. The government had amended the Drugs and Cosmetics Rules to insert Schedule H1 category for regulating use of antibiotics. But it placed only 46 antibiotics under the category instead of the original proposal to include 91 drugs.

The government also made it mandatory for these listed antibiotics carrying a warning. If it contains a drug substance specified in Schedule H1, the formulation shall be labelled with the symbol Rx in red, conspicuously displayed at the left top corner of the label, says the government notification.

Source: *The Hindu, 23rd March 2014*

US Food and Drug Administration Okays Safety of Indian Medicines

The US drug regulator says it has detected no impurity in the Indian version of cholesterol-lowering generic drug Atorvastatin in recent tests. The development, which comes after a section of American experts raised doubts over the quality of India-sourced medicines, is a confidence booster for domestic drug firms.

The US Food and Drug Administration (US FDA) has also said that the 'impurities' in drug samples found in the research of these scientists could have actually crept in during the process of testing of drug samples because of the methodology employed.

Last month, a group of doctors and US academicians had briefed senators on the perils of "substandard and falsified medicines with a focus on India's quality control failures".

Among those who briefed the US congressmen were Roger Bate of Washington-based think tank American Enterprise Institute, Amir Attaran, a professor of law and medicine at University of Ottawa, and whistle-blower in Ranbaxy Labs case, Dinesh Thakur. Harry Lever, a cardiologist at the Cleveland Clinic, and Preston Mason, a scientist at the division of cardiology at Brigham and Women's Hospital, were also part of this team.

However, a US FDA spokesperson said a recent test of generic Atorvastatin versions approved by the FDA showed no such problem. "All of the generic Atorvastatin versions approved by the FDA and sold in the United States were recently tested by the FDA for the impurity described by Mason. We obtained the samples from a retail pharmacy. These products were made in the United States, Canada, India and Slovenia," Christopher Kelly told ET. "In our own analysis, we did not find the impurity problem in any of the Atorvastatin generics that were tested."

On the methodology adopted by Mason, Kelly said, "The FDA found that the methylated impurity was formed during analysis when acidified methanol was used similar to the method Mason used for Lipitor as well as the generics. The FDA feels there is no reason to use acidified methanol in the method."

However, Kelly added, "We cannot directly compare our results to what was tested by Mason because we have not seen the details of that research." The FDA is currently finalising the results of its lab testing and intends to publish a paper soon to describe its testing method and the findings. Details of Mason's research have also been repeatedly sought by leading Indian drug makers, who had strongly objected to such 'sweeping generalisations' on India-made medicines.

Indian drug makers have welcomed the FDA comment."We are equally concerned about quality and safety of generic medicines. It is, therefore, reassuring to know that the US FDA failed to find contaminants in samples of generic heart medicines from the US, Canada, India and Slovenia obtained from retail pharmacies," said DG Shah, Secretary General of Indian Pharma Alliance, a grouping of leading Indian drug firms. Shah said testing of drugs is a scientific and complex process in the absence of universally harmonised standard of quality."So, a product which is meant to pass standards prescribed in UK may not necessarily pass the US prescribed quality standards, which doesn't mean they are substandard," he said.

India is the second-largest source of generics to the US and supplies 40 per cent of generics and over-the-counter drugs to the country. Facilities of many top Indian drug firms such as Ranbaxy, Wockhardt, Sun Pharma have been recently red flagged by the US FDA, which is growing its vigilance here, but maintains, "While the FDA will take appropriate action against any company that doesn't meet our requirements, we are also willing to work with them to address their issues."

Source: *The Economic Times, 4th April 2014.*

Sun Buys Ranbaxy for $3.2 Bn in Biggest Indian Pharma Deal

Sun Pharmaceutical Industries Ltd will buy Ranbaxy Laboratories Ltd for $ 3.2 billion in the biggest ever Indian Pharma deal, creating the world's fifth largest generic drug manufacturer.

Ranbaxy, a subsidiary of Daiichi Sankyo of Japan, will once again be Indian-owned, and may possibly be able to fix quality issues that had led to four of its factories in India being barred from shipping their products to the US, the world's biggest drug market.

The Japanese company bought Ranbaxy for $ 4.2 billion in 2008. Daiichi Sankyo chief executive Joji Nakayama said in Tokyo that the company had learnt a lot about emerging markets through its relationship with Ranbaxy, and saw those lessons as valuable for its global expansion.

According to a Reuters database, the all-share transaction is the biggest deal in the pharmaceutical sector in the Asia-Pacific region in this calendar year. After the acquisition, Sun Pharma's combined revenue will become $ 4.2 billion, and make it India's largest generic drug manufacturer.

Under the terms of the agreement, shareholders will get 0.8 Sun Pharma shares for each Ranbaxy share. During a conference call with analysts, Sun Pharma MD Dilip Shanghvi said the deal offered tremendous growth opportunities as Ranbaxy has a significant presence in India and the US.

"In high-growth emerging markets, (Ranbaxy) provides a strong platform which is highly complementary to Sun Pharma's strengths. There is very little product-specific overlap between Ranbaxy and Sun products," he said.

In January, the US Food and Drug Administration banned Ranbaxy's Toansa plant from exporting anything to the USA because of manufacturing deficiencies.

During a visit by USFDA chief Margaret Hamburg subsequently, the FDA called for improved collaboration with Indian regulators. Sun Pharma's plant at Karkhadi in Gujarat too was banned from the US in March. Shanghvi said the combined entity would focus on fixing manufacturing quality issues at Ranbaxy, so that the current ban on the facilities is lifted.

Under the deal, expected to close by year-end, Daiichi Sankyo will get a stake of about 9 per cent in Sun Pharma. After the deal was announced, the shares of the company emerged as the top gainer for the day, rising 2.68 per at the Bombay Stock Exchange. Ranbaxy ended lower by 3.12 per cent.

Source: *The Indian Express, 7th April 2014*

Indigenous Malaria Vaccine Shows Promise in Mice Studies

Indian scientists experimenting with a novel vaccine candidate against malaria say they have found "promising results" in mice, with "80 to 85 per cent efficacy" observed in a dozen animals they recently vaccinated.

The new vaccine candidate, created by a team at the Indian Institute of Science (IISc), contains live malaria sporozoites (an immature stage of the parasite *Plasmodium berghei*) with an important genetic modification. The researchers knocked out a gene that produces "heme," a molecule central to the pathogen's survival. The vaccine targets the pathogen as it enters the liver, the first destination in the host.

Modus operandi

INSA Senior Scientist, Department of Biochemistry, IISc, G. Padmanabhan, who leads the research at P.N. Rangarajan's laboratory in the Department of Biochemistry, said that the vaccine candidate appeared to prime the immune system of the mice against the disease, most likely by kick starting a T cell immune response.

These results are, however, yet to be published, he said.

"We need to repeat the experiment in a few more animals to confirm our results first," said Viswanathan Arun Nagaraj, a Ramanujan Fellow IISc, and part of the team working on the vaccine. They will next conduct safety trials on their animal models, he added.

The premise of the vaccine — containing mutant, inactivated sporozoites (or genetically attenuated sporozoites) — draws from two critical discoveries made earlier by the same team. The first discovery, made 20 years ago, was that the parasite can produce its own "heme" to sustain itself (although it also draws the molecule from the host's haemoglobin when the parasite finally colonises in the host's blood stream).

Second breakthrough

In 2013, the team made its second breakthrough when it identified all the heme-producing genes and found that the parasite's ability to manufacture heme on its own was essential in its earliest "human stage" — when it enters the host's liver.

"Inactivating the sporozoites is always the main challenge while researching a malaria vaccine," Prof. Padmanabhan said. By knocking out one of the heme-producing genes — ALA synthase gene — the researchers essentially created a parasite that was no longer capable of surviving in the liver, let alone being released in exponential numbers into the host's bloodstream where it manifests as malaria.

"The heme-biosynthetic pathway could be a target for antimalarial therapies in the mosquito and liver stages of infection. The knockout parasite could also be tested for its potential as a genetically attenuated sporozoite vaccine," Dr. Nagaraj and coauthors had anticipated in a paper published in*PLoS Pathogens* journal last year.

A vaccine against malaria has been a longstanding research problem especially because drugs have proved inadequate against the parasite that often develops resistance, Dr. Nagaraj said. "Only recently did we have reports from Cambodia of the parasite developing resistance to artemisinin, the most important anti-malaria drug. The parasites are developing resistance to even combination drugs."

