Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

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EDITORIAL

Dear Readers,

We are happy to publish the 24th issue of Pharma Web Newsletter for Oct – Dec 2014.

In this issue we have published the salient features of second Training programme conducted by Pharma Knowledge and Training Institute (Finishing School) on the subject of Industrial Orientation Training on Production Management Personnel.

We have published two articles namely *"Schedule M Pertaining to Production Under Drugs & Cosmetics Act"* authored by **Mr. M. Bhaskaran**, Director of Drugs Control, TN, [Retd] and *"MHRA V/S Schedule M Requirements and Guidelines for Oral Dosage Forms and External Preparations"* by **Mr. N. Chandar**, Pharma Consultant. We have also published notification issued by Ministry of Health and Family Welfare, Govt. of India. The notifications reveal the following facts

- GSR 889(E) dated 12.12.2014 on the subject of Clinical Trial

We have also published list of Drugs & Pharmaceuticals covered under price control order.

The salient features of Drugs and Cosmetics Act Amendment Bill 2015 as well as National Health Policy 2015 are highlighted in this issue.

This issue published the details of Pharmacy Week Celebration celebrated by Indian Pharmaceutical Association, TN Branch. The Chief Guest for the function was Dr. V. K. Subburaj, I.A.S, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, New Delhi. Various medals for the outstanding pharmacy students instituted by our Trust for the Pharmacy colleges in Tamilnadu were distributed during this function. The Chief editor of Pharm Web Newsletter has been awarded the best pharmacist for the year 2014.

Important events as well as news items on various technical issues are highlighted in this issue

With Best Regards,
R. NARAYANASWAMY
Chief Editor

ARTICLES

SCHEDULE M PERTAINING TO PRODUCTION UNDER DRUGS & COSMETICS ACT

By

M. Bhaskaran,

Director of Drugs Control, TN, [Retd]

(Lecture Delivered on 6th October 2014, during the Training Programme on Production)

Laws relating to manufacture of Drugs

- The manufacture of drug is regulated under
- Drugs & Cosmetics Act 1940 and Rules 1945 thereunder
- Drugs [Prices control] order 2013
- Drugs & Magic Remedies [Objectionable Advertisement]Act 1954
- Narcotic Drugs & Psychotropic Substances Act

SCHEDULE M

- (See rule 71, 74, 76, and 78 of Drugs & cosmetic Rules 1945 for manufacture)
- GOOD MANUFACTURING PRACTICES AND REQUIREMENTS OF PREMISES, PLANT AND EQUIPMENT FOR PHARMACEUTICAL PRODUCTS

Note: To achieve the objectives, each licensee shall evolve appropriate methodology, systems and procedures which shall be documented and maintained for inspection and reference and the manufacturing premises shall be used exclusively for production of drugs and/or no other manufacturing activity shall be undertaken therein.

Part I –GMP for premises and materials

- General requirements
- Location and surroundings.-
- The factory building(s) for manufacture of drugs shall be so situated and shall have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious, odour, fumes, excessive soot, dust, smoke, chemical or biological emissions.

Buildings and premises:-

- The building(s) used for the factory shall be designed, constructed, adapted and maintained to suit the manufacturing operations so as to permit production of drugs under hygienic conditions. They shall conform to the conditions laid down in the Factories Act, 1948 (63 of 1948).

- The premises used for Manufacturing, processing, warehousing, packaging, labeling and testing purposes shall be
- compatible with other manufacturing operation
- Adequate working space
- Designed to prevent entry of insects etc
- Air-conditioned, wherever prescribed
- Provided with adequate drainage system
- Walls and floor shall be smooth, washable, coved and shall permit easy and effective cleaning and disinfection

- Water system
- Validated system for treatment of water
- Comply to pharmacopoeial specification
- Water storage tanks shall not affect quality of water, ensuring freedom from microbiological growth
- Disposal of waste
- Comply to pollution control board norms
- Shall be as per Bio-medical waste [management &handling rules 1996
- Warehousing area
- Adequate area to allow sufficient and orderly warehousing
- Designed and adapted to ensure good storage conditions-clean , dry, acceptable temperature limits—with monitoring & recording
- Receiving & despatch bays

- Quarantine areas
- Sampling areas
- Area for rejected/recall/returned materials
- Safe, separate & secure area for packing materials
- Separate dispensing area for Beta lactum, sex hormones, cytotoxic substances
- Pest control – regular, atleast once a year
- Production area
- Designed to allow Uniflow with logical sequence of operations
- Avoid risk of cross contamination
- Working and in-process space shall be adequate
- Pipe-work ,electrical fittings ,ventilation openings shall be designed, fixed & constructed to avoid accumulation of dust

- Ancillary areas
- Rest & refreshment rooms
- Facilities for changing, storing clothes and for washing and toilet purpose—easily accessible & adequate number
- Maintenance workshops
- Animal house –isolated from other areas –conform to Rule 150-C[3] of D& C Rules 1945

- Quality control area
- Independent of production area
- Separate area for each type of analysis & separate instrument room
- Adequate area to avoid mixup & cross contamination with separate area to keep test samples, retained samples, reference standards, reagents and records separate air handling for biological, microbiological & radio isotopes testing areas

- Personnel
- Manufacture shall be under direct supervision of competent technical staff
- Head of Q.C shall be independent of manufacturing unit
- Personnel shall be suitably qualified & experienced, adequate & in direct propertion to workload
- Health ,clothing and sanitation of workers
- Personnel handling Betalactum antibiotics shall be free of penicillin sensitivity ; periodical testing of persons handling sex hormones, cytotoxic drugs

- Medical examination at the time of employment and then periodically with proper records of the same
- Uniform for all
- No smoking, eating, drinking, chewing & personnel medicines in the Unit
- Manufacturing operation and controls
- All operations under the supervision of competent approved technical staff—validation of each critical step by approved staff---labeling of all containers/vessels indicating their status

- Precautions against cross contamination and mix-up—by proper air handling systems, pressure differential, segregation, status labeling, cleaning with proper records & SOPS
- Packaging operations, line clearance
- Sanitation in the manufacturing premises
- Manufacturing premises –clean, maintained in orderly manner
- Manufacturing area—not used for storage of materials --but only for material being processed
- Routine sanitation programme
- Adequate working space and with in-process storage space
- Production area –well lit

- Raw materials
- Keep inventory of all raw materials and records as per Schedule U
- Raw material quarantine ,stored in proper condition—stock rotation by "first in /first expiry –first out " principle
- Purchased from approved sources ,directly from producers—examination of each consignment —proper labeling indicting their status
- Adequate area for raw material storage-under test, approved & rejected
- All materials to be released by Q.C with in shelf life— shelflife of formulation shall not exceed that of active raw materials
- All raw materials to be stored on raised platform/racks

- Equipment
- located, designed, constructed, adapted and maintained to suit the operations—effective cleaning & maintenance to avoid cross contamination/mixup, build –up of dust/dirt
- Calibration of equipment in conformity with SOP
- Part of equipment coming in contact with product shall be non reactive, additive or adsorptive —removal of defective equipment shall be removed & labeled

- Documentation and records
- Essential part of Q.A related to all aspects of G.M.P—documents designed, prepared, reviewed & controlled—shall be approved, signed & dated—shall specify the title, nature & purpose
- Records shall be maintained for atleast one year after the expiry of the finished product

- Labels and other printed materials
- Labels shall be in bright colors—legible manner—carry all prescribed details
- Different color coded labels for equipment/containers indicating stage-labels shall be stored separately to avoid mixup
- Shall be released only after QC approval
- Records shall be maintained –qty issued, used, unused/rejected. Unused/rejected label shall be destroyed and recorded

- Quality Assurance
- Wide ranging concept concerning all matters that individually & collectively influence the Quality of the product—designed taking into account GMP,--GLP,
- Ensures that product is not released without ensuring its compliance to prescribed standards for production, control and release of the product

- Self inspection and Quality audit
- Constitute a self inspection team
  - –to ensure compliance to GMP/GLP
  - _to audit any specific issue
  - -written instruction for self audit
- Quality control system
  - every unit shall have its own Q.C Lab with qualified staff
  - Q.C lab shall have chemical, instrumentation, microbiological & biological section
- SOP for all its activities -- authorized & dated specification
- product release only after certification by QC
- Maintain reference samples ,conduct stability studies, and
- Shall have reference standards, all relevant pharmacopoeias, text books etc

- Specification
  - For raw materials and packing materials
  - For product containers and closures
  - For in process and bulk products
  - For finished products
- Master formula records—

  for each product and batch size—prepared and endorsed by technical staff for production and QC giving all the particulars /standards relevant to the drug

- Packaging records
  - authorized packaging instruction for each product, pack size and type
  - Batch packaging records—packaging instruction and line clearance

- Batch processing records
  - based on master formula records
  - before starting new batch the work station /equipment shall be free of previous product
- Standard operating Procedures [SOP] and Records

  There shall be SOP for
  - Receipt of raw materials
  - Sampling
  - Batch numbering
  - Testing
  - Records of analysis

- Reference samples
- Each lot of active ingredient shall be retained for period of 3 months after the date of expiry of the last batch of the formulation from that ingredient
- Sample of finished formulation in the same container in which it is marketed

- Reprocessing and recoveries
- established, written procedures approved by QA
- An investigation in to the cause necessitating reprocessing
- Distribution records

  before release it must be approved by QC with pre-dispatch inspection

  records maintenance in such a way as to facilitate complete recall ,if required

- Validation and process validation
- Part of GMP & be as per predefined protocols
- Significant changes in manufacturing process, including equipment/materials shall be validated
- Product recalls
- Effective recall system to recall defective drugs with established SOP
- Effectiveness shall be evaluated from time to time
- Recalled products stored separately

- Complaints and adverse reactions
- Site master file
- It shall have information as
- General, Information, personnel, premises, equipment, sanitation, documentation, production, quality control, loan licence manufacture, self inspection and export of drugs

- Schedule M ,in addition ,specifies Specific requirements for each category of products
- Part IA for SVP/LVP/Sterile ophthalmic products
- Part IB for Tablets/Capsules
- Part IC for oral liquids
- Part ID for topical products
- Part IE for metered –dose –inhalers
- Part IF for API
- Part II specifies Requirements of plant and equipment for each category of drugs

WHO GMP

- World Health Assembly resolution –WHA22.50endorsed GMP as recommended by WHO
- Revised in 1975—WHA 28.65
- And second revision by 32 report of WHO Expert Committee
- Model certificate of GMP given in Technical report series 908 of 2003 This certificate is not part of WHO certification scheme on quality of pharmaceutical products in market

- For ,WHO GMP certification, in India, joint inspection of the manufacturing facility is carried out by a team of Inspectors of both CDSCO and State
- GMP inspection report format is specified in technical report 908
- Technical report 823 specifies the requirements for pharmaceutical product
- Technical report 822 gives the requirements for biological product

Certificate of pharmaceutical product

- This certificate conforms to the format recommended by the World Health Organization
- No. of certificate
- Exporting (certifying country):
- Importing (requesting country):
- 1. Name and dosage form of the product:
- 1.1. Active ingredient(s)[2] and amount(s) per unit dose[3]:
- For complete composition including excipients, see attached[4]:
- 1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] (yes/no)
- 1.3 Is this product actually on the market in the exporting country?
- If the answer to 1.2. is yes, continue with section 2A and omit section 2B.
- If the answer to 1.2 is no, omit section 2A and continue with section 2B[6]:

- 2.A.1. Number of product licence[7] and date of issue:
- 2.A.2. Product licence holder (name and address):
- 2.A.3. Status of product licence holder[8]: (Key in appropriate category as defined in note 8)
- 2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:
- 2.A.4. Is a summary basis for approval appended?[10] (yes/no)
- 2.A.5. Is the attached, officially approved product information complete and consonent with the licence?[11] (yes/no/not provided)
- 2.A.6. Applicant for certificate, if different from licence holder (name and address)[12]:
- 2.B.1. Applicant for certificate (name and address):
- 2.B.2. Status of applicant: (Key in appropriate category as defined in footnote 8)
- 2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]
- 2.B.3. Why is marketing authorization lacking? (not required/not requested/under consideration/refused)
- 2.B.4. Remarks[13]:

- 3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (yes/no/not applicable)[14]
- If not or not applicable, proceed to question 4.
- 3.1. Periodicity of routine inspections (years):
- 3.2. Has the manufacture of this type of dosage form been inspected? (yes/no)
- 3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15] (yes/no/not applicable)[14]

- 4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: (yes/no)
- If no, explain:
- Address of certifying authority:
- Telephone:
- Fax:
- Name of authorized person:
- Signature
- Stamp and date
- **Explanatory notes**
- This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
- Use, whenever possible, International Non proprietary Names (INNs) or national non-proprietary names.

- The formula (complete composition) of the dosage form should be given on the certificate or be appended.
- Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
- When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
- Sections 2A and 2B are mutually exclusive.
- Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

- Specify whether the person responsible for placing the product on the market:
  - manufactures the dosage form;
  - packages and/or labels a dosage form manufactured by an independent company; or
  - is involved in none of the above
- This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

- This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
- This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
- In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.

- Please indicate the reason that the applicant has provided for not requesting registration.
  - the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
  - the product has been reformulated with a view to improving its stability under tropical conditions;
  - the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
  - the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
  - any other reason, please specify.

- Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
- The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
- This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

MHRA v/s SCHEDULE M REQUIREMENTS AND GUIDELINES FOR ORAL DOSAGE FORMS AND EXTERNAL PREPARATIONS

By
N.Chandar
Pharma Consultant

(Lecture Delivered on 9th October 2014, during the Training Programme on Production)

Scope

- Comparison of MHRA vs Schedule M
- Requirements for
  - Oral Dosage forms
  - External Preparations

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Objectives

- Understand - Orange Guide
- Understand – Schedule M of Drugs and Cosmetics Act

- Be – follow the requirement for the manufacture of Oral Dosage Forms External Preparations

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MAJOR REGULATORY AGENCIES OF THE WORLD

USFDA(USA)	SFDA (China)
MHRA(UK)	NAFDAC(Nigeria)
TGA(Australia)	MEDSAFE(Newzeland)
CDSCO(India)	MHLW(Japan)
HEALTH CANADA(Canada)	MCAZ(Zimbabwe)
MCC(South Africa)	SWISSMEDIC(Switzerland)
ANVISA (Brazil)	KFDA(Korea)
EMEA (European Union)	MoH (Sri Lanka)

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OUR TOPIC TODAY

- MHRA & CDSCO
- What are MHRA & CDSCO
- History
- Functions &Responsibilities

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MHRA

- MHRA – Medicines and HealthCare Product Regulatory Agency
- Regulatory Authority of UK
- Has Close integration with EDQM – European Directorate for Quality Medicines

MHRA

- Till 2002 functioned as 2 Separate Agencies
  Medicines Control Agency and
  Medical Devices Agency
- Key objective is to protect the health of the public by ensuring that medicines, healthcare products and medical equipment are safe.
- All licensed medicines available in the UK are subject to rigorous scrutiny by the MHRA before they can be used by patients.

MHRA

- This ensures that the responsibility of the MHRA and the expert advisory bodies set up by the Medicines Act to ensure that the sometimes difficult balance between safety and effectiveness is achieved.
- MHRA experts assess all applications for new medicines to ensure they meet the required standards.
- This is followed up by a system of inspection and testing which continues throughout the lifetime of the medicine.

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MHRA

The roles of the MHRA are to:

- _ provide a system of post-marketing surveillance for reporting, investigating and monitoring of adverse drug reactions to medicines and medical devices;
- _ assess and, where appropriate evidence exists, authorize medical products for sale and supply in UK;
- _ oversee the Notified Bodies that audit medical device manufacturers;
- _ operate a quality surveillance system to sample and test medicines
- – to address quality defects

...continued

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MHRA

The roles of the MHRA are to: ...continued

- – to monitor the safety and quality of unlicensed products
- – investigate internet sales and potential counterfeiting of medicines
- _ regulate clinical trials of medicines and medical devices;
- _ monitor and ensure compliance with statutory obligations relating to medicines and medical devices;
- _ promote safe use of medicines and devices;
- _ manage the

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MHRA

- The MHRA also hosts and supports a number of expert advisory bodies, including the Commission on Human Medicines (which replaced the Committee on the Safety of Medicines in 2005), and the British Pharmacopoeia Commission.
- In addition, as part of the European system of medicines approval, the MHRA or other national bodies may be the Rapporteur or Co-rapporteur for any given pharmaceutical application, taking on the bulk of the verification work on behalf of all members, while the documents are still sent to other members as and where requested.

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MHRA

- **Inspection and Standards Division**
  The MHRA's Inspection and Standards Division is responsible for ensuring compliance with the regulations and standards that apply to the manufacture, control and supply of medicines on the UK market.
- **Inspectorate**
  The Inspectorate Group in the MHRA's Inspection and Standards Division is comprised of dedicated units for Good Manufacturing Practice (GMP),
- Good Distribution Practice (GDP),
- Good Laboratory Practice (GLP),
- Good Clinical Practice (GCP) and
- Good Pharmacovigilance Practice (GPvP).

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CENTRAL DRUG STANDARDS CONTROL ORGANISATION (CDSCO)

- The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act. CDSCO has six zonal offices, four sub-zonal offices, 11 port offices and six laboratories under its control

STATE LICENSING AUTHORITIES- INDIA

ANDAMAN &NICOBAR	MADHYA PRADESH
ANDHRA PRADESH	MAHARASHTRA
ARUNACHAL PRADESH	MANIPUR
ASSAM	MEGHALAYA
BIHAR	MIZORAM
CHANDIGARH ADMN.	NAGALAND
CHATTISGARH	NEW DELHI
DADAR &NAGAR HAVELI	ORISSA
DAMAN &DIU	PONDICHERRY
GOA	PUNJAB
GUJARAT	RAJASTHAN
HARYANA	SIKKIM
HIMACHAL PARDESH	TAMILNADU
JAMMU& KASHMIR	TELANGANA
JHARKHAND	TRIPURA
KARNATAKA	UTTAR PRADESH
KERALA	UTTARAKHAND
LAKSHADWEP	WEST BENGAL

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Functions of CDSCO and State Drug Control Authorities

Under the Drug and Cosmetics Act,

- **State Authorities**
  - Regulation of Manufacture,
  - Sale and Distribution of Drugs
- **Central Authorities**
  - Approval of New Drugs
  - Clinical Trials in the country
  - Laying down the standards for Drugs
  - Control over the quality of Imported Drugs,
  - Coordination of the activities of State Drug Control Organizations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.
  - Approval of licenses of specified categories of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

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Laboratories under CDSCO

- **Central Drugs Laboratory (CDL) Kolkata**
- **Central Drugs Testing Laboratory (CDTL) Chennai , Tamil Nadu**
- **Central Drugs Testing Laboratory (CDTL) Hyderabad, AP**
- **Central Drugs Testing Laboratory (CDTL) Mumbai**
- **Regional Drugs Testing Laboratory (RDTL) Guwahati**
- **Regional Drugs Testing Laboratory (RDTL)Chandigarh**
- **Central Drug Laboratory, CRI Kasauli**

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Central Drugs Laboratory (CDL)

- The Central Drugs Laboratory, Kolkata is the national statutory laboratory of the Government of India
- **Statutory Functions:**
- (a) Analytical quality control of majority of the imported Drug available in Indian market.
- (b) Analytical quality control of drug and cosmetics manufactured within the country on behalf of the Central and State Drug Controller Administrations.
- (c) Acting as an Appellate authority in matters of disputes relating to quality of Drug.

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Central Drugs Laboratory (CDL)

- **Other Functions:**
- (a) Collection, storage and distribution of International Standard International Reference Preparations of Drug and Pharmaceutical Substances.
- (b) Preparation of National Reference Standards and maintenance of such Standards. Maintenance of microbial cultures useful in drug analysis Distribution of Standards and cultures to State Quality Control Laboratories and drug manufacturing establishments.
- (c) Training of Drug Analysts deputed by State Drug Control Laboratories and other Institutions.
- (d) Training of World Health Organization Fellows from abroad on modern methods of Drug Analysis.
- (e) To advise the Central Drug Control Administration in respect of quality and toxicity of drug awaiting license.

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Central Drugs Laboratory (CDL)

Other Functions: continued

- (e) To advise the Central Drug Control Administration in respect of quality and toxicity of drug awaiting license.
- (f) To work out analytical specifications for preparation of Monographs for the Indian Pharmacopoeia and the Homoeopathic Pharmacopoeia of India.
- (g) To undertake analytical research on standardization and methodology of Drug and cosmetics.
- (h) Analysis of Cosmetics received as survey samples from Central Drug Standard Control Organization.

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Central Drugs Laboratory (CDL)

Other Functions: continued

- (i) Quick analysis of life saving Drug on an All-India basis received under National Survey of Quality of Essential Drug Program from Zonal Offices of Central Drug Standard Control Organization.
- In addition to the above functions the Central Drug Laboratory also actively collaborates with the World Health Organization in the preparation of International Standards and Specifications for International Pharmacopoeia. It also undertakes collaborative study on behalf of the Indian Pharmacopoeia Committee. The senior Officers of the Laboratory have been appointed as Government Analysts on behalf of most of the States of the Union for analysis of drug samples.

Central Drugs Testing Laboratory (CDTL)

- **Chennai , Tamil Nadu**
- **Hyderabad, AP**
- **Mumbai**
- The major functions of the laboratory include:
- Testing of imported bulk drugs and formulations referred by ADCs, Mumbai, Nhava Sheva & Chennai, Survey and Watchers samples referred by Deputy Drugs Controller (India), West Zone. Lately, new drugs and formulations are also being referred by the Drugs Controller General (India). The laboratory is notified as Appellate Laboratory for Copper T Intra-Uterine Contraceptive Device and Tubal Rings under the Drugs and Cosmetics Rules, (Medical Stores) & Regional Directors of Department of Family Welfare and procurement and field samples of Oral Contraceptive Pills, Copper T and Tubal Rings referred by the Dept. of Family Welfare.

Regional Drugs Testing Laboratory(RDTL)

- **Guwahati**

Statutory Function:
a. Analytical quality control of drugs and cosmetic manufactured within the country on behalf of the Central and State Drugs Controller Administration.
b. To assists the Central Drugs Standard Control Organization in the testing of Drugs and cosmetic.

- **Chandigarh**

Central Drug Laboratory, CRI Kasauli

Central drug laboratory at CRI Kasauli is a Central laboratory engaged in the testing of vaccines.

- i) Sera
- ii) Solution of serum proteins intended for injection
- iii) Vaccines
- iv) Toxins
- v) Antigens
- vi) Anti-toxins
- vii) Sterilized surgical ligature and sterilized surgical suture
- viii) Bacteriophages, including Oral Polio vaccine.

Indian Pharmacopoeial Commission(IPC)

- Indian Pharmacopoeial Commission functions are :
- a) To develop comprehensive monographs for drugs to be included in the Indian Pharmacopoeia, and to keep them updated by revision on a regular basis.
- b) To accord priority to monographs of drugs included in the national Essential Drugs List and their dosage forms.
- c) To prepare monographs for products that have normally been in the market for not less than 2 years
- d) To give special attention to the methods of manufacture used by the indigenous industry in selecting the pharmacopoeia tests for monitoring the toxic impurities of the concerned drug.
- e) To take note of the different levels of sophistication in analytical testing/instrumentation available while framing the monographs.

Indian Pharmacopoeial Commission (IPC)

- Indian Pharmacopoeial Commission functions –continued
- f) To accelerate the process of preparation, certification and distribution of IP Reference Substances, including the related substances, impurities and degradation products required.
- g) To collaborate with pharmacopoeias like the Ph Eur, BP, USP, JP and International Pharmacopoeia with a view to harmonizing with global standards.
- h) To organize educational programs and research activities for spreading and establishing awareness on the need and scope of quality standards for drugs and related articles/ materials.

Drugs and Cosmetics Act 1940 and Rules 1945

- Schedule M
- PART 1 - GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS
- Part 1 A to 1 F - SPECIFIC REQUIREMENTS FOR MANUFACTURE DIFFERENT CATEGORY OF PRODUCTS
- PART II - REQUIREMENTS OF PLANT AND EQUIPMENT

Topics MHRA

1 Quality Management
2 Personnel
3 Premises and Equipment
4 Documentation
5 Production
6 Quality Control
7 Contract Manufacture and Analysis
8 Complaints and Product Recall
9 Self Inspection

Topics Schedule M

1. **GENERAL REQUIREMENTS**
2. **2. *Warehousing Area.* -**
3. ***Production area.* -**
4. ***Ancillary Areas.* –**
5. ***Quality Control Area.*-**
6. ***Personnel.*-**
7. ***Health, clothing and sanitation of workers.* -**
8. ***Manufacturing Operations and Controls.* -**
9. ***Sanitation in the Manufacturing Premises.* -**
10. ***Raw Materials.* -**
11. ***Equipment.* -**
12. ***Documentation and Records.***
13. ***Labels and other Printed Materials.***
14. ***Quality Assurance.***
15. ***Self Inspection and Quality audit***
16. ***Quality Control System.***
17. ***Specification***
19. ***Packing Records.* -**
20. ***Batch Packaging Records.***
21. ***Batch Processing Records***
22. ***Standard Operating Procedures (SOPs) and Records,***
23. ***Reference Samples.* -**
24. ***Reprocessing and Recoveries.* -**
25. ***Distribution records:***
26. ***Validation and process validation.* -**
27. ***Product Recalls.* -**
28. ***Complaints and Adverse Reactions.***
29. ***Site Master File***

Schedule M

- **PART 1**
- GOOD MANUFACTURING PRACTICES FOR PREMISES AND MATERIALS**.**
- 1. GENERAL REQUIREMENTS
- 1.1. *Location and surroundings.*-
- 1.2. *Building and premises.*-

  The building shall be designed, constructed, adapted and maintained to suit the manufacturing operations & production of drugs under hygienic conditions.

  They shall conform to the conditions laid down in the Factories Act, 1948 (63 of 1948)
- 1.3 *Water System.* –

  shall be validated system for treatment of water

  Purified Water conforming to Pharmacopoeial specification.

  Purified Water shall only be used for all operations except washing and cleaning operations

Schedule M

- PART 1 – continued
- 1.4. *Disposal of waste.* -
- (i) The disposal of sewage and effluents (solid, liquid and gas) shall be in conformity with the requirements of Environment Pollution Control Board.
- (ii) All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 1996.
- (iii) Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste.
- (iv) Provisions shall be made for the proper and safe storage of waste materials awaiting disposal. Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations.

Schedule M

- PART 1 – continued
- 2. *Warehousing Area.* -
- 2.1 Adequate areas shall be for starting and packaging materials, intermediates, bulk and finished products, products in quarantine, released, rejected, returned or recalled, machine and equipment spare parts and change items.
- 2.2 Warehousing areas shall be clean, dry and maintained with acceptable temperature limits,
- 2.3 Receiving and dispatch bays shall be covered
- 2.4.Quarantine ,sampling, rejected, recalled or returned material.
- 2.5. Highly hazardous, poisonous and explosive materials shall be stored in safe and secure areas.
- 2.6. Separate dispensing areas for β (Beta) lactum, Sex hormones and Cytotoxic substances or any such special categories of product shall be provided with proper supply of filtered air and suitable measures for dust control to avoid contamination.

Schedule M

- PART 1 – continued
- *3. Production area.* -
- 3.1. The production area shall be designed in uni-flow and with logical sequence of operations.
- 3.2. Separate dedicated and self-contained facilities shall be made available for the production of penicillin or Beta-Lactum, sex hormones and cytotoxic substances.
- 3.3. Pipe-work, electrical fittings, ventilation openings and similar services lines shall be constructed to avoid creation of recesses.
- 4. *Ancillary Areas.* -
- 4.1 Rest and refreshment rooms shall be separate
- 4.2 Facilities for changing, storing clothes and for washing and toilet purposes shall be easily accessible. Toilets shall not be directly connected with production or storage areas.
- 4.3 Maintenance workshops shall be separate and away
- 4.4. Areas housing animals shall be isolated from other areas.

Schedule M

- PART 1 – continued
- 5. *Quality Control Area.*-
- 5.1. Quality Control Laboratories shall be independent of the production.
- 5.2 Quality Control Laboratories shall have sufficient and suitable storage space shall be provided for test samples, retained samples, reference standards, reagents and records.
- 5.3. Separate air handling units and other requirements shall be provided for biological, microbiological and radioisotopes testing areas.
- 5.4. Quality Control Laboratory shall be divided into separate sections i.e. for chemical, microbiological and wherever required, biological testing. The microbiology section shall have arrangements such as airlocks and laminar air flow work station, wherever considered necessary.

Schedule M

- PART 1 – continued
- 6. *Personnel.*-
- 6.1. The manufacture shall be conducted under the direct supervision of competent technical staff with prescribed qualifications and practical experience in the relevant dosage and / or active pharmaceutical products.
- 6.2 The head of the Quality Control Laboratory shall be independent of the manufacturing unit.
- 6.3. Personnel for Quality Assurance and Quality Control operations shall be suitably qualified and experienced.
- 6.4. Number of personnel employed shall be adequate and in direct proportion to the workload.
- 6.6. The licensee shall ensure in accordance with a written instruction that al personnel in production area or into Quality Control Laboratories shall receive training appropriate to the duties and responsibility assigned to them. They shall be provided with regular in-service training.
- MHRA Article 51 of Directive 2001/83/EC,1 the Qualified Person(s)
- designated for the purpose.

Schedule M

PART 1 – continued

7. *Health, clothing and sanitation of workers*

- 7.1 The personnel handling Beta-lactum antibiotics shall be tested for Penicillin sensitivity before employment and those handling sex hormones, cytotoxic substances and other potent drugs shall be periodically examined for adverse effects.
- 7.2 Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from Tuberculosis, skin and other communicable or contagious diseases. Thereafter, at least once a year. Records shall be maintained thereof
- 7.3 All persons prior to and during employment shall be trained in practices which ensure personnel hygiene.
- 7.4 No person showing, at any time, apparent illness or open lesions which may adversely affect the quality of products, shall be allowed to handle starting materials, packing materials, in-process materials, and drug products until his condition is no longer judged to be a risk.

Schedule M

PART 1 – continued

- 7.5 All employees shall be instructed to report about their illness or abnormal health condition to their immediate supervisor so that appropriate action can be taken.
- 7.6 Direct contact shall be avoided between the unprotected hands of personnel and raw materials, intermediate or finished, unpacked products.
- 7.7 All personnel shall wear clean body coverings appropriate to their duties. Before entry into the manufacturing area, there shall be change rooms with adequate facilities for personal cleanliness such as wash basin with running water, clean towels, hand dryers, soaps, disinfectants, etc.
- 7.8 Smoking, eating, drinking, chewing or keeping plants, food, drink and personal medicines shall not be permitted in production, laboratory, storage and other areas where they might adversely influence the product quality.

Schedule M

PART 1 – continued

8. *Manufacturing Operations and Controls.* -

- 8.1 All manufacturing operations shall be carried out under the supervision of technical staff

  The contents of all vessels and containers used in manufacture and storage during the various manufacturing stages shall be conspicuously labeled
- 8.2. *Precautions against mix-up and cross-contamination*-
- 8.2.1. Shall prevent mix-up and cross-contamination of drug material and drug product by proper air-handling system, pressure differential, segregation, status labeling and cleaning. Proper records and Standard Operating Procedures thereof shall be maintained.
- 8.2.2 Processing of sensitive drugs like Beta-Lactum antibiotics, sex hormones and cytotoxic substances in segregated areas or isolated production areas within the building with independent air-handling unit and proper pressure differential. The effective segregation of these areas shall be demonstrated with adequate records of maintenance and services.

Schedule M

PART 1 – continued

- 8.2.3 To prevent mix-ups during production stages, materials under process shall be conspicuously labeled to demonstrate their status. All equipment used for production shall be labeled with their current status.
- 8.2.4 Packaging lines shall be independent and adequately segregated. It shall be ensured tat all left-overs of the previous packaging operations, including labels, cartons and caps are cleared before the closing hour.
- 8.2.5 Line clearance shall be performed according to an approximate check-list and recorded.
- 8.2.6 The correct details of all printing and overprinting shall be authorized in writing.
- 8.2.7 The manufacturing environment shall be maintained at the required levels of temperature, humidity and cleanliness.
- 8.2.9 There shall be segregated enclosed areas, secured for recalled or rejected material

Schedule M

PART 1 – continued

- 9. *Sanitation in the Manufacturing Premises.* -
- 9.1 The manufacturing premises shall be cleaned by validated cleaning procedure and maintained in an orderly manner.
- 9.2 The manufacturing areas shall not be used for storage of materials, except for the material being processed. It shall not be used as a general through fare.
- 9.3 A routine sanitation program shall be drawn up and observed, which shall be properly recorded and which shall indicate--
- (a) specific areas to be cleaned and cleaning intervals; cleaning procedure to be followed, including equipment and materials to be used for cleaning;
- (c) personnel assigned to and responsible for the cleaning operation.
- 9.4 The adequacy of the working and in-process storage space shall permit the orderly and logical positioning of equipment and materials so as to minimize the risk of mix-up & to avoid cross contamination, .
- 9.5 Production areas shall be well lit.

Schedule M

PART 1 – continued

- 10. *Raw Materials.* -
- 10.1 The licensee shall keep an inventory of all raw materials to be used and maintain records as per Schedule U.
- 10.2 All incoming materials shall be quarantined immediately after receipt or processing. All materials shall be stored to permit batch segregation and stock rotation by a .first in/first expiry. . .first out principle.
- 10.3 All incoming materials shall be purchased from approved sources.
- 10.6 Raw materials in the storage area shall be appropriately labeled with the following information:
- (a) designated name of the product and the internal code reference,
- (b) manufacturer's name, address and batch number;
- (c) the status of the contents (e.g. quarantine, under test, leased, approved, rejected); and the manufacturing date, expiry date and re-test date.

Schedule M

PART 1 – continued

- 10.7 There shall be adequate separate areas for materials .under test, approved. and .rejected. with arrangements and equipment to allow dry, clean and orderly placement of stored materials and products, wherever necessary, under controlled temperature and humidity.
- 10.8 Containers from which samples have been drawn shall be identified.
- 10.9 Only raw materials which have been released by the Quality Control Department and which are within their shelf-life shall be used. It shall be ensured that shelf life of formulation product shall not exceed with that of active raw materials used.
- 10.10 It shall be ensured that all the containers of raw materials are placed on the raised platforms/racks and not placed directly on the floor.

Schedule M

- PART 1 – continued
- 11. *Equipment.* -
- 11.1 Equipment shall be located, designed, constructed and maintained to suit the operations to be carried out. Layout and design of the equipment shall aim to minimize the risk of errors and permit effective cleaning and maintenance Each equipment shall be provided with a logbook,.
- 11.2 Balances and other measuring equipment of an appropriate range, accuracy and precision shall be available.
- 11.3 The parts of the production equipment that come into contact with the product shall not be reactive, additive .
- 11.4 To avoid accidental contamination, wherever possible, non-toxic/edible grade lubricants shall be used .
- 11.5 Defective equipment shall be removed from production and Quality Control areas or appropriately labeled.

Schedule M

PART 1 – continued

- 12. *Documentation and Records.* - Good Manufacturing Practices (GMP). Its aim is to define the specifications for all materials, method of manufacture and control
- 12.1 Documents designed, prepared, reviewed and controlled, wherever applicable, shall comply with these rules.
- 12.2 Documents shall be approved, signed and dated by appropriate and authorized persons.
- 12.3 Documents shall specify the title, nature and purpose. Reproduced documents shall be clear and legible. Documents shall be regularly reviewed and kept up to date. Any alteration made in the entry of a document shall be signed and dated.
- 12.4 The records shall be made or completed at the time of each operation. Records and associated Standard Operating Procedures (SOP) shall be retained for at least one year after the expiry date of the finished product.

Schedule M

- PART 1 – continued
- 13. *Labels and other Printed Materials*. -. The Printing shall be done in bright colors and in a legible manner. The label shall carry all the prescribed details about the product.
- 13.1. Different color coded tablets shall be used to indicate the status of a product (for example under test, approved, passed, rejected).
- 13.2 Printed packaging materials, product leaflets, relating to different products, shall be stored separately.
- 13.3 Prior to release, all labels for containers, cartons and boxes and all circulars, inserts and leaflets shall be examined by the Quality Control Department ..
- 13.4 Prior to packaging, it shall be ensured that samples are drawn from the bulk and duly tested, approved and released by the quality control personnel.

Schedule M

PART 1 – continued

- 13.5 Records of receipt of all labeling and packaging materials shall be maintained for each shipment received indicating receipt, control reference numbers and whether accepted or rejected. Unused coded and damaged labels and packaging materials shall be destroyed and recorded.
- 13.6 The label or accompanying document of reference standards and reference culture shall indicate concentration, lot number, potency, date on which containers was first opened and storage conditions, where appropriate.