Among the vaccine candidates under various stages of trial around the world is the RTS,S vaccine based on a protein from the malaria sporozoite, which has shown a 30 to 50 per cent efficacy in human trials. Another vaccine being tested uses attenuated irradiated (weakened) sporozoites.

According to the WHO, malaria infected 207 million people across the world in 2012 and killed 627,000 people; nearly 80 per cent of the deaths were of children under five years of age.

Source; *The Hindu, 17th April 2014*

US Alerts Likely to Hit India Pharma Export Growth

The sharply higher number of import alerts by the US drug regulator against medicines produced by several large Indian pharmaceutical companies will pull down pharmaceutical exports, industry officials have said.

India, which exported $14.6 billion (Rs 79,500 crore) worth of medicines in 2012-13, was expecting growth to stay stable at 10% during 2013-14, but that is unlikely to happen. Officials tracking pharmaceutical exports said India could record a little over 3% growth during the ten months which ended in January 2014 largely because of frequent disruption of production at facilities under Food and Drug Administration scrutiny. Growth for full year may not exceed 5%.

Large industry players like Ranbaxy, Wockhardt, Sun Pharmaceuticals and Strides Arcolab were among those that suffered fall in exports to the North American market because of actions by the FDA, said the officials.

The US accounts for nearly 28% of Indian pharmaceutical exports, followed by the European Union at 18% and Africa at over 17%. According to the provisional data compiled by the Pharmaceutical Export Promotion Council (Pharmexcil), the country reported $12.4 billion of drug exports during the first ten months of 2013-14.

PV Appaji, Pharmexcil's director general told ET, "The actual export growth rate for fiscal ending March 2014 would be far less than what we had projected at the beginning of the year. This is largely because of the regulatory actions." Exports would have shrunk had it not been for players such as Dr Reddy's Laboratories,Lupin and Aurobindo Pharma picking up the slack, he said.

India is the third-largest exporter of medicines to the US market by volume and it has the second-largest number of FDA-approved manufacturing facilities (370) outside the US. With increased frequency and intensity of inspections by the FDA, Indian copycat drug manufacturers suffered frequent and prolonged disruptions to production at their facilities under the scrutiny. Analysts expect that the problems of Indian generic manufacturers could only go up as the foreign inspections of FDA will only rise.

Source: *The Economic Times, 17th April 2014*

U.S. Court Ruling to Benefit Natco

Hyderabad-based generic pharmaceutical manufacturer Natco Pharma could benefit from US Supreme Court's quashing pharmaceutical major Teva Pharmaceutical interim injunction to revive its patent on Copaxone (Glatiramer Acetate), a generic multiple sclerosis drug.

The U.S. Supreme Court denied a request by Teva to stay a lower-court ruling in a patent case that sided with generic manufacturers of Teva's multiple sclerosis drug.

The decision could help generic companies like Natco launch the drug in U.S. “The Supreme Court of U.S. has denied Teva's request for an injunction relating to generic Copaxone, clearing legal hurdle for Mylan and Natco to launch the same in that market,”

Natco said in a filing to the Bombay Stock Exchange (BSE), adding that this is the second time the chief justice had denied Teva's request for such an injunction.

Copaxone registered sales of U $805 million in the U.S. in the December quarter and the U.S. market for it is about $3 billion.

Natco has in place an agreement with U.S.-based Mylan to market the generic version of Teva's Copaxone.

Teva's Copaxone patents, expiring in September 2015 were held invalid by a US lower court in July 2013, making generic entry possible after May 24 this year when remaining patents expire.

This would allow generic players to launch the product 'at risk' in the U.S. market.

“At risk launch option is before the Supreme court's verdict which could come in Teva's favour,” Siddhant Khandekar, Chief Manager – Research, ICICI Securities told this correspondent.

“The court will hear arguments and rule during its 2014-15 term, which starts in October and runs through the following June.”

Meanwhile, Natco said it would await `concurrence' from its partner Mylan as also other regulatory approvals in the US, including approval from the US Food & Drug Administration (US FDA) before deciding on the launch.

Shares surge

On the Bombay Stock Exchange, Natco Pharma stock surged 13 per cent intra-day trade before reacting to close up 7.5 per cent at Rs. 769.35.

Source: *The Hindu, 22nd April 2014*

Pfizer Complains About Indian Patent Mode Again

US Pharma giant Pfizer BSE -0.49 % Inc has complained about India's Intellectual Property Rights regime yet again, this time to India's Ambassador to the US, S Jaishankar.

In a letter to Jaishankar, a copy of which was seen by ET, Pfizer's senior vice-president for global policy and international public affairs, Justin McCarthy, has said that "a series of regulatory initiatives and legal challenges have frayed relations between the Indian government and global pharmaceutical firms" ..

Pfizer has said that though US multinationals have the highest share of patents (20-30%) in India, it does not imply that the Indian IP system is working. The company's main gripe is that in the patents pool, a small number of patents that are commercially valuable are under threat in India.

In March, the drug maker communicated to the ambassador that India's current IP regime is proving to be a big deterrent to future investment decision for Pfizer. Before this, in 2013, Pfizer's chief IP counsel, Roy Waldron, in his testimonies to an US Congress committee, had slammed India's IP regime.

The company lists five complaints, including India's "discriminatory standards of patentability", use of compulsory licensing, lack of data protection, some of which it claims violates the country's global obligations under Trade Related Aspects of Intellectual Property Rights (TRIPS), a charge both Indian government and domestic industry refute.

"As a result of the Indian Supreme Court's narrow construction of 'efficacy' in the Glivec decision, many valuable pharma innovations that improve the usefulness of existing drugs may be deemed un-patentable in India", McCarthy's letter alleges.

In 2013, the top court had upheld a decision of the patent office to not grant patent to Swiss drug maker Novartis' cancer drug Glivec on the ground that it does not enhance therapeutic efficacy over existing drugs and, hence, fails to meet the criteria of section 3(d) under the Indian Patent Act. Some top pharma companies have been lobbying to get this part of the Patent Act struck off, but this change in legislation would need an amendment.

However, the Indian Pharma Alliance, a grouping of leading domestic drug makers, has dismissed these charges. "The Indian government and the Indian industry believe that our patent law is TRIPS compliant. More importantly, a recent joint publication of World Health Organisation, World Trade Organisation and World Intellectual Property Organisation have also acknowledged section 3(d) as a narrow definition of patentability criteria employed to prevent strategies employed to delay generic competition," the grouping's secretary general, DG Shah, said.

Officials told ET that Pfizer's complains could have partly prompted Jaishankar to suggest that the government should engage with US pharma firms on IPR issues. Shortly after, Cabinet secretary Ajit Seth called a meeting of top bureaucrats on Monday to deliberate on IPR issues, which are being raised by the US.

However, officials present in the meeting told ET that India would not consider diluting its IPR policy, which it believes to be fully TRIPS-compliant, and may even consider challenging the US in multilateral dispute resolution forums if it chooses to impose trade sanctions

Pfizer has also alleged that India's first-ever grant of compulsory license to Natco Pharma BSE -0.25 % in 2012—to manufacture a cheaper version of Bayer's cancer drug Nexavar—violated the TRIPS clause that prohibits WTO members from discriminating based on whether products are imported or locally produced. This was one of the grounds on which the patent office had granted the CL, but subsequently, this ground was overruled by the Intellectual Property Appellate Board, according to Shah.

Source: *The Economic Times, 24th April 2014*

US Pharma Consolidation Hurts Indian Mid-Sized Drug Makers

Several mid-sized Indian drug makers heavily dependent on the United States are beginning to suffer because consolidation in the US pharmacy market has created a few dominant players who are demanding cheaper generic drugs, analysts and industry experts said.

The North American pharmacy market saw at least three mega consolidation deals involving large wholesale distributors, resulting in emergence of seven large pharmacies that together control nearly 85% of the $90 billion (Rs 5.4 lakh crore) US market.

Last March, three large pharmacy distributors - Walgreen, Alliance Boots and Amerisource-Bergen - formed a 10-year international alliance. In December, the second-largest US wholesale distributor Cardinal Heath formed an equal joint venture with another large player CVS Caremark. In January this year, another US pharmacy company McKesson agreed to acquire the European Union's largest distributor Celesio, further consolidating its position.

of India's $15-billion global pharmaceutical exports, domestic drug makers depend on the US market for at least $4 billion in sales. Close to $3 billion of sales is garnered by larger players like Dr Reddy's, Sun PharmaBSE -0.68 %, RanbaxyBSE -0.90 % and LupinBSE -1.45 %. Dozens of mid-sized drug makers such as Torrent Pharma, IPCA LaboratoriesBSE -0.69 % and Alembic Pharma together account for the rest.