Schedule M

- PART 1 – continued
- 14. *Quality Assurance*. -
- 14.1 The system of quality assurance appropriate to the manufacture of pharmaceutical products shall ensure that: -
- (a) the pharmaceutical products are designed and developed to meet the requirement of Good Manufacturing Practices and other associated codes such as those of Good Laboratory Practices and Good Clinical Practices
- (b) adequate controls on starting materials, intermediate products, and bulk products and other in-process controls, calibrations, and validations are carried out.
- (d) the finished product is correctly processed and checked in accordance with established procedures;
- (e) the pharmaceutical products are not released for sale or supplied before authorized persons have certified that each production batch as been produced and controlled in accordance with the requirements of the label claim and any other provisions relevant to production, control and release of pharmaceutical products.

Schedule M

- PART 1 – continued
- 15. *Self Inspection and Quality audit* -
- 15.1 To evaluate the manufacturer's compliance with GMP by a team of independent, experienced, qualified persons from within or outside the company.
- 15.2 Self-inspections shall be performed routinely and on specific occasions, like when product recalls or repeated rejections occur or when an inspection by the licensing authorities is announced..
- 15.3 Written instructions for self-inspection shall be drawn up which shall include the following: - (a) Personnel (b) Premises including personnel facilities.(c) Maintenance of buildings and equipment (d) Storage of starting materials and finished products (e) Equipment (f) Production and in-process controls (g)Quality control (h) Documentation (i) Sanitation and hygiene (j) Validation and revalidation programmes (k) Calibration of instruments or measurement systems. (l) Recall procedures (m) Complaints management (n) Labels control
- (o) Results of previous self-inspections and any corrective steps taken.

Schedule M

PART 1 – continued

- 16. *Quality Control System*. -.
- 16.1 Every manufacturing establishment shall establish its own quality control laboratory manner by qualified and experience staff.
- 16.2 The area of the quality control laboratory may be divided into Chemical, Instrumentation, Microbiological and Biological testing.
- 16.3 Adequate area having the required storage conditions shall be provided for keeping reference samples. The quality control department shall evaluate, maintain and store reference samples.
- 16.4 Standard operating procedures shall be available for sampling, inspecting and testing of raw materials, intermediate bulk finished products and packing materials and, wherever necessary, for monitoring environmental conditions.
- 16.5 There shall be authorized and dated specifications for all materials, products, reagents and solvents including test of identity, content, purity and quality. These shall include specifications for water, solvents and reagents used in analysis.

Schedule M

PART 1 – continued

- 16. *Quality Control System*. -.
- 16.6 No batch of the product shall be released for sale or supply until it has been certified by the authorized person(s) that it is in accordance with the requirements of the standards laid down.
- 16.7 Reference/retained samples from each batch of the products manufactured shall be maintained in quantity which is at least twice the quantity of the drug required to conduct all the tests, except sterility and pyrogen / Bacterial Endotoxin Test performed on the active material and the product manufactured. The retained product shall be kept in its final pack or simulated pack for a period of three months after the date of expiry.
- 16.8 Assessment of records pertaining to finished products shall include all relevant factors, including the production conditions, the results of in process testing, the manufacturing (including packaging) documentation, compliance with the specification for the finished product, and an examination of the finished pack. Assessment records should be signed by the in-charge of production and countersigned by the authorised quality control personnel before a product is released for sale or distribution.

Schedule M

PART 1 – continued

- 16.9 Quality control personnel shall have access to production areas for sampling and investigation, as appropriate.
- 16.10 The quality control department shall conduct stability studies of the products to ensure and assign their shell life at the prescribed conditions of storage. All records of such studies shall be maintained.
- 16.11 The in-charge of Quality Assurance shall investigate all product complaints and records thereof shall be maintained.
- 16.12 All instruments shall be calibrated and testing procedures validated before these are adopted for routine testing. Periodical calibration of instrument and validation of procedures shall be carried out.
- 16.13 Each specification for raw materials, intermediates, final products, and packing materials shall be approved and maintained by the Quality Control Department. Periodic revisions of the specifications shall be carried out wherever changes are necessary.
- 16.14 Pharmacopoeia, reference standards, working standards, references, spectra, other reference materials and technical books shall be available in the Quality Control Laboratory of the licensee.

Schedule M

- PART 1 – continued
- 17. *Specification*
- 17.1 *For raw materials and packaging materials.* - They shall include
- a) the designated name and internal code reference;
- b) reference, if any, to a pharmacopoeia monograph;
- c) qualitative and quantitative requirements with acceptance limits;
- d) name and address of manufacturer or supplier and original manufacturer of the material;
- e) specimen of printed material;
- f) directions for sampling and testing or reference to procedures;
- g) storage conditions; and
- h) maximum period of storage before re-testing.

Schedule M

PART 1 – continued

- *17.2 For product containers and closures.* -
- 17.2.1 all containers and closures intended for use shall comply with the pharmacopoeia requirements. Suitable validated test methods, sample sizes, specifications, cleaning procedure and sterilization procedure, wherever indicated, shall be strictly followed to ensure that these are not reactive, additive, absorptive, or leach to an extent that significantly affects the quality or purity of the drug. No second hand or used containers and closures shall be used.
- 17.2.2 whenever bottles are being used, the written schedule of cleaning shall be laid down and followed. Where bottles are not dried after washing, they should be rinsed with de-ionized water or distilled water, as the case may be.
- 17.3.*For in-process and bulk products.* - Specifications for in-process material, intermediate and bulk products shall be available. The specifications should be authenticated.

Schedule M

PART 1 – continued

- 17.4 *For finished products.* - Appropriate specifications for finished products shall include: -
- a) the designated name of the product and the code reference;
- b) the formula or a reference to the formula and the pharmacopoeia reference;
- c) directions for sampling and testing or a reference to procedures;
- d) a description of the dosage form and package details;
- e) the qualitative and quantitative requirements, with the acceptance limits for release;
- f) the storage conditions and precautions, where applicable, and
- g) the shelf-life.

Schedule M

PART 1 – continued

- 17.5 *For preparation of containers and closures.* –
- The requirements mentioned in the Schedule do not include requirements of machinery, equipment's and premises

- required for preparation of containers and closures for different dosage forms and categories of drugs. The suitability and adequacy of the machinery, equipment and premises shall be examined taking into consideration the requirements of each licensee in this respect.

Schedule M

PART 1 – continued

- 18. *Master Formula Records.*
- There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e. head of production and quality control. The master Formula shall include: -
- (a) the name of the product together with product reference code relating to its specifications;
- (b) the patent or proprietary name of the product along with the generic name, a description of the dosage form, strength, composition of the product and batch size;
- (c) name, quantity, and reference number of all the starting materials to be used. Mention shall be made of any substance that may .disappear. in the courts of processing.
- (d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.

Schedule M

- PART 1 – continued
- (e) a statement of the processing location and the principal equipment to be used.
- (f) the methods, or reference to the methods, to be used for preparing the critical equipments including cleaning, assembling, calibrating, sterilizing.
- (g) detailed stepwise processing instructions and the time taken for each step;
- (h) the instructions for in-process control with their limits;
- (i) the requirements for storage conditions of the products, including the container, labeling and special storage conditions where applicable;
- (j) any special precautions to be observed; and
- (k) packing details and specimen labels.

Schedule M

PART 1 – continued

- 19. *Packing Records.* -
- There shall be authorized packaging instructions for each product, pack size and type. These shall include or have a reference to the following: -
- (a) name of the product;
- (b) description of the dosage form, strength and composition;
- (c) the pack size expressed in terms of the number of doses, weight or volume of the product in the final container;
- (d) complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types with the code of reference number relating to the specifications of each packaging material.
- (e) reproduction of the relevant printed packaging materials and specimens indicating where batch number and expiry date of the product have been applied;
- (f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before the operations begin.

Schedule M

PART 1 – continued

- (g) description of the packaging operation, including any significant subsidiary operations and equipment to be used;
- (h) details of in-process controls with instructions for sampling and acceptance; and
- (i) upon completion of the packing and labeling operation, a reconciliation shall be made between number of labeling and packaging units issued, number of units labeled, packed and excess returned or destroyed. Any significant or unusual discrepancy in the numbers shall be carefully investigated before releasing the final batch.
- 20. *Batch Packaging Records.*
- 20.1 A batch packaging record shall be kept for each batch or part batch processed.
- 20.2 Before any packaging operation begins, check shall be made and recorded that the equipment and the work stations are clear of the previous products, documents or materials not required for the planned packaging operations, and that the equipment is clean and suitable for use

Schedule M

PART 1 – continued

- 21. *Batch Processing Records*
- 21.1 There shall be Batch Processing Record for each product. It shall be based on the relevant parts of the currently approved Master Formula. The method of preparation of such records included in the Master Formula shall be designed to avoid transcription errors.
- 21.2 Before any processing begins, check shall be performed and recorded to ensure that the equipment and work station are clear of previous products, documents or materials not required for the planned process are removed and the equipment is clean and suitable for use.
- 21.3 During processing, the following information shall be recorded at the time each action is taken and the record shall be dated and signed by the person responsible for the processing operations: -
- (a) the name of the product
- (b) the number of the batch being manufactured,
- (c) dates and time of commencement, of significant intermediate stages and of completion of production,

Schedule M

PART 1 – continued

. (d) initials of the operator of different significant steps of production and where appropriate, of the person who checked each of these operations,

- (e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed,
- (f) any relevant processing operation or event and major equipment used,
- (g) a record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained,
- (h) the amount of product obtained after different and critical stages of manufacture (yield),
- (i) comments or explanations for significant deviations from the expected yield limits shall be given.
- (j) notes on special problems including details, with signed authorization, for any deviation from the Master Formula.
- (k) addition of any recovered or reprocessed material with reference to recovery or reprocessing stages,

Schedule M

PART 1 – continued

- 22. *Standard Operating Procedures (SOPs) and Records, regarding.* -
- 22.1 Receipt of materials:
- 22.1.1 there shall be written Standard Operating Procedures and records for the receipt of each delivery of raw, primary and printed packaging material.
- 22.1.2 the records of the receipts shall include;
- (a) the name of the material on the delivery note and the number of containers;
- (b) the date of receipt;
- (c) the manufacturer's and/ or supplier's name;
- (d) the manufacturer's batch or reference number;
- (e) the total quantity, and number of containers, quantity in each container received;
- (f) the control reference number assigned after receipt;
- (g) any other relevant comment or information.

Schedule M

PART 1 – continued

- 22.1.3 There shall be written standard operating procedures for the internal labeling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.
- 22.1.4 There shall be Standard Operating Procedures available for each instrument and equipment and these shall be placed in close proximity to the related instrument and equipment.
- 22.2 *Sampling:* -
- 22.2.1 There shall be written Standard Operating Procedures for sampling which include the person(s) authorized to take the samples.

Schedule M

PART 1 – continued

- 22.2.2 The sampling instruction shall include:
- (a) The method of sampling and the sampling plan,
- (b) The equipment to be used,
- (c) any precautions to be observed to avoid contamination of the
- material or any deterioration in its quality,
- (d) The quantity of samples to be taken,
- (e) instructions for any required sub-division or poling of the samples,
- (f) The types of sample containers to be used,
- (g) any specific precautions to be observed, especially in regard to sampling of sterile and hazardous materials.

Schedule M

PART 1 – continued

- 22.3. *Batch Numbering.* -
- 22.3.1 There shall be Standard Operating Procedures describing the details of the batch (lot) numbering set up with the objective of ensuring that each batch of intermediate, bulk or finished product is identified with a specific batch number.
- 22.3.2 Batch numbering Standard Operating Procedures applied to a processing stage and to the respective packaging stage shall be same or traceable to demonstrate that they belong to one homogenous mix.
- 22.3.3 Batch number allocation shall be immediately recorded in a logbook or by electronic data processing system. The record shall include date of allocation, product identity and size of batch.

Schedule M

PART 1 – continued

- 22.4. *Testing:*
- 22.4.1 There shall be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed shall be recorded.
- 22.5 *Records of Analysis.* -
- 22.5.1 The records shall include the following data:
- (a) name of the material or product and the dosage form
- (b) batch number and, where appropriate the manufacturer and/or supplier,
- (c) reference to the relevant specifications and testing procedures,
- (d) test results, including observations and calculations, and reference to any specifications (limits),
- (e) dates of testing,
- (f) initials of the persons who performed the testing,
- (g) initials of the persons who verified the testing and the detailed calculations
- (h) A statement of release or rejection, and
- (i) signature and date of the designated responsible person.

Schedule M

PART 1 – continued

- 22.5.2 There shall be written standard operating procedures and the associated records of actions taken for:
- (a) equipment assembly and validation
- (b) analytical apparatus and calibration,
- (c) maintenance, cleaning and sanitation;
- (d) personnel matters including qualification, training, clothing, hygiene
- (e) environmental monitoring;
- (f) pest control;
- (g) complaints;
- (h) recalls made; and
- (i) returns received.

Schedule M

PART 1 – continued

- 23. *Reference Samples.* -
- 23.1 Each lot of every active ingredient, in a quality sufficient to carryout all the tests, except sterility and pyrogens / Bacterial Endotoxin Test, shall be retained for a period of 3 months after the date of expiry of the last batch produced from that active ingredient.
- 23.2. Samples of finished formulations shall be stored in the same or simulated containers in which the drug has been actually marketed.
- 24. *Reprocessing and Recoveries.* -
- 24.1. Where reprocessing is necessary, written procedures shall be established and approved by the Quality Assurance Department that shall specify the conditions and limitations of repeating chemical reactions. Such reprocessing shall be validated.
- 24.2. If the product batch has to be reprocessed, the procedure shall be authorized and recorded. An investigation shall be carried out into the causes necessitating re-processing and appropriate corrective measures shall be taken for prevention of recurrence. Re-processed batch shall be subjected to stability evaluation.

Schedule M

PART 1 – continued

- 24.3. Recovery of the product residue may be carried out, if permitted, in the master production and control records by incorporating it in subsequent batches of the product.
- 25. *Distribution records:*
- 25.1. Prior to distribution or dispatch of given batch of a drug, it shall be ensure that the batch has been duly tested, approved and released by the quality control personnel. Pre-dispatch inspection shall be performed on each consignment on a random basis to ensure that only the correct goods are dispatched. Detailed instructions for warehousing and stocking of Large
- Volume Parenterals, if stocked, shall be in existence and shall be complied with after the batch is released for distribution. Periodic audits of warehousing practices followed at distribution centers shall be carried out and records thereof shall be maintained. Standard Operating Procedures shall be developed for warehousing of products.
- 25.2. Records for distribution shall be maintained in a manner such that finished batch of a drug can be traced to the retain level to facilitate prompt and complete recall of the batch, if and when necessary.

Schedule M

PART 1 – continued

- 26. *Validation and process validation.* -
- 26.1.Validation studies shall be an essential part of Good Manufacturing Practices and shall be conducted as per the pre-defined protocols. These shall include validation of processing, testing and cleaning procedures.
- 26.2. A written report summarizing recorded results and conclusions shall be prepared, documented and maintained.
- 26.3. Processes and procedures shall be established on the basis of validation study and undergo periodic revalidation to ensure that they remain capable of achieving the intended results. Critical processes shall be validated, prospectively for retrospectively.
- 26.4. When any new Master Formula or method of preparation is adopted, steps shall be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified shall be demonstrated to yield a product consistently of the required quality.
- 26.5. Significant changes to the manufacturing process, including any changes in equipment or materials that may affect product quality and/or the reproducibility of the process, shall be validated.

Schedule M

PART 1 – continued

- 27. *Product Recalls.* -
- 27.1 A prompt and effective product recall system of defective products shall be devised for timely information of all concerned stockiest, wholesalers, suppliers, up to the retail level within the shortest period. The licensee may make use of both print and electronic media in this regard.
- 27.2. There shall be an established written procedure in the form of Standard Operating Procedure for effective recall of products distributed by the licensee. Recall operations shall be capable of being initiated promptly so as to effectively reach at the level of each distribution channel.
- 27.3 The distribution records shall be readily made available to the persons designated for recalls.
- 27.4 The designated person shall record a final report issued, including reconciliation between the delivered and the recovered quantities of the products.
- 27.5 The effectiveness of the arrangements for recalls shall be evaluated from time to time.
- 27.6 The recalled products shall be stored separately in a secured segregated area pending final decision on them.

Schedule M

PART 1 – continued

- 28. *Complaints and Adverse Reactions.*
- 28.1 All complaints thereof concerning product quality shall be carefully reviewed and recorded according to written procedures. Each complaint shall be investigated /evaluated by the designated personnel of the company and records of investigation and remedial action taken thereof shall be maintained.
- 28.2. Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned licensing authority.
- 28.3 There shall be written procedure describing the action to be taken, recall to be made of the defective product.

Schedule M

- 29. *Site Master File.* –The licensee shall prepare a succinct document in the form of Site Master File containing specific and factual Good Manufacturing Practices about the production and/or control of pharmaceutical manufacturing preparations carried out at the licensed premises. It shall contain the following: -
- 29.1 *General information,* -
- (a) brief information of the firm;
- (b) pharmaceutical manufacturing activities as permitted by the licensing authority;
- (c) other manufacturing activities, if any, carried out on the premises;
- (d) type of product licensed for manufacture with flow charts mentioning procedure and process flow;
- (e) number of employees engaged in the production, quality control, storage and distribution;
- (f) use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis;
- (g) short description of the Quality Management System of the firm; and
- (h) products details registered with foreign countries.

Schedule M

- 29.2 *Personnel.* -
- (a) organizational chart showing the arrangement for quality assurance including production and quality control;
- (b) qualification, experience and responsibilities of key personnel;
- (c) outline for arrangements for basic and in-service training and how the records are maintained;
- (d) health requirements for personnel engaged in production; and
- (e) personal hygiene requirements, including clothing.
- 29.3 *Premises.* -
- (a) simple plan or description of manufacturing areas drawn to scale;
- (b) nature of construction and fixtures/fittings;
- (c) brief description of ventilation systems. More details should be given for critical areas with potential risk of airborne contamination (schematic drawing of systems). Classification of the rooms used for the manufacture of sterile products should be mentioned;
- (d) special areas for the handling of the highly toxic, hazardous and sensitizing materials;

Schedule M

- (e) brief description of water system (schematic drawings of systems), including sanitation; and
- (f) description of planned preventive maintenance programs for premises and of the recording system.
- 29.4 *Equipment.* -
- (a) brief description of major equipment used in production and Quality Control Laboratories (a list of equipment required);
- (b) description of planned preventive maintenance programs for equipment and of the recording system; and
- (c) qualification and calibration including the recording systems and arrangements for computerized systems validation.
- 29.5 *Sanitation.* -
- (a) availability of written specifications and procedures for cleaning manufacturing areas and equipment.

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Schedule M

- 29.6 *Documentation.* -
- (a) arrangements for the preparation, revision and distribution of;
- (b) necessary documentation for the manufacture;
- (c) any other documentation related to product quality that is not mentioned elsewhere (e.g. microbiological controls about air and water).
- 29.7
- *Production.* -
- (a) brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters;
- (b) arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;
- (c) arrangements for the handling of rejected materials and products; and
- (d) brief description of general policy for process validation.

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Schedule M

- 29.8 *Quality Control.* -
- (a) description of the quality control system and of the activities of the Quality Control Department. Procedures for the release of the finished products.
- 29.9 *Loan license manufacture and licensee.* -
- (a) description of the way in which compliance of Good Manufacturing Practices by the loan licensee shall be assessed.
- 29.10 *Distribution, complaints and product recall.* -
- (a) arrangements and recording system for distribution; and
- (b) arrangements for handling of complaints and product recalls.
- 29.11 *Self inspection.* -
- (a) short description of the self inspection system indicating whether an outside, independent and experienced external export was involved in evaluating the manufacturer.s compliance with Good manufacturing Practices in all aspects of production.

Schedule M

- 29.12 *Export of drugs.* -
- (a) products exported to different countries; and
- (b) complaints and product recall, if any.

NEW BOOKS

The following New Books are available in our library for reference

1. **IP addendum 2015**
2. **British Pharmacopeia 2015**
3. **Pharmaceutical Calculations by Payal Agarwal**

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 12th December, 2014

G.S.R. 889(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 and Family Welfare), number G.S.R. 292(E), dated the 24th April, 2014, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 24th April 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 28th April, 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 by 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 (Sixth Amendment) Rules, 2014.

(2) They shall come into force after six months of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945,-

(a) in rule 122DAB,—

(i) for sub-rule (1), the following sub-rule shall be substituted, namely: —

"(1) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.";

(ii) after sub-rule (2), the following sub-rule shall be inserted, namely:—

"(2A) In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject.";

(iii) in sub-rule (5), —

(A) in clause (c), after the words "therapeutic effect", the words, "where, the standard care, though available, was not provided to the subject as per the clinical trial protocol" shall be inserted;

(B) in clause (d), after the words, "placebo controlled trial", the words, "where, the standard care, though available, was not provided to the subject as per the clinical trial protocol" shall be inserted;

(b) in Schedule Y, —

(a) in paragraph 2 relating to 'CLINICAL TRIAL',

(i) in sub-paragraph (2), relating to 'Responsibilities of Sponsor', for clause (iv), the following clause shall be substituted, namely:—

"(iv) Any report of the serious adverse event, after due analysis shall be forwarded by the sponsor to the Licensing Authority as referred to in clause (b) of rule 21, the Chairman of the Ethics Committee and the head of the institution where the trial has been conducted, within fourteen days of the occurrence of the serious adverse event.";

(ii) in sub-paragraph (3), relating to 'Responsibilities of the Investigator(s)', in clause (i), for the portion beginning with the words "The report of the serious adverse event of death" and ending with the words "occurrence of the serious adverse event.", the following shall be substituted, namely:—

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"In case, the Investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay to the satisfaction of the Licensing Authority along with the report of the serious adverse event. The report of the serious adverse event, after due analysis, shall be forwarded by the Investigator to the Licensing Authority, as referred to in clause (b) of rule 21, the Chairman of the Ethics Committee and the Head of the institution where the trial has been conducted within fourteen days of the occurrence of the serious adverse event.";

(iii) in sub-paragraph (5), relating to 'Responsibilities of the Ethics Committee', for clause (iv), the following clause shall be substituted, namely: —

"(iv) In case of serious adverse event occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as referred to in clause (b) of rule 21 for conducting the clinical trial, to the Licensing Authority within thirty days of the occurrence of the serious adverse event.";

(iv) in sub-paragraph 5(A), relating to 'Serious Adverse Events', in clause (2), —

(A) the words "and unexpected" shall be omitted;

(B) after the words "and pass orders as deemed necessary", the following shall be inserted, namely: —

"In case, the Investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay to the satisfaction of the Licensing Authority along with the report of the serious adverse event.";

(b) in APPENDIX V, in serial number 1, in item number 1.1, in sub-item number 9, for clause (a), the following clause shall be substituted, namely:—

"(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.";

(c) in APPENDIX XII,—

(i) for serial number (1), the following shall be substituted, namely: —

"(1) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.";

(ii) in serial number (2), after the words, "medical management of the subject", the words, "In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages" shall be inserted;

(iii) in serial number (5),—

(A) in clause (d), after the words, "therapeutic effect", the words, "where, the standard care, though available, was not provided to the subject as per the clinical trial protocol" shall be inserted;

(B) in clause (e), after the words 'placebo-controlled trial', the words, "where, the standard care, though available, was not provided to the subject as per the clinical trial protocol" shall be inserted;

(iv) in serial number (6), —

(A) in clause (a),

(i) the words, "and unexpected" shall be omitted;

(ii) after the words "occurrence as per Appendix XI.", the following shall be inserted, namely:-

"In case, the Investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay to the satisfaction of the Licensing Authority along with the report of the serious adverse event.";

(B) in clause (b), in para (i),-

(a) in sub-para (B),-

(i) the words, "Chairman of the Expert Committee with a copy of the report to", shall be omitted;

(ii) for the words "ten calendar days", the word "fourteen days" shall be substituted;

(b) in sub-paragraph (C),

(i) the words "to the Chairman of the Expert Committee with a copy of the report", shall be omitted;

(ii) for the words "twenty-one calendar days", the words "thirty days" shall be substituted;

(c) after the sub-paragraph (C), the following shall be inserted, namely:-

"(CA) The Licensing Authority shall forward the report of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting clinical trial and the Ethics Committee to the Chairman of the Expert Committee.";

(d) in sub-paragraph (D), for the words "thirty days of receiving the reports from the Ethics Committee" the words, "one hundred and five days of the occurrence of the adverse event" shall be substituted;

(e) in sub-paragraph (G), for the words "three months of receiving the report of the serious adverse event", the words, "one hundred and fifty days of the occurrence of the adverse event" shall be substituted;

(C) in para number (ii),-

(a) in sub-paragraph (A), for the word "ten calendar days", the words, "fourteen days" shall be substituted;

(b) in sub-paragraph (B), for the words "twenty one calendar days", the words, "thirty days" shall be substituted;

(c) in sub-paragraph (D), for the words "three months of receiving the report of the serious adverse event", the words, "one hundred and fifty days of the occurrence of the adverse event shall be substituted.

[F. No. 18-2/2013-DC/DFQC]

K. L. SHARMA, 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 was last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 718(E), dated the 13th October, 2014.

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Drugs & Cosmetics Act Amendment Bill 2015 (Draft)

Ministry of Health and Family Welfare Government of India published a draft Drugs & Cosmetics Act (Amendment) Bill 2015 on 31.12.2014 in their website http://www.mohfw.nic.in & DCGI website http://www.cdsco.nic.in The Bill yet to be presented in the budget session of parliament for approval. Government has asked all the stake holders including public to give the comments.

The salient points of the Bill are as follows.

1. The new Act is regulating the Import, Manufacture, Distribution & Sale of Drugs, Cosmetics & Medical Devices to ensure their Safety, Efficacy, Quality and conduct of Clinical Trial.
2. The nomenclature of "Drug Inspector" is changed to "Drugs Control Officer"
3. Definition of bioavailability study, bioequivalence study, Board, Central Drugs Laboratory, Central Licensing Authority, Clinical Trial, Cosmetics, Drug are defined.
4. The definition of Manufacture includes a person who himself or through any other person on his behalf manufactures Drug, Cosmetics or medical device.
5. The definition of medical device includes all instruments, appliances, implant, material or other article, in-vitro diagnostics devices including reagents, calibrator control, kit, instrument, etc., for the purpose of Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.
6. Chapter IA has been included for the purpose of controlling clinical trial. This chapter includes functions of ethics committee and penalty clauses for violation of any regulation.
7. Chapter II contains Drug Technical Advisory Board, Central Drug Laboratories and Drug consultative committee. The Drug Technical Advisory Board many experts from various field. Separate medical devices Technical Advisory Board has been created in this chapter under the chairmanship of Director General of ICMR without any member from state Drugs Control Department.
8. Chapter IIA describes import, Manufacture, Sale & Distribution notified category of medical devices. This chapter includes regulatory requirement for medical devices, definition of misbranded, adulterated & spurious devices and penalty clauses for any violation. According to the Act Central Government through DCGI will be the licensing Authority for licensing any medical devices for import, manufacture for sale etc.
9. Central Government is vested with power to suspend or cancellation of licenses issued by State Government
10. Central & State Licensing authorities to impose penalty by way of fine for certain violation under the provisions of this Act.
11. A new Schedule (The Third Schedule) has been introduced in this Act. In this Schedule various biological preparations including antigen, antitoxin, blood products, gene therapeutic products, monoclonal antibodies, recombinant preparations, sera, stem cells and vaccines are included along with fixed dose combination and hormones preparations. The items mentioned in this schedule will be licensed for manufacture for sale by Drugs Controller India only

National Health Policy 2015 – Draft

Ministry of Health and Family Welfare Government of India published a draft National Health Policy on 30.12.2014 in their website http://www.mohfw.nic.in The National Health Policy yet to be presented in the budget session of parliament for approval. Government has asked all the stake holders including public to give the comments.

Salient features of National Health Policy 2015 pertains to Pharmaceutical sector are as follows

2.17. Regulatory Role of Government:

The Government's regulatory role extends to the regulation of drugs through the CDSCO, the regulation of food safety through the office of the Food Safety and Standards Authority of India, support to the regulation of professional education through the four professional councils and the regulation of clinical establishments by the National Council for the same. Progress in each of these areas has been challenging. Some of the challenges relate to institutional strengthening and also the mechanisms of institutional governance, and some of the latter require amendments to the laws. Regulation of drug pricing is under the Department of Pharmaceuticals and this has been playing an active and effective role in monitoring prices and taking actions. Reforms in each of these areas, but especially in professional councils and clinical establishments is also facing resistance from certain stakeholders and will require considerable political leadership and public support to implement these reforms. There are also genuine concerns that it would bring back "license raj" the unnecessary and inefficient Government interference in private sector growth. But clearly as private industry grows at a massive pace, and as this is an area touching upon the lives and health of its population the Government has to find ways to move forward on these responsibilities.

4.3.10.5 To better regulate the AYUSH drugs market the policy would also support establishment of separate Central Drug Controller for AYUSH drugs and strengthening of quality enforcement mechanism in the States for application to mass manufactured drugs. Prescriptions compounded individually by providers themselves are on another footing, and seen as part of development of standard treatment guidelines.

7. Regulatory Frame work :

7.1. The regulatory role of the Ministry of Health and Family Welfare includes regulation of clinical establishments, professional and technical education, food safety, medical technologies and medical products with reference to introduction, manufacture, quality assurance and sales, clinical trials and research, and implementation of other health related laws. Each of these areas needs urgent reforms. This will entail moving away from reactive, voluminous, poorly implemented regulatory regimes, cobbled up in an ad-hoc manner to a more effective, rational, transparent and consistent regime. The regulatory levers need to be wielded, far more consistently and effectively to meet the challenges associated with health care throughout the country, safeguarding the public interest as well as encouraging private initiative. Statutory autonomous bodies regulate Medical Education and Food Safety. The Ministry of Health & Family Welfare directly regulates issues such as drugs, cosmetics, medical devices, other professional education and clinical establishments. The prices and availability of drugs is regulated by the Department of Pharmaceuticals.

7.3. Regulatory Framework for Professional Education: The four professional councils for medical, nursing, dental and pharmacy council face many challenges in enforcing quality in professional education or professional ethics and good practice. The effectiveness of these councils in regulation of professional education or practice or ethics has been a matter of concern. With respect to the medical council there are also concerns about widespread conflict of interests in professional practice with respect to pharmaceuticals and diagnostic industries and within itself. The policy calls for a major reform and strengthening of these bodies and their accountability. It also emphasizes the Government's own accountability in professional education, in ensuring that the process leads to providing professionals who correspond to national needs. One has to build an approach to governance such that there is a balance between autonomy that professional councils require and the good governance, accountability, effectiveness and responsiveness to national priorities and needs.

7.4. Availability of safe, wholesome, and healthy foods is an important requirement for health. Microbial contamination of the food contributes to communicable disease burden and the rise in the Non-Communicable Diseases (NCDs) has links to the consumption of food high in fats, sugars and salts; residues of pesticides, food additives and contaminants. Though enacted in 2006, the Food Safety and Standards (FSS) Act, was operationalized only from late 2011. Implementation of the Act has been far from adequate due to insufficient infrastructure including manpower, budgetary constraints and also the framework of the Act, Regulations and the scope and the degree of enforcement. Since there were few standards in place, science based standard setting has been one of the challenges to its implementation. Harmonization with international standards is also required. The experience gained during implementation and various court judgments and views of stakeholders have all pointed to areas in the law that require amendment and this will be taken up. Simultaneously the Government will strengthen and put in place the necessary network of offices, laboratories, e-governance structures and human resources needed for the enforcement.

7.5. India is known as the manufacturing hub and pharmacy of the world with exports to over 200 nations. To ensure the safety, efficacy, and quality of drugs and medical devices and cosmetics that are manufactured, imported, or sold in the country, a dynamic regulatory regime would be put in place. This is essential to safeguard the public from sub-standards or unsafe drugs and medical devices and to ensure the Indian pharmaceutical industry's global and domestic reputation and leadership. Regulation systems have to be on par with international standards and aligned with WHO and other relevant international guidelines. Post market surveillance program for drugs, blood products and medical devices shall be strengthened to ensure high degree of reliability and to prevent adverse outcomes due to low quality and/or refurbished devices/health products. The Drugs and Cosmetics Act would be amended to incorporate chapters on medical devices-which is essential to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India. Strengthening testing and surveillance capacities in Center and States, a national data bank of all regulatory actions, and e-governance tools would strengthen and speed up regulatory processes. Building capacities in line with international practices in our regulatory personnel and institutions would have the highest priority.

7.6. Clinical trials are essential for new product discovery and development. But these have great risks for the human volunteers. With the objective of ensuring the rights, safety and well-being of clinical trial participants, while facilitating such trials as are essential a separate chapter is being included in the Drugs and Cosmetic Act for its regulation, transparent and objective procedures shall be specified, and functioning of ethics and review committees strengthened. The Global Good Clinical Practice Guidelines, which specifies standards, roles and responsibilities of sponsors, investigators and participants would be adhered to. Further accreditation of sites, investigators and ethics committees and formula for payment of compensations shall be laid down and compliance with it monitored.

7.7. Vaccine safety and security requires development of a rational vaccine policy and effective regulation. It will encompass commissioning more research and development for manufacturing new vaccines, including against locally prevalent diseases; to build more manufacturing units to generate healthy competition; and to guard against the risks of batch failure; and to develop innovative financing and assured supply mechanisms with built in flexibility. In this context units such as the integrated vaccine complex at Chengalpattu would be set up and vaccine, anti-sera manufacturing units in the public sector upgraded with rise in their installed capacity. The challenge lies in taking timely steps to ensure sufficient availability of quality vaccines at affordable prices.

8. Medical Technologies:

8.1. India is the pharmacy of the developing world; but about half of its population does not have access to essential lifesaving medicines and the situation is worse when it comes to medical devices and in-vitro diagnostics. India has a great tradition and capacity for innovation in most areas, but despite having the technical capacity to manufacture any drug, its role in new drug discovery and drug innovation including in bio-pharmaceuticals and biosimilar, even for its own health priorities is limited. India has a public health

system with a stated commitment to providing universal access to free care, but out of pocket expenditures as a proportion on account of access to drugs and diagnostics is prohibitively high, one of the highest in the world. These are the paradoxes that the national health policy addresses.

8.4. Pricing of drugs, medical devices and equipment: The regulatory environment around pricing of durgs, medical devices and equipment requires a balance between the patient's concern for affordability and the industry's concern for adequate returns on investment for growth and sustainability. Pricing for drugs shall continue to be regulated for an increasing range of essential drugs via notifications released by National Pharmaceutical Pricing Authority (NPPA) under National Essential List of Medicines (NELM). Both the list and the cap on prices shall be periodically revised. Timely revision of NELM along with appropriate price control mechanisms for generic drugs shall remain a key strategy for decreasing costs of care for all those patients seeking care in the private sector. An approach on the same lines but suiting specific requirements of the sectors would be considered for price control with regard to a list of essential diagnostics and equipment.

8.5. Availability of drugs and medical devices also requires corresponding industrial growth and trade policies. The Indian pharmaceutical industry has already established itself as a leader in the production of generic drugs- and indeed a large part of the drugs used not only in third world, but also in the developed world are Indian generics. National Health Policy requires the need to strengthen and sustain this not only as part of its economic growth strategy but also as an imperative for the health security of the nation. Special focus on production of Active Pharmaceutical Ingredient (API) which is the back-bone of the generic formulations industry must be provided. In medical devices and equipment over 80% is imported. The goal with respect to medical devices shall be to encourage domestic production, in consonance with the "Make in India" national agenda, and such a development would ensure more affordable prices as well as increased access to life saving technologies.

8.6. Drug Innovation and New Drug Discovery are important aspects of access. One aspect of this is access to drugs for neglected diseases, diseases which are our public health priority- but are not viable commercial propositions to discover and bring to the market because only the poorest need them or the numbers requiring them are small. Another aspect of this is affordable access to the new drugs that would come into the market tomorrow- the next generation of drugs. In certain areas this link is obvious- the most well-known being anti-HIV drugs, drugs for multi-drug resistant tuberculosis, drugs against hepatitis, and against vector borne diseases, drugs for new and emerging infections, and anti-cancer drugs. However in many other non-communicable diseases also there is a potential for improving available therapies with better medicines and diagnostics. Government policy would be to both stimulate innovation and new drug discovery as required to meet health needs as well as ensure that new drugs discovered and brought into the market are affordable to those who need them most. The main constraints to innovation are : funding, the inadequate structure and functioning of regulatory institutional mechanisms, barriers to clinical and animal research and problems of sustaining an innovation ecosystem even if one is developed. Public procurement policies and public investment in priority research areas must also be aligned to drug discovery in areas which are our priority. Similar policies are required for discovering more affordable, more frugal and appropriate point of care diagnostics and robust medical equipment for use in our rural and remote areas.

8.7. There is a need to align our policies in trade, commerce, industry and science and technology and external affairs policies so that they are in consonance with the public health goals of access to new drugs at affordable rates and sustaining our advantage in generics. For medical devices and equipment trade barriers such as inverted duty structures would be corrected for facilitating cross border trade and indigenous development. Establishing sufficient labeling and packaging requirements on part of industry and effective port - clearance mechanisms for required medical products on part of authority shall be an immediate priority. Such alignment requires that Ministry of Health and Family Welfare takes a more pro-active and informed role in this area and institutional mechanisms of coordination are established.