""While several large Indian companies with a unique product portfolio will not yield to the demands of the dominant pharmacies, some large Indian companies with economies of scale can afford to lower their prices," said a chief executive of a Hyderabad-based mid-sized drug maker who did not want to be identified.

"The new adverse position is forcing mid-sized drug makers to rework their US market strategy. This involves forging alliances with large global pharmaceutical companies or strengthening the product portfolio with unique, niche and difficult to make generic products," said the same CEO, whose company forged alliances with global firms to launch niche generics.

Acknowledging the pricing pressure on Indian drug makers in general and mid-sized to small companies in particular, Nitin Agarwal, analyst with IDFCBSE -0.36 % Securities, said, "Though everyone is vulnerable to this development, smaller firms will get affected most due to their vanilla portfolios."

Agarwal said drug makers with niche product portfolios possess an advantageous position in price bargains with the US pharmacies. "Companies either with plain vanilla product portfolios or small in economies of scale find it difficult in bargaining with the dominant players of US pharmacy market."

Through the large consolidations, the US pharmacy players have set ambitious targets on savings through downward price bargaining on generic drugs. According to IDFC Securities, McKesson set a target of $300 million of savings over the next 3-4 years, while Cardinal estimated some $100 million savings. We believe that the US pharmacy giants will extract most of these benefits from generic companies, leading to pricing pressure on small to medium drug makers and resultant margin erosion from this fiscal onwards. In the process, we expect the bigger players to grab larger market share in the US," said IDFC's Agarwal.

Indian government officials have noted the development and are looking at measures to bail out the small and medium drug exporters, said P V Appaji, the director general of Pharmaceutical Export Promotion Council. "We are considering measures like intervening and negotiating with certain US pharmaceutical distributors on behalf of small and medium Indian drug makers," he said.

Source: *The Economic Times, 26th April 2014*

840 Persons Prosecuted For Flouting Drug Rules

In the past three years, the Tamilnadu Drug Control authority has prosecuted 840 persons for violating the Drugs and Cosmetics Act. Since 2011, the number of prosecution each year has been increasing steadily. However, experts say the number is small considering the mushrooming medical shops.

The violations are mostly selling drugs without receipt/prescription, not possessing valid sales licence or not having a full-time pharmacist.

In 2011-12, a total of 4,074 samples were drawn leading to 270 prosecutions. The sample size rose to over 6,000 the next year and the prosecution stood at 301. In 2013-14 (till February) the drug control authority lifted 6,607 samples and the number of prosecution stood at 302.

Late induction of new inspectors

Director of Drugs Control Abdul Khader attributes the rise in samples to increase in manpower but says the low level of prosecution is due to late induction of new inspectors. “We now have 136 drug inspectors and each person is responsible for inspecting 200 to 300 licences depending upon the jurisdiction they are given. Each inspector takes 50 samples a month from medical shops, grocery shops and pharmacies attached to hospitals, clinics and government medical stores. We see a lot of minor defects and less than half of the violations are defects in manufacture of drugs,” an official says.

Though 96 per cent of the prosecutions lead to conviction, experts say the number is low, considering the number of pharmacies in the State. “It is a good sign that more samples are picked up but there should also be a corresponding increase in the number of convictions,” a former drug controller says.

Another expert says the scope for prosecution will increase if sample size is increased. “The number of samples taken is high but it is difficult to accept that there can be so few violations,” he says.

Source: *The Hindu, 26th April 2014*

Pharma Traders Want Higher Margins Restored

There is another stand-off in the offing between the pharmaceutical trade and manufacturers over the issue of margins paid to retailers and wholesalers of medicines by the manufacturers.

Trade believes industry should restore margins to pre-July 2013 levels before the Drug Price Control Order (DPCO) came into effect reducing prices of several drugs and setting ceiling prices for them.

The trade hopes original margins will be restored by July 1, 2014. After negotiations in September 2013, about 70 per cent of the industry had restored margins to original levels, but global giants such as Abbott, Aventis, Sanofi, Intas and Indian giants Sun Pharmaceuticals and Dr. Reddy's Laboratories have not given in.

J. S. Shinde, President, All India Organization of Chemists & Druggists, (AIOCD), the nodal body representing 7.5 lakh members, said, “they were supposed to have restored the margins from September 2013. It has been too long and they should restore it by July”. The DPCO 2013 reduced prices of several drugs under the National List of Essential Medicines (NLEM) and the list includes prescription drugs such as cardiac drugs, antibiotics and pain-killers.

Cut in margins

With lower realisations, manufacturers cut margins paid to wholesalers and retailers by 2 per cent and 4 per cent to 8 per cent and 16 per cent respectively.

Suresh Gupta, Secretary General, AIOCD, told *The Hindu* that after talks with several players, he was hopeful of a positive response by the deadline set by AIOCD.

Indian Drug Manufacturers Association (IDMA) has chosen not to get involved "as it concerns individual companies and their choice as to what margins they offer trade," Daara Patel, Secretary-General, IDMA, told this correspondent.

Additional burden

"The DPCO has mandated retailer margins at 16 per cent. If companies choose to pay more, it is their decision," he said. "Trade is benefiting from sale of products outside of the DPCO. The DPCO has already seen industry take a hit of around Rs.2,000 crore," said D. G. Shah, Secretary-General, Indian Pharmaceutical Alliance (IPA).

"There are more than 650 formulations under the DPCO and anything beyond the mandated margins would go from the manufacturer's pocket.

Going back to original margins would mean an additional burden of Rs.400-500 crore. It does not seem likely," he said.

Source: *The Hindu, 27th April 2014*

Pfizer Still Wants to Pop Astrazeneca

Pfizer publicly unveiled its interest in acquiring AstraZeneca of Britain on Monday, in what would be one of the biggest in an already swelling series of deal efforts among drug makers.

In a statement, Pfizer said that it was willing to pay £58.7 billion, or $98.7 billion. That would make it one of the largest ever acquisition efforts in the pharmaceutical industry, surpassing Pfizer's $90 billion takeover of Warner-Lambert 14 years ago. Pfizer's prospective bid was valued at £46.61 a .. where AstraZeneca was trading at the beginning of the year.

The move is aimed at putting pressure on the British drug maker, which has turned down a number of informal takeover approaches from its competitor, including in recent months

The pharmaceutical industry has helped push deal activity to heights unseen since before the financial crisis of 2008. On April 22 alone, drug makers unveiled $74 billion worth of potential deals, including the potential takeover of the maker of Botox and a complicated series of asset swaps between NovartisBSE -1.13 % of Switzerland and GlaxoSmithKline of Britain.

These companies have been driven to deals in many cases to find new areas of growth as onetime blockbuster treatments lose patent protection. Instead of pouring money into researching new products that could sputter out, they are looking to buy what they hope are likely winners.

To Pfizer, AstraZeneca may be attractive because of its portfolio of cancer drugs, an area that the American company has also made a priority as it seeks to restock its product pipeline.

A takeover bid for the British company would also let Pfizer use some of the cash that it keeps abroad without incurring a big tax bill. The company has disclosed holding about $69 billion in earnings from international subsidiaries as of December 31.

In its statement on Monday, Pfizer added that it would re-incorporate the combined company in Great Britain, a corporate maneuver that could reduce the company's tax bill. It would maintain offices in the United States and Great Britain and would remain listed on the New York Stock Exchange.

"We believe patients all over the globe would benefit from our shared commitment to R&D, which is critical to the future success of the pharmaceutical industry," Ian Read, Pfizer's chairman and CEO, said. "A potential combination with AstraZeneca aligns with Pfizer's current structure and fully supports its existing strategy to build world class businesses."

But the board of AstraZeneca has viewed the previous approaches as opportunistic and ill-timed, with too small a takeover premium, according to a person briefed on those discussions. The British drug maker has tried to improve its fortunes on its own, trying to reverse declines in sales and profits because of the loss of patent protection on some of its best-selling treatments and setbacks in developing new drugs.

Source: *The Economic Times, 29th April 2014*

Aurobindo Pharma Faces Patent Infringement Cases In U.S.

Three multinational drug makers — The Medicines Company, Hospira and Kowa Company Ltd — in separate cases — have dragged Indian firm Aurobindo Pharma to court on allegations of patent infringement.