8.8. A public sector capacity in manufacture of certain essential drugs and vaccines is also essential to retain in the larger long term understanding of health security and to address some needs which are not attractive commercial propositions. Institutions like CRI, Kasauli, the BCG Institute, Chennai, the Institute of Serology, Kolkata, the National Biological Institute, Noida, and Indian Pharmacopeia Commission play vital roles in production of biologicals and vaccines and in quality assurance and testing mechanisms. Most of these institutions perform functions that none in the private sector can or would take up. Though for the developing world, these are unique achievements, these institutions need more investment and appropriate HR policies and governance initiatives to enable them to become comparable with their benchmarks in the developed world.

8.9. One special problem area is anti-microbial resistance and the failure of the pharmaceutical industry to keep pace with the increased resistance shown by organisms, by developing new antibiotics. Microbial resistance is being seen even among the most common organisms, largely due to antibiotic misuse by physicians in the country. This calls for a rapid standardization of guidelines, regarding antibiotic use, limiting the use of antibiotics as Over- the -Counter medication (but permitting certain antibiotics to front line paramedics), banning or restricting the use of antibiotics as growth promoters in animal livestock and hospital infection control guidelines a mandatory part of all hospital quality guidelines. Pharmaco-vigilance regarding antibiotic usage in the hospital and community is a must, in order to enforce change in existing practices.

8.10. One important capacity with respect to introduction of new technologies and their uptake into public health programmes is health technology assessment. This new multi-disciplinary domain, modeled on the work of the National Institute of Clinical Excellence in the UK, is required to ensure that technology choice is participatory and is guided by considerations of scientific evidence, safety, cost effectiveness considerations and social values. This approach is extended also to technology choice involved in the development of standard treatment guidelines and in public health programmes. The National Health Policy commits to the development of capacity in this areas and the use of this approach for making technology choices that impact on public health.

10. Knowledge for Health:

10.5 For drug and devices discovery and innovation, Steering Committees that bring together the Department of Pharmaceuticals, the Department of Biotechnology, the regulatory bodies, the Department of Industrial Policy and Promotion, the Departments of Science and Technology with the Health Ministry are important. A common sector innovation council for the Health Ministry should be strengthened and made functional to play this role with its leadership shared between the Department of Health & Family Welfare and Department of Health Research. Here the challenges are not only in discovery, but in managing intellectual property rights, testing of products especially clinical trials, health technology assessment, and managing the transition from laboratory to the market. Here innovative strategies of public financing and careful leveraging of public procurement can help generate the sort of innovations that are required for Indian public health priorities.

12 Legal Framework for Health Care and the Right to Health:

12.1 There are a large number of laws that govern health policy and implementation in a number of areas- and health policy has not only to be compliant with these laws but also contribute to strengthening implementation. There are unfortunately a number of laws that have over time developed inadequacies due to changed contexts and a number of newly emerged services and technologies where laws are needed. Laws under review include the Mental Health Bill, the Medical Termination of Pregnancy Act, the bill regulating surrogate pregnancy and assisted reproductive technologies, Food Safety Act, Drugs and Cosmetics Act and the Clinical Establishments Act. The process of aligning many of these laws to meet our needs and changed circumstances and understanding becomes one of the urgent tasks in the coming years.

List of NLEM drugs with Ceiling Prices						
S. No	S.O. No.	Date	Name of Schedule Formulation	Strength	Unit	Ceiling Price(Rs.)
1	3126(E)	10-12-2014	Bleaching Powder (Contains not Less than 30% w/w of available chlorine as per I.P.)	--	1 kg	17.42
2	3126(E)	10-12-2014	Ketamine Hydrochloride Injection	10mg/ml	1 ml	10.54
3	3126(E)	10-12-2014	Zinc Sulfate Syrup	20mg/5ml	1 ml	0.61
4	3127(E)	10-12-2014	Ascorbic Acid Tablet	500mg	1 Tablet	0.94
5	3127(E)	10-12-2014	Cloxacillin capsule	250mg	1 Capsule	1.29
6	3127(E)	10-12-2014	Gentamycin Injection	10mg/ml	1 ml	3.18
7	3127(E)	10-12-2014	Glucose Injection	5%	1 ml	0.06446
8	3127(E)	10-12-2014	Glucose+ Normal Saline Injection	5%+0.9%	1 ml	0.06167
9	3127(E)	10-12-2014	Griseofulvin Tablet	125mg	1 Tablet	0.75
10	3127(E)	10-12-2014	Normal Saline Injection	0.9%	1 ml	0.08596
11	3128(E)	10-12-2014	Codeine Phosphate Syrup	15mg/5ml	1 ml	0.63
12	3128(E)	10-12-2014	Diazepam Suppository	5 mg	1 Supposi tory	5.48
13	3128(E)	10-12-2014	Efavirenz capsule	600 mg	1 Capsule	59.50
14	3128(E)	10-12-2014	Hormone Releasing IUD	--	1 IUD	455.01
15	3128(E)	10-12-2014	Iodine Solution	8mg/5ml	1 ml	0.32
16	3128(E)	10-12-2014	IsosorbideDinitrate Tablet	20 mg	1 Tablet	2.00
17	3129(E)	10-12-2014	Ascorbic Acid Tablet	100mg	1 Tablet	0.14
18	3129(E)	10-12-2014	Chlorpromazine Injection	25mg/ml	1 ml	1.22
19	3129(E)	10-12-2014	Methyldopa Tablet	250mg	1 Tablet	1.69
20	3129(E)	10-12-2014	Vitamin A capsule	50000 IU	1 Capsule	0.51
21	3130(E)	10-12-2014	Ciprofloxacin Hydrochloride Drops	0.30%/ml	1 ml	1.49
22	3131(E)	10-12-2014	Glucose Injection	10%	1 ml	0.05316
23	3132(E)	10-12-2014	Sodium MeglumineDiatrizoate Injection	60% (Iodine Conc.=292 mg/ml)	1 ml	8.05

24	3132(E)	10-12-2014	Sodium MeglumineDiatrizoate Injection	76% (Iodine Conc.=370 mg/ml)	1 ml	9.81
25	3133(E)	10-12-2014	Co-Trimoxazole(Trimethoprim + Sulphamethoxazole) Tablet	160mg + 800mg	1 Tablet	1.32
26	3134(E)	10-12-2014	Mannitol Injection	20%	1 ml	0.55
27	3135(E)	10-12-2014	Paracetamol Infusion/ Injection	Each ml contains Paracetamol 10mg	1 ml	2.10
28	3136(E)	10-12-2014	Amoxycilline + Potassium Clavulanate tablet	AmoxycillinTrihydrate eq. to Amoxycillin 875mg Potassium Clavulanate Diluted eq. to Clavulanic Acid 125mg	6 Tablet	160.00
29	3137(E)	10-12-2014	.Metoprolol Succinate+ Cilnidipine Tablet (Cardiocil M)	Each film coated tablet contains Metoprolol Succinate eq. to MetoprololTartarate– 50mg (in extended release form) Cilnidipine 10mg	1 Tablet	7.66
30	3138(E)	10-12-2014	Cefixime + Azithromycin Tablets (Trusten AZ tablet)	Each film coated tablet contains Cefixime eq. to Anhydrous Cefixime 200mg Azithromycin as Dihydrate eq. to Anhydrous Azithromycin 250mg	1 Tablet	15.88
31	3139(E)	10-12-2014	Levofloacin + Azithromycin Tablets (Levobact AZ 250)	Each film coated tablet contains LevofloacinHemidhydrate eq. to Levofloxacin 250mg Azithromycin Dihydrate eq. to Anhydrous Azithromycin 250mg	1 Tablet	12.15
32	3139(E)	10-12-2014	Levofloacin + Azithromycin Tablets (Levobact AZ 500)	LevofloacinHemidhydrate eq. to Levofloxacin 500mg Azithromycin Dihydrate eq. to Anhydrous Azithromycin 500mg	1 Tablet	21.55
33	3140(E)	10-12-2014	Gatifloxacin + Prednisolone and Benzalkonium Chloride Eye drops	Each ml contains Gatifloxacin eq. to Gatifloxacin (anhydrous) – 3mg Prednisolone Acetate – 10mg Benzalkonium Chloride 0.01% w/v (as preservative)	1 ml	2.47
34	3141(E)	10-12-2014	Atorvastatin calcium+ Clopidogrel Bisulphate Capsules(Clopid AT10)	Each hard gelatin capsule contains Atorvastatin calcium eq. to Atorvastatin 10mg (As pellets) Clopidogrel bisulphate eq. to Clopidogrel 75mg (As pellets)	10's Capsule	87.52

35	3141(E)	10-12-2014	Atorvastatin Calcium+ Clopidogrel bisulphate Capsule(CLOPID AT 20)	Atorvastatin Calcium eq. to Atrovastatin 20 mg (as pellets) Clopidogrel bisulphate eq. to Clopidogrel 75 mg (as pellets)	10 Capsule	110.48
36	3142(E)	10-12-2014	Gliclazide+ Metformin Tablet (Glikey MF 60)	Each uncoated bilayered tablet contains Gliclazide 60mg Metformin 500mg (in sustained release form)	1 Tablet	6.61
37	3142(E)	10-12-2014	Gliclazide+ Metformin Tablet (Glikey MF 80)	Gliclazide 80mg Metformin 500mg (in sustained release form)	1 Tablet	4.63
38	3143(E)	10-12-2014	CefpodoximeProxetil+ Azithromycin Tablets	Each film coated tablet contains CefpodoximeProxetil Eq. to Cefpodoxime - 200 mg Azithromycin Dihydrate Eq. to Azithromycin Anhydrous - 250 mg q.s	1 Tablet	17.70
39	3144(E)	10-12-2014	Povidone Iodine+ Ornidazole Ointment (Zuventdine OZ)	Each gm contains Povidone Iodine 5% w/w (Available Iodine 0.5% w/w) Ornidazole 1% w/w	1 gm	3.00
40	3145(E)	10-12-2014	Telmisartan + Hydrochlorothiazide + Amlodipine Tablet	Each uncoated bilayered tablet contains Telmisartan 40mg Hydrochlorothiazide 12.5mg Amlodipine besylate eq. to Amlodipine 5mg	1 Tablet	7.80
41	3146(E)	10-12-2014	Losartan Potassium+ Chlorthalidone Tablet	Each film coated tablet contains Losartan Potassium 50mg Chlorthalidone 12.5mg	1 Tablet	4.55
42	3147(E)	10-12-2014	Paclitaxel Injection (NAB Tortaxel)	Each vial contains Paclitaxel 100mg (Human Albumin)	1 Injection	7954.28
43	3148(E)	10-12-2014	L-Thyroxine Sodium Tablet (Uthyrox 25)	Each uncoated tablet contains L-Thyroxine Sodium eq. to anhydrous L-Thyroxine Sodium 25 mcg	1 Tablet	1.14
44	3148(E)	10-12-2014	L-Thyroxine Sodium Tablet(Uthyrox 75)	Each uncoated tablet contains L-Thyroxine Sodium eq. to anhydrous L-Thyroxine Sodium 75 mcg	1 Tablet	1.25
45	3149(E)	10-12-2014	Rosuvastatin + Aspirin capsule	Each hard gelatin capsule contains Rosuvastatin calcium eq. to	1 Capsule	4.55

				Rosuvastatin 10mg (as granules)Aspirin 150mg (as enteric coated tablets)		
46	3150(E)	10-12-2014	Clobetasol Propionate+ Neomycin Sulphate+ Miconazole Nitrate Cream (Clobetavate NM)	Each gm contains Clobetasol Propionate 0.05% w/w Neomycin Sulphate eq to Neomycin 0.1% w/w Miconazole Nitrate - 2.0%w/w	1 gm	2.06
47	3151(E)	10-12-2014	Ilaprazole + Domperidone Capsules (Chekcid-D SR)	Each hard gelatin capsule contains Ilaprazole 10mg (as enteric coated tablet) Domperidone 30mg (as film coated sustained release tablet)	1 Capsule	4.37
48	3152(E)	10-12-2014	Cyclosporine+ Benzalkonium Eye Drop	Each ml contains Cyclosporine 0.5mg Benzalkonium Chloride 0.01% w/v (as preservative)	3ml Vial	266.25
49	3153(E)	10-12-2014	Diclofenac Potassium+ Serratiopeptidase tablet	Each film coated tablet contains Diclofenac Potassium – 50mg Serratiopeptidase – 15mg (30,000 units of Serratiopeptidase) (as enteric coated granuals)	1 Tablet	2.70
50	3154(E)	10-12-2014	Clobetasol propionate+ Neomycin Sulphate+ Miconazole Nitrate+ Zinc Sulphate Ceam (Clobetavate GM)	Each gm contains Clobetasol propionate 0.05% w/w Neomycin sulphate eq. to Neomycin 0.5% w/w Miconazole Nitrate 2.0% w/w Zinc Sulphate 2.0% w/w	1 gm	1.77
51	3155(E)	10-12-2014	Calcium+Mecobalamin Calcitriol+ Folic Acid + Pyridoxine Capsule	Each soft gelatin capsule contains Calcium carbonate eq. to Elemental Calcium 200mg Mecobalamin 1500mcg Calcitriol 0.25mcg Folic Acid 1.5mg Pyridoxine HCl 3mg	1 Capsule	7.68
52	3156(E)	10-12-2014	DicyclomineHCl+ Diclofenac Sodium+ Benzalkonium Chloride njection (Superspas –RF)	Each ml contains Dicyclomine HCl-10 mg Diclofenac Sodium - 25 mg Benzalkonium Chloride Solution - 0.05% w/v(as preservative) Water for Injections – q.s	1 Ampoule (2ml)	8.06

INFORMATION

M. PHARM & PHARM D SCHOLARSHIP 2014 -2015

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awarded scholarship to selected **M. Pharm & Pharm D final year students** from various colleges in Tamilnadu for their on-going project work.

The scholarship scheme was imitated in the year 1998. The received applications are codified, so that the identity of the student is not disclosed to the evaluator and sent to institutions outside the state of Tamilnadu for evaluation

This was the 17th year of these awards. We have received 90 applications from eight different branches – six from M Pharm and two from Pharm D, from 12 institutions. All synopses were sent to **Dr. V. Padmaja**, Professor, College of Pharmaceutical Sciences, Thiruvandram Medical College, Kerala her team for evaluation. Based on their best marks, **24 students** have been selected for award for scholarship as per the following details:

Rank	No of Candidates (M.Pharm)	Amount (Rs.) (each)	No of Candidates (Pharm D)	Amount (Rs.) (each)
First Rank	6	10,000/-	2	12,000/-
Second Rank	6	8,000/-	2	9,000/-
Third Rank	6	6,000/-	2	6,000/-

COLLEGE-WISE BREAK-UP

Name of the college	:	Awards	Received
1. J. S. S. College of Pharmacy, Ooty	:	5	24
2. Madras Medical College, Chennai	:	9	18
3. SRIPMS, Coimbatore	:	3	13
4. P. S. G. College of Pharmacy, Coimbatore	:	3	10
5. Sri Ramachandra College of Pharmacy, Chennai	:	1	8
6. SRM College of Pharmacy, Chennai	:	1	7
7. Adiparashakthi College of Pharmacy, Melmaruvathur	:	1	2
8. Annai JKK Sampoorani Ammal College of Pharmacy	:	1	1
9. School of Ph. Sciences, Vels University, Chennai	:	*	2
10. KMCH College of Pharmacy, Coimbatore	:	*	1
11. JKK Nataraja College of Pharmacy, Komarapalayam	:	*	3
12. R. V. S. College of Pharmacy, Coimbatore	:	*	1
TOTAL	**:**	**24**	**90**

SUBJECT-WISE BREAK-UP

Subject		Applications	First	Second	Third
Pharmaceutics	:	14	1	1	1
Pharmaceutical Chemistry	:	05	1	1	1
Pharmaceutical Analysis	:	06	1	1	1
Pharmacology	:	07	1	1	1
Pharmacognosy	:	10	1	1	1
Pharmacy Practice	:	08	1	1	1
Pharm D Pharmacy Practice	:	12	1	1	1
Pharm D Clinical Pharmacy	:	28	1	1	1
TOTAL	:	**90**	**8**	**8**	**8**

RESULT

PHARMACEUTICS

Rank	Name	Institution	Amount (Rs.)
First	Mr. E. Surendra	JSS College of Pharmacy, Ooty	10,000/-
Second	Mr. Ch. Sai Krishna Reddy	JSS College of Pharmacy, Ooty	8,000/-
Third	Ms. R. Nithya	PSG College of Pharmacy,, Coimbatore	6,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	Institution	Amount (Rs.)
First	Mr. T. Ananthakumar	College of Pharmacy, MMC, Chennai	10,000/-
Second	Mr. L. Ragu Bharathi	College of Pharmacy, MMC, Chennai	8,000/-
Third	Ms. S. Saranya	College of Pharmacy, MMC, Chennai	6,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	Institution	Amount (Rs.)
First	Mr. Avendra Yadav	JSS College of Pharmacy, Ooty	10,000/-
Second	Ms. P. Ponguzhali	Adhiparasakthi College of Pharmacy, Melmaruvathur	8,000/-
Third	Ms. Manasi K Patel	JSS College of Pharmacy, Ooty	6,000/-

PHARMACOLGOY

Rank	Name	Institution	Amount (Rs.)
First	Mr. V. Gopi	College of Pharmacy, MMC, Chennai	10,000/-
Second	Ms. M. Dhivya	College of Pharmacy, MMC, Chennai	8,000/-
Third	Mr. Mohamed Tharic. A	College of Pharmacy, MMC, Chennai	6,000/-

PHARMACOGNOSY

Rank	Name	Institution	Amount (Rs.)
First	Mr. G. Arunkumar	College of Pharmacy, MMC, Chennai	10,000/-
Second	Ms. G. Praveena	College of Pharmacy, MMC, Chennai	8,000/-
Third	Ms. Mushahida Parveen S Z	College of Pharmacy, MMC, Chennai	6,000/-

PHARMACY PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Mr. M. Ananthan	Annai JKK Sampoorani Ammal College B. Komarapalayam	10,000/-
Second	Mr. Tijo Sam Thomas	SRIPMS, Coimbatore	8,000/-
Third	Mr. Pribin Thomas	SRIPMS, Coimbatore	6,000/-

PHARM D – PHARMACY PRACTICE

Rank	Name	Institution	Amount (Rs.)
First	Ms. Dhanu Josey, Ms. Divya Ann Jetto Ms. Evelyn Harold, Ms. Mabel Elizabeth V. K	SRIPMS, Coimbatore	12,000/-
Second	Ms. Brejeet K. V, Ms. Elen Charly, Ms. Grace Mary John	PSG College, Coimbatore	9,000/-
Third	Mr. Anna John Viany, Mr. Parul Elsa Thomas, Mr. Vivek Thomas John	PSG College, Coimbatore	6,000/-

PHARM D – CLINICAL PHARMACY

Rank	Name	Institution	Amount (Rs.)
First	Ms. G. Charishma Devi, Ms. CH Divya Sree, Ms. M. Gayathri, Mr. Mohammed Rafi	SRM College of Pharmacy, Chennai	12,000/-
Second	Ms. Chittineni Priyanka, Mr. Yeswanth .G, Ms. Sneha. K, Mr. Abha Singh	Sri Ramachandra College of Pharmacy, Chennai	9,000/-
Third	Ms. Jemy Rajan, Ms. Mahima Thankam Koshy, Ms. Stefin Mary Mathew	JSS College of Pharmacy, Ooty	6,000/-

ESSAY COMPETITION 2014 – FOR FINAL YEAR B. PHARM STUDENTS

Tamilnadu Pharmaceutical Sciences Welfare Trust conducted 4th consecutive Essay Competition for the final year B. Pharm students in Tamilnadu and Puducherry, on the subject: **"From Bench to Bedside - Perceptional Change in A Pharmacist's role"**

We received totally 22 applications from 10 Colleges and it was evaluated by **Dr. M. Ramesh**, Professor, Department of Clinical Pharmacy, JSS Medical College and Hospital, Mysore. Based on their best marks, 3 students have been selected for awards as per the following details:

RESULT

Rank	Name	Institute	Amount
First	Ms. B. Jenifer	Periyar College of Ph Sciences, Trichy	Rs 10,000/-
Second	Ms. C. A. Afshan Fathima	Aadhi Bhagawan College, Cheyyar Thiruvannamalai District	Rs. 8,000/-
Third	Mr. R. Arun	Nandha College of Pharmacy, Erode	Rs. 6,000/-

COLLEGE-WISE BREAK-UP

S. No	Name of the college	Received	Awards
1.	S.S.M College of Pharmacy, Erode	1	
2.	J.K.K. Nataraja College of Pharmacy, Komarapalayam	3	
3.	Mother Theresa Post Garduate and Research Inst of Health Sciences, Puduchery	5	
4.	Aadhi Bhagawan College of Pharmacy, Cheyyar	2	1
5.	Adhiparasakthi College of pharmacy, Melmaruvathur	2	
6.	Periyar College of Pharmaceutical Sciences, Trichy	2	1
7.	Vinayaka Mission's College of Pharmacy, Salem	2	
8.	K.K.College of Pharmacy, Chennai	1	
9.	School of Pharmaceutical Sciences, Vel's University	1	
10.	Nandha College of Pharmacy, Erode	3	1
	TOTAL	**22**	**3**

EVENTS

53rd NATIONAL PHARMACY WEEK CELEBRATION, IPA, TN Branch

Tamilnadu IPA celebrated 53rd National Pharmacy Week Celebration in a very successful and productive manner on 19th November 2014, 1000 Pharmacy shop was covered by Tamilnadu IPA members and Students members. They explained about “The Responsible use of Medicine” and Do's and Don'ts while handling drugs to the patients.

IPA celebrated 53rd National Pharmacy Week Celebration on 22rd November 2014 Saturday at Hotel Savera. The theme was **“Responsible Use of Medicines: Role of Pharmacist”**

The Chief Guest for the function was Dr. V. K. Subburaj, I.A.S, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, New Delhi. Dr. J. Radhakrishnan IAS, Secretary to Govt Health and Family Welfare Department, Tamilnadu attended the function. The function was felicitated by Thiru. Mr. S. V. Veerramani, President - IDMA and Chairman Tamilnadu Pharmaceutical Sciences Welfare Trust, Guests of Honour was Prof. K. Chinnaswamy, President Pharmacy Council Tamilnadu, Thiru. S. Abdul Khadar, Director of Drugs Control, Tamilnadu, Dr. S. Manivannan, Deputy Drugs Controller (I) CDSCO, South Zone. The theme lecture was delivered by Thiru. J. Jayaseelan, Secretary IPA Tamilnadu. Welcome address given by Thiru. T. Sathish, Joint Secretary IPA Tamilnadu. The meeting was presided by Dr. V. Ravichandiran, Vice President IPA Tamilnadu.

The best pharmacist award for the year 2014 was given to Thiru. R. Narayanaswamy, Deputy Drugs Controller of India (Retd.). The award was sponsored by M/s. Lalchand Bhimraj, Chennai.

During this function Scholarships and Award was given by Tamil Nadu Pharmaceutical Sciences Welfare Trust. There was a contest on projects from Pharmaceutics, Pharmaceutical Chemistry, Pharmaceutical Analysis, Pharmacology, Pharmacognosy, Pharmacy Practice for M. Pharm students and Pharmacy Practice, Clinical Pharmacy for Pharm. D students. An Essay competition on the subject: **"From Bench to Bedside - Perceptional Change in A Pharmacist's role"** was kept for B. Pharm students. The total number of 18 - M. Pharm Students, 6 - Pharm D Students and 3 - B. Pharm students were awarded scholarships to tune of Rs. 2,22,000/-. The function was a grand success and was attended by more than 250 members and delegates.

53rd National Pharmacy Week Celebration, IPA, TN Branch (L to R) Thiru. J. Jayaseelan, Dr. S. Manivannan, Thiru. A. Krishn Dev, Dr. V. Ravichandran, Dr. V. K. Subburaj, Shri. S. V. Veerramani, Thiru. S. Abdul Khadar, Prof. K. Chinnaswamy

53rd National Pharmacy Week Celebration, IPA, TN Branch,
Best Pharmacist of the year award 2014 to Thiru. R. Narayanaswamy

TANIPA Student Orientation Programme for Pharmacy Students (L to R) Dr. A. Abdul Hasan Sathali, Thiru A. Arunachalam, Thiru. Sanjay Kumar Das Mohapatra, Thriu. A. Krishna Dev, Capt. Dr. B. Santhakumar, Dr. V. Ravichandran, Thiru. T. Sathish

TANIPA Student Orientation Programme for Pharmacy Students, Felicitation to the Dean, Madurai Medical College, Madurai

INDIAN PHAMACEUTICAL ASSOCIATION (TAMIL NADU BRANCH) & TAMIL NADU INDIAN PHARMACEUTICAL ASSOCIATION TRUST (TANIPA), CHENNAI CONDUCTED REGIONAL LEVEL STUDENTS' SEMINAR AT MADURAI

A one day-day regional level student seminar on the topic ***"Orientation Programme for Pharmacy Students"*** was organized by IPA (Tamil Nadu branch) and TANIPA, Chennai on November 29, 2014 at College of Pharmacy, Madurai Medical College, Madurai. The main objectives of the seminar were to provide an excellent opportunity and platform to know about the activities of Pharmaceutical Industry. Since the students from southern districts of Tamil Nadu have poor industrial exposure and access, this programme was very useful to them to have an idea about Pharma industry and its job requirements. About 300 delegates (250 students and staff) from College of Pharmacy, MMC, Madurai, KM College of Pharmacy, Ultra College of Pharmacy, SankaralingamBhuvaneshwari College of Pharmacy and ArulmiguKalasalingam College of Pharmacy attended the programme.

Capt.Dr.B.Santhakumar, Dean, Madurai Medical College, Madurai was the Chief guest of the function. **Prof. Dr. V.Ravichandran**, Vice-President, IPA, (TN branch) welcomed the gathering. **Mr.A.Krishnadev**,, Chairman of TANIPA presided over the function.He stressed the importance this type of seminar in motivating the students to gain the knowledge the through the various sources. The Chief guest **Capt.Dr.B.Santhakumar, Dean, Madurai Medical College**, **Madurai,** empasised the importance of Pharmacy Profession and its research activities' usefulness in the health care of public. He also, opined that the pharmacy is playing vital role in improving the health care by coming with new molecules to combat the new and existing diseases.

Mr.T.Sathish, GM, Tablets India Ltd, Chennai gave seminar on the topic of ***"Field of Indian Pharma & Opportunities"*** for Pharmacist. In his topic he elaborated the various job opportunities available in the Pharma industry for the Pharmacy graduates.

The topic ***"Pharma Manufacturing"*** is covered by **Mr.Sanjay Kumar Das Mohapatra**, President, Tech & operations of Medopharm, Chennai. In which, he explained the basic principles of Good manufacturing practices followed in the Pharma Industry,

In the topic,***"Regulations Governing Pharmaceuticals"*,Mr. Jayakumar**, Head-Quality of Apex labs, Chennai, explained the various law governing the Pharma Industry and authorities regulating the Pharma Industry. Also, discussed the requirements fulfilled by the Pharmaceuticals as per the different regulatory authorities. He narrated the importance of GMP and explained with fun filled stories for the proper understanding of GMP by the students. Mr. R. Sabapathy Executive Director of M/S Medopharm, Chennai also participated in the inagural function. Dr.A.Abdul HasanSathali, Principal, College of Pharmacy, Madurai Medical College, Madurai. proposed vote of thanks.

INDUSTRIAL ORIENTATION TRAINING
on
PRODUCTION MANAGEMENT PERSONNEL

The second Training programme for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held from **6th October 2014 to 8th November 2014.** As no of trainees exceeded more than 30, the training programme was conducted at The Checkers Hotel, Saidapet, Chennai instead of our Trust office due to space constraint. Mr. R. Narayanaswamy, Mr. K. Prafulla Chandra, Mrs. Pratima Mathur & Dr. V. Ravichandran, co-coordinators to conduct this programme.

Trainees participated from various Institution are as follows.

1. Vels University, Chennai 24 (B. Pharm Final Year students)
2. PSG College of Pharmacy, Coimbatore 4 (B. Pharm Final Year students)
3. Ultra College of Pharmacy, Madurai 3 B. Pharm graduates
4. JSS College of Pharmacy, Ooty 1 B. Pharm graduate
5. M/s. Medopharm, Chennai 2 Trainees.

Theoretical Training Programme (6th October 2014 to 18th October 2014)

- **Overview of Pharma Industry** Mr. J. Jayaseelan, Managing Director M/s. Delvin Formulations P Ltd.
- **Manufacturing License, forms & Guide lines from Drugs & Cosmetics Act -** Mr. A. Arunachalam, Deputy Drugs Controller (Retd.), Tamilnadu
- **WHO- GMP Guide lines, COPP and Schedule "M" pertaining to Production, under D&C Act** Mr. M. Bhaskaran, Rtd. Director, Drugs Control, Tamil Nadu.
- **Regulatory requirements for import of API's**. Mr. R. Narayanaswamy, Deputy Drugs Controller, India (Retd.)
- **Site master File**. Mr. S. Vanchi Nathan, M/s. Fourrts (India) Lab Pvt Ltd.
- **Basics of Production Planning & Inventory Control.**
- **Batch Manufacturing Records.**
- **Batch Packing Records and importance of online recording -** Mr. D. Satish Kumar, M/s. Fourrts (India) Lab Pvt Ltd.
- **What is quality and why it is essential for manufacture of products.**
- **How QA plays vital role in shop floor.**
- **cGMP's for manufacturing including entry & exit procedures.**
- **IQ, OQ, PQ and DQ of equipments, Validation.**
- **Qualification and calibration.**
- **What happens to the product when Temp, RH, and differential pressure is out of limit.**

  What is containment? Essential steps to control contamination, Market complaints, CAPA,OOS and OOT etc, Risk Assessment - Mr. Sanjay Kumar Dasmohapatra, President Technical & Operations, M/s. Medopharm.
- **MHRA vs Schedule M requirements & guidelines for Oral dosage forms and External preparations.**

Inaugural function of the Training Programme (Photo 1 to 3)

1

2

3

Lecture by Thiru J. Jayaseelan, MD, Delvin Formulations

Lecture by Thiru Sanjay Kumar Das Mohapatra, Medopharm

Felicitation to Thiru. S. Vanchinathan, M/s. Fourrts (India) Lab Pvt Ltd

Trainees of the Training Programme

Trainees of the Training Programme

- **What is line clearance, its importance, what to observe and document during line clearance while starting a new batch during Manufacturing and during packing, on line sampling of products during packing operation, and other in process checks to be carried out during packing of tablets, Capsules and Liquids, the Role of Q.A during line clearance and packing operations** Mr. N. Chandar, Pharma Consultant.
- **Environmental monitoring, Plate exposures, Air Sampling , Laminar Flow etc in Manufacturing -** Mr. M. Madan Raj, M/s. Tablets(India) Ltd.
- **Change control, Deviation control and their importance -** Mr. Murali Raman, M/s. Apex Laboratories Pvt Ltd.
- **Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing etc and selection of different materials according to stability of products Viz: tablets & Capsules, Powders etc. -** Dr. D. Natarajan, Pharma Consultant
- **Facilities & special requirements for Hormonal preparations** Mr. Jayendra Kumar, HLL.
- **Production, Q.C, Q.A and Regulatory Divisions and their inter- relationship with each other. Importance of labeling of products. Air Systems, Water Systems, their sampling and testing** Mr. S. Jaya Kumar, M/s. Apex Laboratories Pvt Ltd.
- **Validation of Tabtletting Process & Solving Problems Arising During Manufacture of Tablets** Mr. M. Murugan, Sai Mirra Innopharm Pvt. Ltd
- **A list of labor Management, Factories Act, Boiler Act.**
- **Safety Management and Effluent Treatment (Pollution Control Act). Raw Materials, Packing materials and labels, their receipt, storage, issue and maintenance of records. Preventive maintenance, Predictive maintenance & Break down maintenance.**
- **Facilities & special requirements for the manufacture of lactum dosage forms such as Tablets & Capsules. Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc.**
- **Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets** Mr. S. Sridhar, M/s. Medopharm (Malur Plant)
- **ICH guidelines for production of Pharmaceuticals.**
- **How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production of tablets.**
- **Different types of Coating of Tablets, Materials used for coating & coating process -** Dr. P. Ram Kumar, M/s. Fourrts India.
- **Processes involved in the production of Capsules such as size reduction, sieving, granulation, Filling, Cleaning & Polishing etc.**
- **Various components of a Capsules with examples of different materials used. Different sizes of Capsules available in the market, Filling of Capsules: hand filling, Machine Filling High speed filling Machines.**
- **In process tests to be carried during production of Capsules, How to control and rectify(incase of failure) weight variation, Disintegration time, Dissolution etc during production of Capsules. -** Mr. Gopinath, M/s. Fourrts (India) Lab Pvt Ltd.
- **Standard Operating Procedures.**
- **Documentation -** Mr. K. Saravana Kumar, M/s. Fourrts (India) Lab Pvt Ltd

- **Repacking of Drugs** Mr. S. Balaji, M/s. Sipali Chemicals
- **Powders for Dry Syrups : Main ingredients with examples of various materials used, equipment used for their manufacture, In process tests to be done, and their packaging, Effervesant Powders their main ingredients their manufacture and packing.**
- **Oral Rehydration Powders(ORS), Equipment used for their manufacture, WHO approved formula, Materials used for formulation of ORS, in process tests to be done and packing of ORS powders -** Mr. S. Ganesan, Allianz Biosciences Pvt. Ltd.
- **Various types of Machinery used for the production & packing of Tablets (Including their Tooling), capsules and ORS etc including their qualification..** Mr. Mohammed Nadir, ACG, PAM
- **Availability and Quality of Foils and Blister Packing, etc. and Printing of Foils, etc. -** Mr. Rajendran, Thirumala Foils
- **Different types of Oral Liquid Dosage Forms such as Liquids, Syrups , Suspensions & Emulsions etc. Facilities required and their methods of manufacture,**
- **In process tests to be carried out during their manufacture** Mr. M. Radhakrishnan, M/s. Fourrts (India) Lab Pvt Ltd
- **Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above products -** Mr. D. Srinivasa Rao, M/s. Apex Laboratories Pvt Ltd.
- **Soft Skill Program** Full Day Ms. R. Padma, Soft Skill Trainer & Behavioural Assessor.

There was a daily written assessment on topics covered during the day.

Practical Training (27th October to 6th November 2014)

The practical training on Production Department of the industries was held from 27th October to 6th November 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, The Madras Pharmaceuticals, Chennai offered their facilities for training the participants. The candidates were sent for training in a group of 4 - 5. During the industrial training, they were assessed on common parameters by the Heads of Production department of the respective industries.

The final written evaluation was held on 7th November 2014.

On 8th November 2014, all the participants were awarded course completion certificates by Mr. C. V. Ramiah, Rtd. Director, Drugs Control, Tamil Nadu and Mr. A. Krishna Dev, Deputy Drugs Controller, (India) (Retd.) and Trustee, Tamilnadu Pharmaceutical Sciences Welfare Trust.

Following this, placement interviews were conducted. Technical and HR Department personnel from Sai Mirra Innopharm Pvt. Ltd., Apex Laboratories Pvt. Ltd., The Madras Pharmaceuticals Ltd., MMC Health Ltd and Tanmed Pharmaceuticals.

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 QA and Regulatory Affairs.

Certificate issued to Trainees (Photo 1 & 2)

1

2

Group Photo of the Trainees

53rd National Pharmacy Week Celebrations 2014 at Periyar College of Pharmaceutical Sciences, Trichy-21

Periyar College of Pharmaceutical Sciences, Trichy-21

53rd National Pharmacy Week Celebrations 2014

53rd Pharmacy Week Celebrations was organized by Periyar college of of Pharmaceutical Sciences with the theme **"Responsible Use of Medicines: Role of Pharmacist".** During the Rally Prof. Dr. R. Senthamarai, Principal welcomed the guests and mentioned regarding 53rd Pharmacy Week Celebrations and the importance to the public with the highlight of Responsible use of medications. The Rally was flagged off by Thiru. K. Chandrasekaran, Asst. Director of Drugs Control, Trichy Zone, Trichy. The Chief Guest of the program highlighted the importance of Pharmacy profession and advised the budding Pharmacist to get involved in Research and Development of newer Pharmaceuticals thereby improving the Community Health. Mr. D. Joshuva Devapriyan, Manager - HR and Mr. Solomon Samuel Executive - HR of Apollo Pharmacy Groups, Correspondent of PCPS, Thiru Gnana Sebastian and Prof Dr.A.M. Ismail, Vice Principal of the college offered felicitations during the programme. Vote of thanks was offered by Prof. Dr. G. Krishnamoorthy, Head, Dept. of Pharmaceutical Chemistry. The Rally started from K.K.Nagar. Bus Terminus and culminated at the Periyar Statue of Periyar Centenary Educational Complex. The placards containing messages were carried by students who raised slogans to create awareness about the Pharmacists role in Public Health among the people. The event of Pharma Rally being conducted by Periyar College of Pharmaceutical Sciences for the past sixteen years with the theme specified by Indian Pharmaceutical Association, New Delhi.In the after noon, a Pharma Quiz programme has been organized for all Pharmacy students of our college. The programme was conducted by Dr.T.Shri Vijaya Kirubha, Head, Department of Pharmacognosy with the participants of fifteen teams.