According to the petition copies, Hospira has alleged that Aurobindo Pharma's Abbreviated New Drug Application (ANDA) to make generic version of dexmedetomidine hydrochloride injection would infringe its patented drug Precedex.

Aurobindo Pharma officials were unavailable for comments.

Hospira filed the petition in the U.S. District Court of Delaware. The drug is used for the sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting.

Similarly, the Medicines Company in a separate petition filed in the District Court of New Jersey alleged that the Indian drug maker's ANDA would infringe on its drug, Angiomax, on two counts.

Angiomax (bivalirudin) is used as an anticoagulant in patients with unstable angina undergoing percutaneous translurninal coronary angioplasty. Kowa in its petition filed in District Court of Southern District of New York alleged that Aurobindo Pharma's recent ANDA with U.S. Food and Drug Administration would infringe on its patented drug Livalo (Pitavastatin) on four counts.

Pitavastatin is used as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase high-density lipoprotein cholesterol.

“Plaintiff request the following relief...a permanent injunction restraining and enjoining against any infringement by defendants...of the Livalo patents, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Aurobindo Pharma's pitavastatin drug product or any drug product containing Pitavastatin,” Kowa prayed the court in its petition.

Kowa also filed a similar petition against another Indian drug maker Zydus Pharmaceuticals on the same drug.

Source: *The Hindu, 29th April 2014*

Antibiotic Resistance A Global Threat, Says WHO

Resistance to antibiotics was on Wednesday declared a “major global threat” to public health by the World Health Organization in a first-ever global surveillance report that collated data from 114 countries.

It said some superbugs have evolved so much that up to 50% of the affected patients don't get cured by drugs commonly used against them. Common microbes such as E coli, for instance, are posing a major emergency in intensive care units across the world.

“Without urgent, coordinated action by many stakeholders, the world is headed for a post-antibiotic era in which common infections and minor injuries which have been treatable for decades can once again kill,” said WHO's Dr Keiji Fukuda while releasing the report.

The report had a special warning for India. “The infectious disease burden in India is among the highest in the world and the inappropriate, irrational use of antimicrobial agents against these diseases has led to an increasing trend in development of

antimicrobial resistance," it said. The report — Antimicrobial Resistance: Global Report on Surveillance — studied antibiotic resistance in nine different bacteria responsible for common diseases such as sepsis, diarrhoea, pneumonia, urinary tract infections and gonorrhoea.

Failure of the last resort of treatment for gonorrhoea — third generation cephalosporins — has been confirmed in Austria, Australia, Canada, France, Japan, Norway, Slovenia, South Africa, Sweden and the UK. Over 1 million people are infected with gonorrhoea around the world every day.

Said an intensivist in a south Mumbai hospital, "An increasing number of patients who reach the ICU with urinary tract infection are resistant to normally prescribed medicines." The doctor said the medical fraternity couldn't depend on one antibiotic alone. "We are using drugs in combinations most of the time."

The WHO report found half the patients treated for sepsis caused by K pneumoniae don't respond to carbapenem antibiotics. It also noted that fluoroquinolones used for urinary tract infections caused by E coli, don't work in 50% cases. "In the 1980s, when fluoroquinolones were introduced, resistance was virtually zero. Today, there are countries where this treatment is ineffective in more than half of patients," the report noted.

It stressed that antibiotic resistance was causing people to be sicker for a longer time and increasing the risk of death. "People with MRSA (methicillin-resistant Staphylococcus aureus) are 64% more likely to die than people with a non-resistant form of the infection," it said.

In India, the emergence of extremely drug resistant TB drove home the extent of antibiotic resistance. Mumbai's doctors had in 2011-2012 highlighted TB cases that were resistant to all the known antibiotics usually used to treat it. WHO, in 2011, estimated that there are 6.3 lakh cases of multi-drug resistant tuberculosis (MDRTB) among the world's 12 million cases of TB.

The WHO report blamed poor regulation in the medical sector, with respect to prescription, in India.

Source: *The Times of India, 1st May 2014*

Govt Mulls Cancer Drug Patent Waiver

The health ministry has reopened the issue of waiving a global drug giant's patent rights for Dasatinib, a cancer drug, arguing the move is needed to deal with an "emergency". The latest development - which the ministry expects will go through - comes at a time when India has won a reprieve from the US over its intellectual property regime but is facing flak from the civil society, which is critical of the government "going soft" on affordability and availability of medicines for life-threatening diseases.

In a letter to the department of industrial policy and promotion (DIPP) last week, the health ministry has answered the concerns raised earlier and said the cost of the drug produced by pharma major Bristol-Myers Squibb (BMS) will be met through government schemes. Many experts see BMS along with Pfizer at the forefront of the battle to get the US authorities to downgrade India's patent regime by a notch and open it to possible punitive action.

Officials in DIPP refused to comment on the latest move, but health ministry sources said they plan to use around half-a-dozen schemes to fund the cost

of making the drugs available to patients for what is called public non-commercial use and the position has been made clear in last week's letter. Dasatinib is used to treat chronic myeloid leukemia.

If the move goes through, it will be the first instance of the government invoking emergency provisions in the law to waive the patent rights. So far, the compulsory license provisions have been used by the Patents Office, which waived Bayer Corporation's patent rights over Nexavar, a renal cancer drug, allowing Natco Pharma to manufacture and sell it at a fraction of the cost. Natco had offered to sell the medicine at Rs 8,800 for a month's therapy, compared to Bayer's Rs 2.8 lakh.

But unlike last time, this time the government will itself have to issue the compulsory license, which is provided for in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (Trips). Even in this case, the sources said, the government will have to hear the arguments put forward by BMS to "follow the principles of natural justice". Once the government issues its order, the Patents Office will be required to notify the availability of a compulsory license for the drug and will be required to go through another round of hearing.

Initially, the health ministry was pushing for compulsory license for three cancer drugs, but had to drop plans for two of them.

Given the international scrutiny, the government is treading with caution and had earlier turned down health ministry's plea that the government issue a compulsory license under section 84 of the Indian Patents Act on the grounds of affordability and had suggested an application be made with the Patents Office. DIPP is extra cautious over the issue as it will undergo the legal process and it does not want to be caught doing something which is against the law.

Last October, the Patents Office had rejected an application from BDR Pharma to make a generic version of BMS's Dasatinib, which is sold under the Sprycel brand. The proposal was rejected on the grounds that the Indian company did not make enough efforts to obtain a voluntary license for the anti-cancer drug.

Source: *The Times of India, 5th May 2014*

Bayer To Buy Merck's Consumer Biz For $14.2 B

Germany's Bayer has agreed to buy Merck & Co.'s non-prescription medicine and consumer care business for $14.20 billion, gaining products such as Claritin allergy pills, Coppertone sun lotion and Dr. Scholl's foot care products.

Bayer said the deal would make it the leader in over-the-counter products in North and Latin America. Bayer already has a major non-prescription division whose brands include Aleve pain reliever, Alka-Seltzer and One-A-Day vitamins. Bayer also makes prescription drugs, industrial materials and farm chemicals.

Marijn Dekkers, Bayer's CEO, said the deal, which is subject to regulatory approval, “marks a major milestone on our path towards global leadership in the attractive non-prescription medicines business.”

Bayer said it has also entered an agreement with Merck to cooperate on developing and selling drugs known as sGC modulators, which have potential for treating heart failure and pulmonary hypertension.

Merck would initially pay Bayer $1 billion, with further payments contingent on sales.

Merck CEO Kenneth C. Frazier said the sale was part of an effort to align the company's businesses with its strategy of being the premier research intensive drug company. Merck said it would use the money from the sale to invest in business areas with the highest growth potential and augment its drug pipeline with “external assets.”

Merck, like other major drug makers, has seen its pharmaceutical sales slide due to the onset of cheaper generic versions of several drugs that once raked in billions annually. Those include the asthma and allergy pill Singulair, the allergy spray Nasonex and the blood pressure drugs Cozaar and Hyzaar.

Merck, which is headquartered in Whitehouse Station, New Jersey, reported a 7 per cent rise in first-quarter earnings late last month. But that was mainly thanks to steep cuts to administrative and marketing expenses and research spending. It reduced its global workforce by 2,000 in the quarter to 74,000.

The company has said it plans to rely on its pipeline of experimental drugs for future sales, which would make it an exception to the trend among many other drug makers, which are pursuing big acquisitions to keep sales growing. Earlier this month, a Food and Drug Administration panel voted against a Merck proposal to sell the drug maker's one-time best-seller, Singulair, as an over-the-counter allergy medication. Bayer AG, which is based in Leverkusen, Germany, said the combined consumer care business would be headquartered at a Bayer site in Whippany, New Jersey.