NEWS

Centre For Quality Checks on Ayurvedic Drugs

The Central Government is working towards setting up a separate Central Drug Controller for traditional medicines to ensure quality in production standards. This was announced by the Union Minister for Health and Family Welfare Harsh Vardhan on Thursday while inaugurating the first "Arogya Expo", which started in the Capital.

The Expo is organised by the Ministry's AYUSH Department as part of the World Ayurveda Congress.

The Minister added that "it is a pity that India's experience and strengths in traditional medicine have not translated into market shares in the global traditional medicines market".

"Call it whatever — Ayurvedic medicines or herbal medicines or traditional medicines — the global market is estimated at about $100 billion today. India's share in this is negligible because quality standards are not maintained to international specifications. The government has decided to address this lacuna," he said.

The institutionalisation of a regulatory authority backed up by Central and State laboratories would ensure for traditional and indigenous medicine pride of place in mainstream healthcare, the Health Minister said.

Dr. Harsh Vardhan said with the launch of the National AYUSH Mission, the government will focus on building up brand value for Ayurvedic drugs.

Source: *The Hindu, 7th November 2014*

Scientists Find Alternative to Antibiotics

In a major breakthrough, scientists have developed the first effective alternative to antibiotics that may aid the fight against drug-resistant infections. In a small patient trial, the drug was shown to be effective at eradicating the superbug Methicillin-resistant Staphylococcus aureus (MRSA).

Researchers said it is unlikely that the infection could develop resistance against the new treatment, which is already available %as a cream for skin infect-%ions. They hope to develop a pill or an injectable version of the drug within five years.

The treatment marks "a new era in the fight against antibiotic-resistant bacteria", according to Mark Offerhaus, chief executive of the biotechnology company Micreos, which is behind the advance.

The treatment attacks infections in an entirely different way from conventional drugs and, unlike them, exclusively targets the Staphylococcus bacteria responsible for MRSA, and leaves other microbes unaffected. The approach is inspired by naturally occurring viruses that attack bacteria using enzymes called endolysins. It uses a 'designer' endolysin, Staphefekt, which the scientists engineered to latch on to the surface of bacteria cells and tear them apart, 'The Times' reported.

"Endolysins exist in nature, but we've made a modified version that combines the bit that is best at binding to the bacteria with another bit that is best at killing it," said Bjorn Herpers, a clinical microbiologist, who tested the drug at the Public Health Laboratory in Kennemerland, the Netherlands.

Conventional antibiotics need to reach the inside of %the cell to work, and part of the reason they are becoming less effective is that certain stra8ins of bacteria have evolved impenetrable membranes. By contrast, endolysins target basic building blocks on the outside of bacterial cells that are unlikely to change as infections genetically mutate over time.

Source: *The Times of India, 7th November 2014*

Indian Drug Cos Eye Global Brand Buys to Storm US Market

Several Indian pharmaceutical firms with sizeable resources are preparing to buy global medicine brands with good sales potential in the US, as they try to offset constraints including price erosion and long gestation for product approvals that have of late dented their revenue.

Strengthening their US portfolio is key for these companies. The North American market contributes nearly half their global formulation sales and the US is the biggest segment of that. The targets for these companies are brands costing $5-10 million each.

India's second-largest drug firm, Dr Reddy's Laboratories, recently bought nicotine patch brand Habitrol from Novartis, while Lupin is scouting for a portfolio of US brands. Indian manufacturers are looking at buying brands with good sales potential in the US market, instead of acquiring the companies, said KPMG India's partner and head of life sciences practice, Utkarsh Palnitkar. "Recent moves by some of the larger companies seem to validate this. This trend is likely to help Indian companies overcome price erosion constraints and contain the impact on their revenue caused by the long gestation for product approvals."

The US market alone accounted for nearly 30% of India's medicine exports of $15 billion in the fiscal year through March 2014.Dr Reddy's, Sun Pharmaceutical Industries, Ranbaxy Laboratories, Lupin, Glenmark Pharmaceuticals and Aurobindo Pharma are among the top exporters of generic medicine to North America.

Indian drugmakers are stepping up shopping at a time when an increasing number of multinational drug companies are exiting non-core therapeutic segments to focus on a few core therapeutics. While the MNCs are known for their focus on brand building and brand consolidation for decades, the Indian companies, which are relatively not so focused on brands, now consider optimising spending on brands inevitable to stay afloat first and consolidate later.

According to Palnitkar, large Indian generic players are likely to be the first ones to step up their brand shopping in the US, which in turn could also imply further challenges for small and midsized players operating in the North American market. "Brand acquisition may also be a viable market entry strategy for companies who wish to establish a footprint in the US. Acquiring a successful brand would be a more risk averse, albeit an expensive, approach to increase market presence," he told ET.

Dr Reddy's chief operating officer Abhijit Mukherjee said the acquisition of Habitrol franchise from Novartis was part of the company's over-the-counter strategy. Given the client base in the US and the value the latest brand acquisition brings to the table, "it's a good deal for us", he said.

Lupin's chief financial officer, Ramesh Swaminathan, confirmed the company's plans to buy brands in the US market. "We are looking at acquiring a portfolio of brands in the US. We may close some of them or at least one before the end of the current financial year."

Lupin, the fifth largest Indian generic player in the North American market, is aiming at growing its US sales by 20-25% a year. During the last fiscal year, it posted $803 million sales, reflecting growth of 16% over the previous fiscal year.

On the preference of Indian companies for brands instead of buying companies, KPMG India's Palnitkar said strong brands would facilitate the franchise building exercise of pharma companies with doctors and patients.

"The brand value of medicines is what attracts attention after the expiry of patent exclusivity and is indicative of continued product acceptance. Additionally, companies are increasingly looking at alternatives to avoid the predominant manufacturing and other risks associated with acquiring companies." Some Indian copycat drug firms blame delayed approvals from the US drug regulator for denting their US sales and hampering growth.

Source: *The Economic Times, 10th November 2014*

Botched Op: Pharma co Burns Down Drugs

The Chhattisgarh health department on Thursday raided two pharma companies, Mahawar Pharma Pvt Ltd at Raipur and Kavita Pharmaceuticals in Bilaspur, suspected manufacturers of drugs administered on victims of botched sterilizations.Anticipating raids, one of the firms burned down drug stocks in its backyard.

Officials claimed they were able to retrieve some samples from burned stocks. Their company premises were sealed and seized drug samples were sent for analysis to the Central Drug Laboratory, Kolkata. The raids followed the government's decision to ban sale of antibiotic Ciprocin, manufactured by these two firms, which were locally purchased by Bilapsur health authorities.

Raids at Mahawar Pharma in Khamaridih, Raipur, revealed that the factory was operating from a residential area in violation of rules and had only two employees who were manufacturing and testing drugs for quality. Mahawar Pharma's licence was issued in 1996.

However, it's not known how medicines were locally purchased when the state has a centralized system controlled by Chhattisgarh Medical Services Corporation for buying and distributing drugs to government-run hospitals. Talking to TOI, food and drug comptroller Dr Ravi Prakash Gupta said that sale of drugs by the pharma company has been banned across the state.

Mahavar Pharma's promoter Ramesh Mahawar said there was nothing wrong with the drugs. “We are a reputed company and have been in business since 1996. The drugs had an expiry date of December 2016,“ he said. Till filing of this report, raids continued at Kavita Pharmaceutical in Bilaspur. Officials did not rule out possibility of arrests.

Source: *The Times of India, 14th November 2014*

CM Orders Probe, Doc Says Bad Quality Drugs Not Ops, The Killer

Chhattisgarh CM Raman Singh on Thrusday ordered a judicial probe into the botched sterilizations in Bilapsur district that killed 13 women and left 60 ailing and also sacked disgraced surgeon Dr RK Gupta and former Bilaspur CMO Dr R K Bhange.

Dr Gupta, arrested on Wednesday night, alleged that he was being made a scapegoat. Talking to reporters at Bilaspur police station, Gupta said that casualities were not triggered by infection caused by operative procedure but due to poor quality of drugs. He said that the state was trying to put the blame on him to hush up it sown shortcomings. He said “The CMO and other doctors responsible for purchase of drugs should have been booked on similar criminal charges.” Gupta was remanded in 15 day judicial custody.

The CM said all possible “angles” of the tragedy were being probed and that the cause of deaths would be known only after a detailed autopsy and analysis of seized drugs. “The guilty, whether drug manufacturers, distributors or doctors, won't be spared he said.

Source: *The Times of India, 14th November 2014*

Sterilization Deaths: Drugs Had Rodent-Killing Chemical

A preliminary report of an inquiry committee probing botched sterilizations in Chhattisgarh has revealed medicines given to the victims were contaminated with zinc phosphide, a rodent killing chemical. This could have led to death of 13 women.

Bilaspur divisional commissioner Sonmani Borah said traces of zinc phosphide were found in Ciprocin 500mg tablets, manufactured by Mahavar Pharmaceutical Pvt Ltd. These tablets were distributed among women, who underwent sterilizations at three camps in Bilaspur district.

Experts said zinc phosphide mixed with food is commonly used to kill rodents. Acid in the digestive system of rodent reacts with zinc phosphide and generates toxic phosphine gas. A similar reaction is triggered in humans too.

"It reacts with water and stomach juices to release phosphine gas which can enter blood stream and

adversely affect lungs, liver, kidneys, heart and central nervous system," said an expert.

Police have arrested Mahavar Pharma directors Ramesh Mahavar and his son Sumit Mahavar. More arrests are likely, including those of promoters of Bilaspur-based Kavita Pharmaceuticals. These firms have manufacturing licences for drugs, but lack required facilities.

(RK Gupta, the doctor who conducted 83 sterilization surgeries at the government-organized family planning camp, is in police custody in Bilaspur: PTI Photo)

Officials said these companies were buying medicines from other sources and packaging them under their own names. Police are looking for actual manufacturer of Ciprocin tablets.

The drug controller department failed to notice these illegal operations, while the health department regularly purchased medicines in bulk from these companies.

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

Poison Found in Botched Op Meds: Chh'garh Minister

Chhattisgarh health minister Amar Agarwal on Sunday confirmed that medicines used during the botched sterilization surgeries that claimed 13 lives and left 122 women ill in Bilaspur district earlier this month were laced with zinc phosphide – or rat killer poison.

The statement came four days after TOI reported that a Delhi-based drug laboratory had confirmed the presence of zinc phosphide in the antibiotic, Ciprocin 500, that was administered to women in state run tubectomy camps at Pendari and Gaurella villages in Bilaspur. The deaths occurred on November 10 and 11.

The state sent drug samples for tests to Kolkata, Nagpur and two labs in Delhi – Shri Ram Lab and National Institute of Immunology. Lab reports from Delhi confirmed the presence of rat poison and traces of toxic materials, including aluminium.

Agarwal said the reports had been sent to police. State officials said the Delhi report also revealed that the content of the main salt, Ciprolfloxacin, in the antibiotic was found to be 300 mg, when it should have been 500 mg.The findings have delivered a further jolt to Pharma companies Mahawar Pharmaceutical Pvt Ltd, Raipur and Bilaspur based Kavita Pharma, whose promoters – Ramesh and Sumit Mahawar, and Rakesh Khare, respectively – have already been arrested.

The spurious medicines given to the women during the sterilisation surgeries were allegedly supplied by the two companies. The Chhattisgarh government has suspended the sale and supply of the companies products across the state.

Source: *The Times of India, 24th November 2014*

Our Big Pharma Swindle

A tragedy is still unfolding in Bilaspur, Chhattisgarh, where 14 women died as a result of botched sterilisation procedures earlier this month. Initial investigations have identified two causes: a lack of basic hygiene in the facility and equipment used to perform this procedure, and the use of adulterated and substandard drugs.

Officials arrested the promoters of Mahawar Pharma and Kavita Pharmaceuticals, whose products were apparently dispensed to the victims. The fact that the promoters of Mahawar Pharma torched their stocks ahead of an inspection doesn't inspire confidence in the quality of their products.

However, it appears that officials have already concluded that this was a one-off incident, and prosecuting the principals in these two firms closes this chapter as far as adulterated drugs go.

It is astounding to see why no one seems to question the role of the regulatory bodies whose job is to ensure quality of medicines available in India. Is it not important to ask how a manufacturer was able to get its products to the consumer without proper regulatory oversight?

When the story broke last year of the case against Ranbaxy for manufacturing and distributing substandard and adulterated drugs in the US, the

general reaction from the industry was that the seven counts of felony that Ranbaxy pled to were purely “documentation related”. The media opined that vague western pharmaceutical interests were mounting a vendetta through the US Food and Drug Administration (FDA) against Indian industry. It was much ado about nothing since our government did nothing to sanction Ranbaxy. Will the same talking heads still feel that what happened in Bilaspur was a 'documentation issue'?

Does it take a tragedy of this magnitude to admit that we have a problem with quality of our drug supply? It is very difficult to prove 'causal relationship' between adulterated and sub-standard drugs and immediate health outcomes. Many of the medicines we take are for chronic conditions.

Impact of poor quality doesn't manifest immediately. A substandard drug used to control hypertension doesn't lead to a cardiac arrest in a week . Even antibiotics used to treat acute infections usually don't show up in surveillance systems (which India doesn't really have).

In February 2013, the Ghana Food and Drug Authority published a report on the quality of uterotonics (Oxytocin and Ergometrine), which were used to control post-partum bleeding in women in the Ghanaian market between August and September 2012. Ninety per cent of Ergometrine samples were manufactured in India. Of the 99 injection samples studied, 73% failed for the active ingredient and 95% of the failed sterility testing. Of the 11 tablets tested, 100% failed. The testing was done by an internationally recognised laboratory, and backed by both the US government and the independent US Pharmacopiea. While this is a single instance, it offers an insight into the quality of the drugs that the Indian pharmaceutical industry exports.

Indian pharma wields enormous power, and policymakers often subscribe to its point-of-view without fully appreciating the damage it is causing to the industry's — and the country's — reputation. Since May 2013, when the Ranbaxy story broke, 15 Indian manufacturing companies have been cited by the US FDA for poor 'data integrity' — they faked the testing data that they provided to the US FDA to secure approval to sell their product in the US market. All this while, the Indian regulator, the Central Drugs Standard Control Organisation (CDSCO) continues with business as usual.

Those who argue that India's drug regulatory system is up-to-date and ensures that Indian drugs are safe are simply not honest. The system is outdated and weak by design. The Drug and Cosmetics Act, dates back to 1940. Technology has advanced far since then, but the powers of drug regulation have not.

It is unfortunate that the previous Minister of Health Harsh Vardhan did precious little to fix this mess despite calling the CDSCO a “snake pit of vested interests”. The CDSCO needs a leader with unimpeachable integrity, not a politically-appointed bureaucrat. The government needs to bring in fresh thinking in structuring the regulatory oversight. Only then will we be assured that our drug supply is safe.

Source*: The Economic Times, 25th November 2014*

Infection, Not Just Fake Drugs, Behind C'garh Deaths

An independent report has indicated that septicemia that is infection during or after the mass sterilization surgeriesand not just spurious medicines could be behind the deaths of the 16 women in the Bilaspur mass sterilization botch up.

Demanding an independent inquiry in to the Chhattisgarh disaster, the team found that 85% of the budget for family planning in Chhattisgarh was spent on incentives and compensation for women while only 1.3% was spent on equipment, transport, awareness campaign and staff expenses and 1.5% in spacing methods like oral pills and condoms. The team included members from Population Foundation of India, Family Planning Association of India, Parivar Seva Sansthan and Common Health.

The team found that some of the critical cases admitted at Apollo Hospital showed raised levels of pro- calcitonin that suggests septicaemia. Post mortem examinations of the first seven deaths at the Chhattisgarh Institute of Medical Sciences and the District Hospital had evidence of peritonitis and septi foci in the lungs and kidneys, also suggesting septicaemia. "These indicate deaths by infection during or after the operation, and not just from spurious medicines as is being made out to be the

case. Further, according to forensic medicine and toxicology experts, the amount of zinc phosphide required to be lethal for women is 4.5 gms, which is much higher than what could possibly have been consumed by the women in 500mg of Ciprofloxacin. This also strengthens the argument that it was not the medicines alone that caused these deaths," the report said.

The report ``Robbed of choice and dignity: Indian women dead after mass sterilization'' was released on Monday after the team surveyed the camp sites, interviewed women who were sterilized, doctors and support staff.

The team has urged the state government to immediately make public the reports of post mortem, laboratory reports on drug analysis and the state committee set up by it to probe the tragedy. The team found that the families of the deceased had not been given the hospital records, nor told about the possible cause of death.

Source: *The Times of India, 2nd December 2014*

Chhattisgarh Sterilization Drugs Not Toxic

The case of botched-up sterilization deaths in Chhattisgarh has become murkier. Tests done on the dozen drug samples seized in Bilaspur by the approved national laboratory has nearly given a clean chit to the medicines used at the sterilization centre, saying they were substandard, but not toxic. Reports submitted by the state government to the health ministry last month had said the medicines contained poisonous substances like zinc phosphide (used as rat poison).

Official sources said there was no toxic element in the drug samples, adding only four samples were 'not of standard quality', while the rest of the samples met with the quality parameters. The result of one sample is still awaited.

Giving details, a health ministry official told TOI: "We have received reports from the Central Drugs Laboratory (CDL) in Kolkata intimating us about the samples seized from the Bilaspur hospital. These reports said that only four samples were 'not of standard quality'."

Source: *The Times of India, 12th December 2014*

Ranbaxy sues US FDA for revoking approvals

Drug maker Ranbaxy Laboratories, which is yet to resolve its long pending issues with the US drug regulator, has sued US Food and Drug Administration (US FDA) for revoking approvals granted to the firm for launching low-cost versions of two bestselling medicines -- Nexium and Valcyte -- used in treatment of heartburn and for infection caused by HIV, respectively.

Earlier this month, the US FDA withdrew its decision to grant tentative approvals to Ranbaxy for the two generic drugs citing the compliance status of Ranbaxy production facilities. The regulator had said its original decisions were in error because it found Ranbaxy's plants at the time were not compliant with the regulatory norms.

In its latest suit filed in the US district court of Columbia, Ranbaxy alleged US FDA's move violated "constitutional rights" and was "arbitrary, capricious, and otherwise contrary to law".

"FDA has no power to correct an alleged mistake it made six years ago," Ranbaxy said in the court filing, reviewed by TOI. In the law suit, Ranbaxy also requested the court to restrain FDA from approving any other generic versions of Valcyte or Nexium.