Merck's consumer business has about 2,250 employees and is headquartered in Summit, New Jersey. About 113,200 people work for Bayer worldwide, while Merck has about 74,000 employees.

Source: *The Hindu, 7th May 2014*

Woman Who Sued J & J For Faulty Hip Implant Dead

An elderly Parsi woman from Dadar, who was the first person from the city to sue pharmaceutical giant Johnson & Johnson for faulty hip implants, died of an aggressive brain cancer last week. Daisy Bharucha's family, shocked at the sudden onset and progression of the disease, has vowed to take the fight forward.

Bharucha (72), like thousands the world over, was fitted with the controversial metal-on-metal articular surface replacement (ASR) hip implant manufactured by J&J subsidiary DePuy Orthopaedics. The device was recalled in 2010 following a high failure rate, besides other adverse effects such as metal deposition in the body, loosening of parts and fluid accumulation.

A fall at Bandra station had left Bharucha with a broken hip. The replacement surgery took place in 2007, following which she never had a pain-free day, or a day without painkillers, said her daughter Jeniffer. "Her independence was everything to her. She continued to work even four years after the surgery, but it was never the same. She, of course, could no longer use public transport after the surgery. Taking a bus or train was out of the question as she could not even lift her leg without being in pain," Jennifer told TOI. The septuagenarian, who wished to work till her last breath, was eventually asked to "retire" as her agility diminished.

Jeniffer recalled how the implant had started making a crackling sound within five months of the surgery. "We laughed it off initially. Even people in her office did. The sound did not stop and her pain only worsened," said Jennifer. Bharucha ultimately had to go for a revision surgery in 2011. It was funded by DePuy and her metal-on-metal implant was replaced with a metal-on-ceramic one. "Nothing changed much for her, though. She decided to file a case in the consumer court only because the surgery had made her dependant on others," said Jeniffer.

Last November, the diagnosis of brain tumour shook the family. "It popped out of nowhere during an MRI investigation. We have no history of cancer in the family," she said. The family believes that deposition of cobalt and chromium from the implant (one of the main reasons for recall) could have a role to play. Bharucha could not longer eat or walk towards the end. "She died in immense pain. And, no amount of compensation can take that away," Jeniffer said.

A spokesperson from DePuy told TOI that there was no proven connection between metal-on-metal devices such as ASR and cancer. "The National Joint Registry for England and Wales 2012 report stated: metal-on-metal hip replacements are not associated with an increased risk of diagnosis of cancer in the first seven years after hip replacement."

The head of Sion Hospital's orthopaedic department, Dr Arvind Goregaonkar, said, "While metal depositions are known to be carcinogenic, it is unlikely that disease progression happens so soon after surgery. There is no concrete link between orthopaedic implants and cancer so far, though the medical fraternity is talking about it."

Source: *The Times of India, 13th May 2014*

Chemicals in Soap, Toothpaste Tied to Male Infertility

Chemicals in common household products such as toothpaste, soap and plastic toys have a direct impact on human sperm which could help explain rising levels of male infertility, scientists have found.

One in three "non-toxic" chemicals used in the manufacture of everyday items significantly affected the potency of sperm cells, which may account for the high incidence of unexplained infertility in the human population, the researchers said.

It is the first time that a study has found a direct effect of the many ubiquitous man-made chemicals in the environment on a vital function of human sperm. The findings will raise further concerns about the hidden toxicity of chemicals deemed safe by toxicology tests.

But the researchers believe they have developed a new way of testing the impact of household chemicals on human sperm which will allow regulatory authorities in Europe to decide whether to ban or impose restrictions on their use in certain products.

The study was part of wider research into so-called "endocrine-disrupting" chemicals that for several years have been linked with declining sperm counts and widespread male infertility.

In some cases, these chemicals are thought to mimic female sex hormones – oestrogens – and in other cases act as anti-androgens, the male sex hormones, thereby interfering with the male reproductive system.

However, the scientists found that one in three common household chemicals found in products such as sun screens, detergents and plastics directly sabotaged the human sperm's swimming behaviour and caused them to prematurely release the critical enzymes needed to penetrate and fertilise the egg cell – which would render the sperm infertile.

They also found that the concentrations needed to trigger these adverse reactions were similar to the very low levels commonly found within the human body. In addition, they showed for the first time that there was a "cocktail effect", when a number of chemicals worked together to amplify their individual effects.

Source: *The Times of India, 13th May 2014*

KKR's Rs 1400 Cr Plan to Buy Stakes in 2 Drug Cos Get Okay

The government on Tuesday cleared private equity firm KKR's proposal to acquire stakes in two drug firms — Gland Pharma and Gland Celsus Bio Chemicals — in deals of over Rs 1,400 crore. KKR plans to pick a 37.9% stake in Gland Pharma for $191 million (Rs 1,150 crore), and invest $39.8 million (Rs 240 crore) for a 24.9% in Gland Celsus Bio Chemicals. The deal had already got green signals from the Competition Commission of India and Foreign Investment Promotion Board (FIPB) earlier this year.

KKR had entered into the share purchase agreements with Gland Pharma and Gland Celsus in November last year. In the bigger investment, KKR Floorline Investments PTE Ltd will acquire 37.98% in Gland Pharma through subscription to new shares and purchase of shares from EILSF Co-Invest I LLC, an existing private equity investor in Gland Pharma.

The final proposal which got Cabinet clearance doesn't have noncompete clauses, to meet the new norms floated under pharma FDI policy in brownfield ventures, according to officials. This basically means the promoters of Gland Pharma are not bound by the share purchase agreement from again establishing similar business.

Gland Pharma makes and markets specialised injectable formulations for generic versions of drugs, it also manufactures a limited quantity of APIsBSE 0.00 % (Active Pharmaceutical Ingredients) for inhouse consumption. While India allows 100% FDI in green-field pharma projects under automatic .. route, investments by multinational entities into brownfield ventures have need to be vetted by FIPB.

Deal valuations have skyrocketed in recent years. In 2008, Daiichi paid $4.9 billion for a 63.5% stake in RanbaxyBSE 1.15 % in all-cash deal, valuing the company at $8.5 billion, over five times its annual sales of 2007. Two years later, Abbott acquired the Piramal unit by valuing it at nine times annual sales.

Source: *The Economic Times, 14th May 2014*

Antibiotics Given to Newborns up Asthma Risk

Scientists have discovered that children who are given antibiotics before their first birthday have an increased risk of developing asthma. UK researchers examined data from the Manchester Asthma and Allergy Study (MAAS) which has followed over 1,000 children from birth to 11 years.

Antibiotics are routinely given to children to treat respiratory infections, ear infections and bronchitis.

The study's findings are believed to be the first to show that children with wheezing who were treated with an antibiotic in the first year of life were more than twice as likely as untreated children to experience severe wheeze or asthma exacerbations.

Of particular interest was that these children also showed significantly lower induction of cytokines which are the bodies key defense against virus infections such as the common cold. The researchers also identified two genes in the 17q21 region that were associated with an increased risk of early life antibiotic prescription.

Lead author Adnan Custovic from the University of Manchester said, “We speculate that hidden factors which increase the likelihood of both antibiotic prescription in early life and subsequent asthma are an increased susceptibility to viral infections due to impaired antiviral immunity and genetic variants 17q21.

But further studies will be needed to confirm that the impaired immunity was present at the time of the early childhood respiratory symptoms and predated antibiotic prescribing rather than as a consequence of the antibiotics.

In this study, information on antibiotic prescription, wheeze and asthma exacerbations were taken from medical records.

Source: *The Times of India, 15th May 2014*

WHO Faces Civil Society Ire for Pharma Meet

The World Health Organisation is drawing flak from public health organisations for its participation in a pharmaceutical industry backed conference which they say aims to serve only business interests.

At the ongoing 67th World Health Assembly in Geneva, public health organisations have objected to the World Health Organization's (WHO) participation in the International Conference on Harmonisation (ICH), which they describe as "a de facto standard setting body set up by transnational pharmaceutical industry to serve their business interests". Raising the bar on manufacturing standards and using these standards to keep out companies from developing countries has been of great concern especially to the Indian pharmaceutical industry which exports 50% of its $10 billion annual generic medicine production.

A statement issued by Medicus Mundi International Network (MMIN) and People's Health Movement (PHM) stated that while ICH sought to raise the bar on acceptable manufacturing standards and to globalise these; higher standards beyond a point, do not add to medicines quality and public health outcomes. "It adds to the cost of manufacturing and is a barrier to the entry of generics in low and middle income countries (L&MIC)," said the statement International Conference on Harmonization (ICH) in which majority of the WHO member countries have no voting rights is dominated by pharmaceutical industry groups. The International Federation of

Pharmaceutical Manufacturers and Associations (IFPMA), closely involved with ICH since its inception, hosts the ICH secretariat in Geneva. So, the two share the same address --15, Chemin Louis-Dunant, PO Box 195, 1211 Geneva-20. IFPMA participates in the steering committee of the ICH as a non-voting member. Six voting members of the ICH steering committee include the European Federation of Pharmaceutical Industries' Associations (EFPIA), the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Japan Pharmaceutical Manufacturers Association (JPMA). The WHO is just an observer in ICH.

The joint statement of MMIN and PHM on one of the agenda items at the World Health Assembly (WHA) on regulatory system strengthening said that ICH compromised the neutrality of the process of setting regulatory norms and standards and urged member states of the WHO to ask for disengagement of the WHO from ICH and for exclusion of the ICH from WHO Expert Committee meetings.

PHM also stated that ICH was an industry body and where industry and public interests were in conflict, the effort of the ICH would bend towards the interests of the corporations.

It also urged member states to call upon WHO to address the issue of unethical clinical trials in L&MIC by developing a global mechanism under the aegis of the WHO for registration of clinical trials and to monitor all ethical issues regarding these trials.

Source: *The Times of India, 25th May 2014*

Indian Drugmakers Suffer in American Generics Joust

Indian generic drug producers are devising fresh strategies to continue benefiting from the world's largest pharmaceutical market, the United States, because exclusive marketing rights for off-patent drugs are not so exclusive any more. The US Food and Drug Administration (FDA) has been clearing applications to make generic drugs that are going off patent at a faster pace, which is resulting in increased competition. Moreover, the FDA has been granting joint first to file (FTF) status for several generics, diluting the value of the exclusive marketing right that comes with such a status.FTF refers to drugs whose generic, or low-cost, versions can be launched by a drug maker who enjoys a 180-day exclusive marketing period during which no other generic versions can be sold. FTFs are the main growth drivers for most leading Indian companies that make generic versions of expensive drugs that have gone off patent. Industry experts and analysts point out that many domestic pharmaceutical companies that once enjoyed windfall gains frequently through 180-day market exclusivity are realising that they cannot remain the sole players to reap benefits of market exclusivity after the FDA amended guidelines to allow joint firsts to copycat drug makers. Out of India's $15-billion global pharmaceutical exports, domestic drug makers depend on the US market for at least $4 billion in sales. Abhijit Mukherjee, COO of India's second largest drug maker Dr Reddy's Laboratories, said the era of windfall gains from FTF is over. Because of the increasing competition among the generic drug companies, there is no guarantee that one company can solely enjoy the 180-day market exclusivity. Because of the changing dynamics of the US generic market, Dr Reddy's has devised new business strategies, including shifting focus to complex and difficult - to -

make generics, which address competition and ensure better growth and higher margins. IDFC Securities Pharma analyst Nitin Agarwal said the value of the 180-day market exclusivity, which is considered the holy grail of the US generics market, now stands considerably diminished thanks to growing competition among players. Reflecting the changing situation in recent months, more than a dozen generics makers have been sharing marketing exclusivity for about 70% of the applications for off-patent drugs. A recent example is Vimpat, an anti-epileptic drug with innovator rights belonging to UCB.As many as 15 Indian companies including Ranbaxy, Aurobindo, Glenmark, Sun Pharma, Cadila, Alembic and Hetero are competing to share the exclusivity, apart from multinationals like Mylan, Sandoz and Watson. But this does not mean sole exclusivity is absent among the beneficiaries are Dr Reddys and Lupin. The latter reported windfall gains from ophthalmic solution Zymaxid ($60 million) and anti-HIV drug Trizivir ($110 million), while Dr Reddy's enjoyed market exclusivity from anti-psychotic medicine Ziprasidone. Analysts said large Indian drug makers are shifting their focus towards niche products with huge entry barriers ,like complex generics. Accordingly, the expenditure of Indian medicine manufacturers towards research and development has risen significantly. A senior executive of a Hyderabad-based generic firm said on condition of anonymity that the strategy of focusing on FTFs for market exclusivity and spending large amounts on patent infringement battles are slowly losing takers.

The new game is to judiciously shift attention to injectables and drugs with limited competition to maintain growth and earn high margins, he said.

Expedited clearance of generic applications by FDA offers both rewards and drawbacks said IDFC Securities Nitin Agarwal. “While this will lead to accelerated monetization for larger players, it will also reduce opportunities for profits arising out of delay in approval of competing generic products.

Source: *The Economic Times, 27th May 2014*

Pharma Dept to Bat for Revival of Bulk Drug Industry

The Department of Pharmaceuticals in a presentation, it is preparing to brief Prime Minister Narendra Modi, may pitch for the revival of the domestic bulk drug industry, which has lost much of its sheen over the past decade. Citing instances of depending too much for drug raw materials from China, which has built an immense competitive edge in API (Active Pharma Ingredients, main raw materials) and intermediates, the Pharma department could bat for measures to boost the domestic bulk drug sector, government officials told ET.

"In our presentation, we would focus on steps to reboot the bulk drug industry and overall measures to improve the competiveness of the Pharma sector," an official told ET. India's API imports have grown at a CAGR of 18 per cent in the last decade from a base of $801 million in 2004 to $3.4 billion in 2013, according to EXIM (Export-Import) database.

An estimate of Indian Pharma Alliance, a grouping of leading domestic drug makers, reckoned earlier this year that for the API of many common drugs, India is close to 90 per cent dependent on China for imports. The top Indian drug makers cite the case of APIs needed to manufacture Vitamin C, antibiotics — Metronidazole, Ofloxacin, Livofloxacin — to

buttress their argument on high dependence on Chinese imports of bulk drugs. The dependence is much higher in intermediates, raw material other than APIs used in finished drugs. This exposes the Pharma sector to price volatility and supply side shocks like the one during Beijing Olympics of 2008, when China decided to shut down many of its API plants due to pollution they were causing, which led to sharp spike in prices of many bulk drugs at that time.

Pushing for improving the competitiveness of the Indian drug industry, pegged at over Rs 1,50,000 crore including exports, the Pharma department is likely to make a case for helping small and medium scale firms upgrade their good manufacturing practices and encourage R&D in the sector. It would also seek a mechanism to institutionalize coordination of different ministries that deal with pharma and healthcare.

"We would seek a formal arrangement to make inter-departmental coordination a rule rather than exception. Today, it happens largely on a case-to-case basis whenever the need arises. But because the policymaking mandate in this space is divided between different bits, such as the ministry of health, Drug Controller General of India, Department of Pharma, National Pharma Pricing Authority, to some extent department of Industrial policy and promotion, it's important to create an institutional mechanism to facilitate closer working between these different arms of the government," the official said.

Source: *The Economic Times, 31st May 2014*

Drug Helps Breast Cancer Patients Preserve Fertility

Women undergoing chemotherapy for certain types of breast cancer may be able to preserve their fertility by adding the drug goserelin to their treatment, researchers said on Friday.

The cancer drug also appeared to improve survival, according to the results of a phase III clinical trial unveiled at the American Society for Clinical Oncology annual meeting. Early menopause can be triggered by breast cancer chemotherapy. Some women resume menstruating after chemo and can have children but many cannot. These findings are going to change our clinical practice, ' said study author Kathy Albain of Loyola University Medical Centre.

About 15% of young women have cancers that are hormone receptor negative, and these are the women who could benefit from taking goserelin to put the ovaries at rest during chemo, researchers said.

The study assigned 131 patients to receive chemotherapy and 126 to receive chemotherapy plus goserelin by injection once every four weeks. Around 45% women on chemo stopped menstruating after two years. Only 20% of the women receiving goserelin had stopped menstruating. Pregnancies were twice as common in the gosorelin group – 21% compared to 11%. And 89% of the women taking gosorelin had no signs or symptoms of cancer four years later.

Source: *The Times of India, 1st June 2014*

Anti-Diabetic Drug May Slow Aging

Metformin, the world's most widely used antidiabetic drug, may slow aging and increase lifespan, a new study suggests.

Researchers at the University of Leuven, Belgium decoded the mechanism behind metformin's age-slowing effects: the drug causes an increase in the number of toxic oxygen molecules released in the cell and this, surprisingly, increases cell robustness and longevity in the long term.

“As long as the amount of harmful oxygen molecules released in the cell remains small, it has a positive long term effect on the cell. Cells use the reactive oxygen particles to their advantage before they can do any damage,” said doctoral researcher Wouter De Haes.

“Metformin causes a slight increase in the number of harmful oxygen molecules. We found that this makes cells stronger and extends their healthy lifespan,” he added.

The researchers studied metformin's mechanism in the tiny roundworm Caenorhabditis elegans, an ideal species for studying aging because it has a lifespan of only three weeks. PTI

Source: *The Times of India, 4th June 2014*

Japan's Meiji Buys Medreich for Rs 1720 Cr

Pharma co's partners include GSK, Adcock Ingram, Pfizer, Sanofi, Novartis & Mylan, among others Japanese pharmaceutical major Meiji Holdingshas bought out Temasek-backed Medreich for $290 million (Rs 1,720 crore), the company informed Tokyo Stock Exchange on Wednesday, marking the first inbound investment in the Indian pharmaceutical sector by a Japanese company after Daiichi Sankyo's ill-fated acquisition of Ranbaxy in 2008.

Temasek, the private equity arm of the Singapore government, had invested Rs 109 crore in 2005 for a 25 per cent stake in Medreich which manufactures therapeutic generic and branded drugs. Temasek has made almost a four-fold return on its investment in the company by getting around Rs 430 crore from this transaction.

"Meiji, through its operating subsidiaries, Meiji Seika Pharma, has bought out 100 per cent stake in Medreich as it plans to enter the Indian market," said a person with direct knowledge of the deal. As part of the Japanese company's 2020 vision, it wants to expand to newer geographies, the person explained.

Medreich sells generic pharmaceuticals products to Europe, Asia, and Africa. Its main business partners include GSK, Adcock Ingram, Pfizer, Sanofi, Novartis and Mylan, among others. "The Meiji Group wants to enter the global generics field, particularly in Asia and emerging countries," the company's release in Japanese read.

The $5-billion Meiji Group's acquisition signals a return of long term confidence in the Indian pharmaceutical sector. Last month, in an all-share transaction, Sun Pharmaceutical Industries bought generic drug maker Ranbaxy Laboratories for $3.2 billion. Daiichi had paid $4.2 billion for a 69 per cent stake in Ranbaxy in 2008.

"If multinational companies have to make a mark in India, they cannot grow organically, and if they have to acquire companies, they will trigger the foreign direct investment issue," said Sujay Shetty, head of

life sciences at consultancy PwC when the Ranbaxy-Sun Pharma deal was announced.

Investment bank JP Morgan was the advisor to Meiji Holdings and NM Rothschild advised the investors and promoters of Medreich. Medreich, founded in 1976 by Rajeev Mehta, Keith De Souza and CP Bothra, has the capability to produce over 500 products with an R& D team of over 75 scientists. The company has been profitable since its inception. The company's branding and name will not be changed post the acquisition, Meiji Holdings has said.

For Temasek, this marks a blockbuster exit from an Indian company. Temasek has made several large private equity investments in India, including in Bharti Airtel, Tata Teleservices in Maharashtra, GMR Energy, National Stock Exchange and Godrej Consumer Products.

Source: *The Economic Times, 13th June 2014*

Cheaper, More Effective Oral Cholera Vaccine on The Cards

In four years' time, the world is likely to get a new oral cholera vaccine that will have a greater impact at a significantly lower cost. Hilleman Laboratories, a joint-venture partnership between pharma major Merck and U.K.-based Wellcome Trust, on Tuesday announced a collaboration with Gotovax AB.

Gotovax AB is a University of Gothenburg Biopharma company.

According to Hilleman Labs CEO Davinder Gill, the new vaccine, which is currently undergoing final pre-clinical studies, would provide 85-90 per cent higher protection in the first six months. It would also provide extra protection against diarrhoea caused by the bacteria Enterotoxigenic Escherichia coli.

Speaking to *The Hindu*, Dr. Gill said the aim was to make the price significantly lower than the lowest in the market, thereby expanding accessibility. Currently, a vaccine manufactured by Shantha Biotech was the lowest, at $1.85 per dose, he said. The final price would be lower and be made available for both mass public health vaccination campaigns and the open market, Dr. Gill said. While the prophylactic would be targeted at children aged between 1 and 14 years, it would be suitable for adults too, Dr. Gill said. “Our 'thermostable technologies will enhance the stability of the formulation, making the vaccine more attractive for worldwide stockpiling purposes,” he said.

Cholera, with an estimated mortality of 1-1.2 lakh deaths, is endemic to over 50 countries.

Source: *The Hindu, 18th June 2014*

Anti-Diabetic Formula is Largest Selling Drug

In a grim reminder of the rise of lifestyle diseases, particularly diabetes, an anti-diabetic molecule has for the first time become the largest-selling formulation in the domestic pharma retail market.

The formulation, which is also the most-prescribed anti-diabetic drug—a combination of glimepiride and metformin (marketed as Glycomet GP and Gluconorm-G)—has dethroned the popular class of anti-infective medicines, led by widely-used medicine brands like GSK's Augmentin (a combination of amoxycillin and clavulanic acid) in May.

Widely-prescribed anti-diabetic drugs (glimepiride plus metformin) clocked sales of Rs 105 crore, surpassing the anti-infective therapy at Rs 103 crore, in the pharma retail market valued at Rs 6,636 crore, in May this year. Analysts tracking the market said the anti-infective therapy had always been ranked on top.

The primary reason for the anti-diabetic molecule taking the lead is because of its faster growth, as well as the anti-infective molecule coming under price control.

The anti-diabetic sub-class, a combination of glimepiride and metformin, registered a growth of 34.4% in May, as against a meager growth of nearly 4% in the anti-infective amoxycillin and clavulanic acid market, figures culled from market research firm, AIOCD AWACS said.

Interestingly, the anti-infective molecule witnessed a downward revision in prices over the last few months as it came under price control, with prices declining by over 9% for the 12-month period ended May 2014, while its volumes grew around 7% in the same period. As against this, the anti-diabetic sub-group clocked robust sales month on month, posting a volume growth of 26%, while its prices jumped 6.4% (MAT, May 2014).

Not only has the anti-infective sub-group lost value because of price control, but the anti-diabetic therapy is growing faster, Hari Natarajan VP, AIOCD AWACS told TOI, adding the overall pharma retail market seemed to be showing signs of revival in May, with a strong growth registered at 8.1%, as against 5% witnessed in April.

In fact, sales of diabetes molecule have been climbing up over the last few years, and have shown a steady increase month on month from Rs 97 crore in December.

Doctors say that the anti-diabetes combination is widely used as its affordable and effective.

“While metformin is the best drug to treat diabetes, combination therapy with glimepiride is required in most cases sooner or later. In India, this combination is most commonly-used since it is cheap and effective. Because of unabated diabetes increasing use of this combined therapy is understandable", says Dr Anoop Misra, director of Delhi-based Fortis-CDOC hospital for diabetes.

Source: *The Times of India, 18th June 2014*

Dr Reddy's Recalls Blood Pressure Drug From US Market

Dr Reddy's Laboratories is recalling 13,560 bottles of the high blood pressure drug metoprolol succinate in the US market after it failed a dissolution test.

Metoprolol succinate extended release is a cheaper generic form of AstraZeneca's Toprol XL.

The recall was voluntarily started by Dr Reddy's on May 23, and posted on the FDA website on Thursday.

Wockhardt had also recalled 1,09,744 bottles of the same drug last month citing the same reason.

Source: *The Times of India, 20th June 2014*

Pharmaceutical Firms Find It Hard to Exit Essential Drugs Market

Pharmaceutical companies having more than a 1% market share for any essential drugs may find it difficult to stop manufacturing those products. Since May, when the government brought into force a new drug-pricing system after a gap of 18 years, the National Pharmaceutical Pricing Authority has denied such requests whenever the market share of the essential drugs the companies wanted to discontinue was more than 1%, government officials told ET.

"If we allowed one such player with a significant market share to withdraw, we cannot stop other such players from doing it. This may create an exodus of many players from essential drugs, change the market dynamics drastically and even create a shortage," an official said. The pricing authority has internally set a 1% mark beyond which it refuses to grant permission for companies to exit unless it is assured that there would be no shortage of the drug in the market, he added.

According to Amit Backliwal of IMS Healthcare, a global pharma market research firm, a decision on this matter should be taken only after a detailed assessment of multiple factors like whether there were new treatments in the therapy, changes in the prescription behaviour of physicians and the financial burden on a company from making such a product.

"By such an arrangement, the government wants to ensure there is no disruption in the availability of a particular essential drug in the market, which is what it is expected to do," Backliwal said. On the flip side, forcing companies to sell molecules or categories that are not performing well can lead to them unnecessarily getting burdened on their cost and overall business performance.

"Once a company stops marketing their drugs, in a branded generics market like India, it will slip in rank and lose market share below 1%," he said. Under the latest pricing policy, pharma firms cannot just quit making essential drugs citing non-viability.

They would have to issue a public notice and alert the government about their decision at least six months in advance. The government can ask a company to continue producing an essential drug at a certain level for another year in public interest. The government can do this for any of the 348 drugs that are part of the National List of Essential Medicine.

Drug makers also have to disclose on a quarterly basis the levels of essential drugs and bulk drugs they are producing to enable the government to monitor their availability in the Rs 75,000-crore domestic drug market. The need for such a move was felt in the latest pricing policy as many pharma firms had stopped making and investing in drugs that were put under regulations in the current price system. The companies claim they have been forced to discontinue as these drugs are no longer economically viable.

Source: *The Economic Times, 24th June 2014*

Veterinary Drug Given to Patients in Jodhpur

Patients at a government hospital here were administered injections of a veterinary drug, procured under the government's free medicine scheme, last week. While no adverse reactions have been reported by the patients who received shots intended for animals, the Rajasthan government has suspended the store keeper and ordered a high-level inquiry into the lapse.

The matter became public on Sunday when the attendant of a patient admitted to the Mathura Das Mathur (MDM) Hospital found that the injection being administered to the patient was meant for use on animals only. The drug (Meropenem) was procured over the hospital counter, free of cost under the Chief Minister's Free Medicine Programme, which was launched by the previous UPA government.

The free medicine scheme, applicable only in public health facilities, has been continued by the Vasundhara Raje government.

Meropenem is a antibiotic used to cure acute bacterial infections in the kidneys, lungs and other vital organs. It is also used in veterinary medicine.

The government has appointed a high-level committee, comprising the Drugs Controller and medical specialists, to enquire into the matter. In addition to monitoring reports of adverse reactions, the committee will also probe whether and how many such injections were supplied to other health facilities and administered to patients. The committee has been asked to submit its report within 7 days, an official release issued by the State government said.

Unconfirmed reports suggested that 1,000 such injections had been procured by the government, 400 of which had been administered. The rest were seized following uproar in the city. Unaware that that the supplier was delivering 'Meropenem' injections meant for animals, the hospital staff continued to use it on patients for the past three days.

Officials maintain that the patient can be deemed safe if he has not had a reaction to the injection in 8 hours.

Source: *The Hindu, 24th June 2014*

Drugs for Human Use, Label Was Wrong

While the enquiry committee is yet to initiate proceedings into the administration of veterinary injection in humans at a government hospital here, the manufacturers have said the drug was indeed meant for humans.

The warning label was wrongly put, Himachal Pradesh-based Pushkar Pharma that manufactures the injection 'Meropenem,' said in an email to the hospital authorities.

More than 150 patients at Mathura Das Mathur Hospital here were given this shot in the past one week. The hospital is said to have procured 1000 vials on June 16. The unused vials were seized from the hospital and a few more from a company that procured the drug from the pharma company.

The pharmacist and storekeeper of the hospital have already been placed under suspension and a high-level inquiry has been ordered. A report has to be submitted within seven days.

An FIR is likely to be lodged after the enquiry report comes. Wrong labelling too is a serious offence under the Drugs and Cosmetics Act, 1940 and can attract suspension or withdrawal of license to the manufacturing company.

Source: *The Hindu, 25th June 2014*

10 இடங்களில் 'அம்மா' மருந்தகம் திறப்பு

சென்னை, ஜூன் 27– கூட்டுறவுத் துறை சார்பில், 10 இடங்களில் அமைக்கப்பட்டுள்ள, 'அம்மா' மருந்தகத்தை, முதல்வர் ஜெயலலிதா, நேற்று, 'வீடியோ கான்பரன்ஸ்' மூலம் திறந்து வைத்தார்.

தமிழகத்தில், நியாயமான விலையில், தரமான மருந்துகளை விற்பனை செய்ய, கூட்டுறவுத் துறையில், புதிதாக, 'அம்மா' மருந்தகம் துவக்க, முதல்வர் ஜெயலலிதா உத்தரவிட்டார்.

அதன்படி, காஞ்சிபுரம் மாவட்டம், நங்கநல்லூர் கூட்டுறவு பண்டக சாலை; கடலூர் வேளாண்மை உற்பத்தியாளர் கூட்டுறவு விற்பனை சங்கம்; ஈரோடு வேளாண்மை உற்பத்தியாளர் கூட்டுறவு விற்பனை சங்கம்; மதுரை மாவட்டம், பேரையூர் வேளாண்மை உற்பத்தியாளர் கூட்டுறவு விற்பனை சங்கம்; கே.கே., நகரில் அமைந்துள்ள, மதுரா கோட்ஸ் பணியாளர் கூட்டுறவு பண்டக சாலையில், அம்மா மருந்தகம் அமைக்கப்பட்டது.

சேலம் என்.ஜி.ஒ., கூட்டுறவு பண்டக சாலை, தாரமங்கலத்தில் உள்ள, சேலம் மாவட்ட நுகர்வோர் கூட்டுறவு மொத்த விற்பனை பண்டக சாலை; காரைக்குடியில் உள்ள, சிவகங்கை நுகர்வோர் கூட்டுறவு மொத்த விற்பனை பண்டக சாலை; விருதுநகர் மாவட்டம், சிவகாசி கூட்டுறவு பண்டக சாலை, ஸ்ரீவில்லிபுத்தூர் வேளாண்மை உற்பத்தியாளர் கூட்டுறவு விற்பனை சங்கம் ஆகியவற்றிலும், தலா 10 லட்சம் ரூபாய் செலவில், அம்மா மருந்தகம் அமைக்கப்பட்டது.

இவற்றை, முதல்வர் ஜெயலலிதா, நேற்று, தலைமைச் செயலகத்தில், 'வீடியோ கான்பரன்ஸ்' மூலம், திறந்து வைத்தார்.

இந்த மருந்தகங்களில், உயிர் காக்கும் மருந்துகளை, சிறப்பாக பாதுகாக்க, குளிர்சாதனப் பெட்டி வழங்கப்பட்டுள்ளது. கூட்டுறவு சங்கங்களில் பணிபுரியும், கம்ப்யூட்டர் பயிற்சி பெற்ற விற்பனையாளர்களோடு, 'அவுட் சோர்சிங்' முறை மூலம், மருந்தாளுனர்களும் பணி அமர்த்தப்பட்டுள்ளனர்.

தற்போது, 10 அம்மா மருந்தகங்கள் திறக்கப்பட்டுள்ளன. விரைவில், 90 அம்மா மருந்தகங்கள் திறக்கப்பட உள்ளன. இதற்கு தனியே நிதி ஒதுக்கப்பட்டு உள்ளது.

Source: Dinamalar, 27th June 2014.

Important Announcement

The next training programme on the subject of **"Production Management"** will be conducted by the Pharma Knowledge and Training Institute (Finishing School) from 1st week of October 2014 for a period of 4 weeks. The training programme will included important lectures on manufacture of oral dosage forms like Tablets, Capsules, Liquids and External Preparations. The faculties are from the pharmaceutical companies in and around chennai. The training programme will include practical demonstrations for 2 weeks. The lecture programme will be held in our trust office. The eligibility criteria for the participants are as follows:

1. Bachelor of Pharmacy / Master in Pharmacy (from Tamilnadu pharmacy colleges).
2. The Pharmacy students in final year B. Pharm or M. Pharm who have appeared / will be appearing the final exam in 2014 (from Tamilnadu pharmacy colleges).

The candidates who are interested to participate in the training programme may please contact our trust office and also to send email. The principles of pharmacy colleges are requested to enlighten the training programme to the students. The maximum number will be 20 trainees for the training programme.

There will be a placement interview at end of the training programme for the trainees.