Source: *The Times of India, 19th November 2014*

Using a Diabetes Drug to Treat TB Shows Promise

Thanks to metformin, a drug that is commonly prescribed for type 2 diabetes patients, treating TB both the drug-sensitive and drug-resistant types may become far more effective if clinical trials in humans produce the same results as laboratory and animal studies.

According to a study published today (November 20) in the journal *Science Translational Medicine,* metformin was found to “inhibit intracellular growth of TB bacteria, restrict disease immunopathology and enhance the efficacy of anti-TB drugs.”

“These data suggest that metformin could be used as an adjuvant therapy to treat TB infection,” says the note from the journal Editor.

Besides the higher effectiveness, the biggest advantage is that metformin offers little chance for the TB bacilli to develop resistance against the drug.

The reason: unlike the age-old practice of developing new drugs that directly target the TB bacteria, the focus now is to choose drugs that are already being used in humans and investigate their ability to ramp up the body's responses to the pathogen's ravaging attack in several ways.

Besides the ease with which the pathogen can be eradicated and the disease cured, the novel route has other advantages. As the drug does not directly target the TB bacteria, the chances of the bacteria developing drug resistance are slim. Currently, drug resistance is one of the biggest problems in TB treatment. Since the drugs being investigated are already in use by humans, there is less likelihood of them being dumped on safety grounds when used for treating TB.

Test results

Of the 13 drugs tested using human monocytic cell lines, the team of researchers led by Amit Singhal of the Singapore Immunology Network Agency for Science, Technology and Research, Singapore, chose metformin for detailed studies. They found that the diabetes drug was capable of inhibiting the growth of intracellular BCG within one day and also “restricted” the replication of multi-drug resistant TB strains (MDR-TB).

The growth inhibition of TB bacteria was achieved by prompting the body's innate immune response to produce reactive oxygen species. If TB bacteria have an inherent mechanism of suppressing the synthesis of reactive oxygen species, the drug not only overcame this but also enhanced ROS production. This turned out to be the critical factor by which the drug was able to control the intracellular growth of the bacteria.

Animal studies

After testing the drug on cell lines, the scientists studied the effects of 500 mg per kg metformin in mice that had both acute and chronic drug-sensitive TB. The drug reduced the bacterial load in the lungs and spleen.

This was through a reduction in lung tissue damage of mice. When given along with isoniazid (INH) or ethionamide, the tissue damage reduction was even better compared to mice treated with only anti-TB drugs.

They also found that the drug had superior ability to reduce the disease-induced chronic inflammation. The reason: 45 of the 48 gene pathways affected by TB infection became normal after metformin treatment.

Although the researchers conducted studies in cell lines and in mice, the potential benefit of metformin in humans was evaluated through retrospective analysis of human data.

In humans

To do this, they chose diabetics who had TB and used metformin drug. They compared 106 diabetics who were on metformin with 164 patients who were on other anti-TB drugs. Chest X-rays revealed that those on metformin had fewer pulmonary cavities than those who were on other anti-TB drugs.

Besides improving the health parameters, the drug was found to have other beneficial effects. It was found to apparently lower the mortality risk. Also, diabetics who were on metformin and did not have TB were found to be less likely to get infected with TB. This protective effect was due to the drug's ability to enhance the TB-specific T cell immune response.

Source: *The Hindu, 20th November 2014*

Poor Quality Vaccine Led to FMD Outbreak : Report

Was poor quality vaccine administered to cattle the reason for foot-and-mouth disease (FMD) going uncontained last year?

The conclusion drawn by CCS National Institute of Animal Health (NIAH) in Uttar Pradesh that the vaccine was not up to the prescribed standard and lacked consistency and quality has raised this doubt.

The NIAH comes under the Department of Animal Husbandry, Dairying and Fisheries (DADF) of the Ministry of Agriculture.

The outbreak of FMD in 2013 had killed thousands of head of cattle across the country, including in districts like Kolar, Chickballapur, Mandya and Bengaluru Rural.

The disease had claimed 15,230 head of cattle in the State alone.

The report, prepared by CCS NIAH Acting Director Bhoj Raj Singh, a copy of which is available with *The Hindu* , said, “Poor quality vaccine used in FMD-CP programme might be responsible for the series of outbreaks encountered in vaccinated population in different parts of the country and the same reason might be responsible for huge economic losses incurred by the farmers and livestock owners.”

Source: *The Hindu, 20th November 2014*

Awareness on Pharmaceuticals

In keeping with the theme of this year's Pharmacy Week Celebration 'Reponsible use of Medicines, Role of Pharmacists',the Tamilnadu chapter of the Indian Pharmaceutical Association on Wednesday created awareness by educating public who visited pharmacy outlets on the dos and don'ts of medication use.

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

Bring 12 Cancer Drugs Under Price Control

Tata Memorial Highlights Price Disparity Between Innovator And Generic Drugs

The country's premier oncology treatment institute, Tata Memorial Centre, has written to the Centre and the drug price regulator seeking inclusion of 12 key cancer medicines in the National List of Essential Medicines. Prices of the drugs on the list are regulated by the government.

Tata Memorial said there was huge scope for price reduction. The 12 medicines include those used for brain tumor, colorectal cancer, cervical and ovarian cancer as well as those used in treatment of breast, lung, kidney and prostate cancers. Most of the medicines are used in multiple therapies.

The cancer institute has also explained the basis of its recommendations. For instance, the Centre has asked the government to make Zoledronic acid affordable. This drug has been found to reduce the incidence of skeletal related events such as severe pain, fracture etc in patients suffering from multiple myeloma and a variety of solid tumors including breast, lung kidney, prostate etc. According to doctors, zoledronic acid is commonly prescribed because it has better results. However, there is a huge price disparity between the innovator brand and the generics and therefore, scope for price reduction.

Essential Medicines

Drugs recommended by Tata Memorial Institute for addition in National List Of Essential Medicine

Medicine	Current Cost	Total cost of treatment for the drug for an average size adult
Bendamustine	**Rs 2,756** per vial of 100 mg Innovator brand- **Rs 25,291** per vial of 500 mg;	**Rs 35,000** For innovator brand – **Rs 2,28,000**
Rituximab	Generics – **Rs 19,695** per vial of 500 mg	Generics – **Rs 1,32,000**
All Trans Retinoic Acid (ATRA)	**Rs 5,795** for 100 capsules of 10 mg each	**Rs 75000**
Lenalidomide	**Rs 2,425** for 10 capsules of 25 mg	**Rs 60,000**
Trastuzumab	Innovator brand–**Rs 50,583 per vial of 440 mg;** Generics – **Rs 45000** per vial of 440 mg	Innovator brand – **Rs 8,00,000** Generics – **Rs 6,75,000**
Capecitabine	Innovator brand–**Rs 577** for 10 tablets of 500 mg; Generics – **Rs 277** for 10 tablets of 500 mg	Innovator brand – **Rs 30,000** Generics – **Rs 14,000**
Temozolomide	Innovator brand – **Rs 24,000** for 5 capsules of 250 mg Generics – **Rs 1,826** for 5 capsules of 250 mg	Innovator brand – **Rs 2,16,000** Generics – **Rs 20,000**
Irinotecan	Innovator brand – **Rs 7,780** per vial of 100 mg Generics – **Rs 918** per vial of 100 mg	Innovator brand – **Rs 1,87,000** Generics – **Rs 25,000**
Eriotinib	Innovator brand – **Rs 16,358** for 10 tab of 150 mg	Innovator brand – **Rs 3,00,000** Generics – **Rs 18000**
Zoledronic acid	Generics – **Rs 2730** for 30 tablets of 150 mg each	Innovator brand – **Rs 1,20,000** Generics – **Rs 3,180**
Megestrol acetate	Innovator brand – **Rs 10,000** per vial of 4 mg Generics – **Rs 265** per vial of 100 mg	**Rs 12,000** (Assuming 6 months of treatment)
Letrozole	**Rs 189** for 10 tablets of 40 mg each Innovator brand–Rs 1,568 for 10 tablets of 2.5 mg each Generics – Rs 46 for 10 tablets of 2.5 mg each	Innovator brand – **Rs 2,82,000** Generics – **Rs 8,280**

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

Indian Pharma Industry Is Highly Innovative, Set to Grow 5 Times in Coming Years: Dr V K Subburaju

The pharmaceutical industry in India is highly innovative and set to achieve five times growth in the coming years. With its present potential, the industry will continue to play a more significant role as an innovative manufacturing leader, according to Dr VK Subburaju, secretary, Department of Pharmaceuticals.

Pharmaceutical industry is a knowledge-based industry which carries a major role in the healthcare management system and continues to be a strong contributor of jobs to myriad number of pharmacy, biotechnology and other healthcare professionals in the country, besides posting growing revenues. It is expected to see rapid growth in coming years supported by increasing demand for drugs for curing various diseases. India's drugs are making impacts all over the world now.

The pharmaceutical secretary was delivering a lecture as chief guest in a function organized as part of the National Pharmacy Week celebration in Chennai.

Although the progress of Indian pharma industry is commendable, the sector is facing many challenges including lack of security for the imported bulk drugs, medical devices and its complex position due to the control of more than

one department. India was importing drugs for major diseases from other countries till the end of 1940s. But the situation in the drug sector changed later, and now Indian made drugs are being exported to foreign countries. About 220 countries in the world have the medicinal presence of India. The total drug production in the country is worth around Rs.180,000 crore today, he said.

According to him, the need of the hour is to focus on invention of new drugs and vaccines. Biotechnology should also be encouraged for more researches which will accept the services of potential pharmacists. The area of biotechnology has high potential for job opportunities, and institutions in the national level need to be developed in order to produce competent professionals in that field. He said a special 'task force' has been formed to work out the strategy for developing biotechnology. Likewise, in the pharmaceutical industry area another task force has been formed to study the problems of the bulk drugs industry and the safety of the imported bulk drugs.

He said India has to strengthen the area of vaccine production immensely as the country has only six vaccines which are available in almost all the countries. There are about 30 vaccines available in the world for curing various diseases. More innovations are required for inventing vaccines and new drugs for curing diseases like those which have no cure at all. The manufacturing companies which are investing more on R&D for new molecules can create waves in the world, said Dr Subburaju who was previously the principal secretary of Tamil Nadu.

IDMA chairman, SV Veeramni said in the meeting that the Tamil Nadu Pharma industry is not getting due recognition from the government though its contribution to the health and pharmacy sectors is beyond any limit.

J Jayaseelan, secretary of TN IPA, which organised the program, elaborated the role of pharmacists in society and Dr S Chinnaswamy, president of Tamil Nadu pharmacy council announced the names of award winners. CDSCO deputy drugs controller Dr S Manivannan, TN drugs controller S Abdul Khadar and Prof. Revichandran spoke at the meeting.

Former deputy drugs controller in the CDSCO, N Narayana Swami has been awarded the 'Best Pharmacist of the Year' 2014.

Source: *Pharmabiz, Wednesday, November 26, 2014*

New Class of Potent Antimalarial Drugs Found

An international team of scientists has found a new class of molecules that showed a high level of potency against human malaria parasites in animal trials.

The new compounds, known as pyrazoleamides, were effective against*Plasmodium falciparum* as well as *Plasmodium vivax*, the two most prevalent parasite species causing human malaria, say Akhil B. Vaidya of the Drexel University College of Medicine in the U.S. and the other scientists in a paper just published in *Nature Communications*.

Globally, there were about 207 million malaria cases and some 627,000 deaths in 2012, according the World Health Organization's estimates.

“Many of the existing antimalarial drugs stop working because of resistance development, [and] so it is essential to feed the pipeline with new antimalarial drugs through discovery and development,” remarked Prof. Vaidya in an email.

“The compounds we describe in this paper work very rapidly through a novel mechanism in malaria parasites, and thus would work against drug resistant parasites currently infecting humans.”

At one stage in its complicated lifecycle, the parasite infects red blood cells and replicates inside them. Using a mouse model carrying human red blood cells, the scientists examined the drug's effect on *P. falciparum*, which causes the most dangerous forms of malaria.

As the parasite matures inside the red blood cells, it produces a change in the permeability of the membrane around those cells. That leads to a sharp increase in sodium levels in the red blood cells.

The new pyrazoleamides affect a molecular pump the parasite relies on to control its own sodium levels. As a result, the parasite swells rapidly, followed by what the paper described as “dramatic

apparent bursting."

"However, we believe the mechanisms for parasite demise and clearance are complex," said Prof. Vaidya in his email. The increased sodium levels inside the parasite could also be providing a premature signal for it to try and leave the red blood cells. "This would be lethal for parasites since they would not have completed the complicated process of assembling all the components necessary for generating infectious progeny called merozoites." (The merozoites go to infect more red blood cells.)

An added attractive feature of the new compounds was their activity against the mature sexual stages of *P. falciparum,* the paper noted. The parasite's male and female forms mate after being ingested by a blood-feeding mosquito. Inhibiting the production of those sexual stages would help prevent onward transmission of the parasite by mosquitoes.

One of the new molecules has been identified for further development as a candidate antimalarial drug.

A novel antimalarial drug now in human clinial trials, which belongs to a different class of chemicals (known as spiroindolones), also targets the malaria parasite's ability to control its sodium levels.

Source: *The Hindu, 27th November 2014*

Dr.Reddy's Plant Gets USFDA Fiat

U.S. health regulator FDA has found nine possible procedural deviations in a manufacturing plant of Dr. Reddy's Laboratories during a recent inspection and has sought reply from the drug maker on these issues.

The company is in the process of responding to the FDA's observations, a Dr. Reddy's spokesperson said.

"We have received nine inspectional observations from the U.S. FDA after their visit to our API (active pharmaceutical ingredients) manufacturing facility in Srikakulam district in Andhra Pradesh.

"We will respond to the agency within the stipulated timelines with our remedial plans and start implementing the necessary measures immediately," the official told PTI. These observations largely related to procedural and other compliances of the plant systems. At this stage, production continued in the normal course, and there was no implication on any activity at the plant, the spokesperson added. According to analysts, the company received 'Form 483' observations from USFDA for its unit 6 of the Vizag plant.

Source*: The Hindu, 27th November 2014*

Road to Japan Pharma's Next Frontier

The Prime Minister of India, Narendra Modi, in his 2014 landmark Japan visit said : "India-Japan ties have been elevated from a 'strategic and global partnership' to a 'special strategic and global patnership'. The visible bonhomie between the two democracies and old allies has a potential to start a new era in their relationships across various areas including nuclear technology, military, high speed transport and healthcare.

Indian pharmaceutical industry is truly global. With a strong domestic market, growing fastest in the world after China, India is global leader by volume in pharmaceutical exports. Pharmaceutical exports were pegged at US $ 15 billion with a CAGR of 15% over last five years. In US alone, India has exports over US$ 4 billion. Today, Indian companies hold 22% market share in total generic prescription with 7 Indian companies in top 25 generic companies in US. This tectonic change has happened in the last 10-121 years when the market shares were less than 2%.

India has been at the helm of revolution in the pharmaceutical industry in terms of best quality affordable medicines. One of the most remarkable examples is almost 98% reduction in cost (from $10,000 per year to under $200 per year) of HIV medications in Africa to increase access to the AIDS striven countries. Today, India is the leader in providing supplies globally with over 75% of volume

share. India also boasts of leadership in global vaccines with over 30% of volume share. All this can be credited to strong focus on R&D by the Indian companies, who spend 7-9% of revenues on R&D. In fact, R&D spend is projected to cross US $ 4-5 billion by 2016.

While India is a growing economy and pharmaceutical market, Japan is the 3rd largest economy(GDP of US$ 5.9 trillion) and 2nd largest pharmaceutical market (US$ 112 billion) of the world. The pharmaceutical market is expected to grow to US$ 126 billion by 2018. Ageing population, rising incidence of chronic diseases and liberalized OTC medicine sector remain the key drivers of increasing demand for pharmaceuticals. The new government has also brought in progressive economic reforms in the pharmaceutical sector. The government is looking to sign innovative research.

Despite huge market size and great potential, India has had limited partnering opportunities with Japanese companies. In result, Japan constitutes only 1% of US$ 15 billion Pharma exports from India.

The relationship has a massive potential to be strengthened as depicted aptly in a statement by Japanese Prime Minister Shinzo Abe's joint parliamentary session address in India in 2007: "Japan-India relationship is blessed with the largest potential for development of any bilateral relationship anywhere in the world". There exist multiple strategic symbiotic business opportunities between India and Japan.

With a very strong preference for patented drugs and very low generic penetration (26% by volume compared to 70% in US), Japan has the highest per capita spend (US$ 882) in the world. The Japanese government has set an ambitious target to increase the generic penetration to 60% by 2017. India could add strategic value in reduction of cost burden in Japanese healthcare system by supplying affordable, quality generic medicines and active pharmaceutical ingredients. It has the highest US FDA approved plants outside of US (over 100) and over 150 European Directorate of Quality Medicine (EQDM) approved plants.

Indian companies have been at the forefront of developing cost-effective Biosimilars in the last decade targeting insulin, growth hormone, filgrastim, erythropoietin and monoclonal antibodies. These could provide safe and quality products in areas of oncology, diabetes and nephrology, which form the bulk of disease burden in Japan.

India also offers huge advantage on clinical research as 15% of global trials are conducted in the sub-continent. An access to a billion people, 'western' disease distribution, large number of medical specialists, low cost and 'therapy naïve' patients could be ideal for Japanese companies to explore clinical trial options in India.

Indian companies boast of global manufacturing base and keep abreast through ongoing innovation by investing in complex API technologies and continuous cost reduction technologies led by skilled manpower. A Japanese major has already set up a manufacturing facility in Vishakhapatnam underlining the significance of India at the helm of their strategy. Other pharmaceutical multinationals also have their facilities across the country to garner the emerging markets advantage.

Suzuki came to India 30 years back and did fantastically well. They still rule cose to 40% market share in passenger car segment. Unfortunately, Indian automobiles have not enjoyed that access and penetration in the Japanese market. However, a beginning has already been made for pharmaceuticals and there are ample opportunities in Japan and Japanese companies in India. Indian Pharma is at the pivotal point to tap growth opportunities for Japan, where we were a decade ago for US and Europe.

Source: *The Economic Times, 28th November 2014*

If US Had A Patent Law Like Ours, They Would Discover Many More Drugs:

India's intellectual property (IP) law has been hailed as one of the most progressive for safeguarding public interest, and several nations like Argentina, the Philippines and Brazil are looking to learn from it. Senior advocate and former UN special rapporteur on the right to health Anand Grover talks to Rema Nagarajan about the pressure the country is facing, primarily from the US, to change its IP laws.

Why is the US turning the heat on India over IP?

The US government is under pressure from its companies to take action against India over its IP law. But our law is 100% compliant with the Trade-Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organisation (WTO). So, if they take it up with WTO, they will lose 100%. That's why they have taken the unilateral route of pressurizing India by placing it on the Special 301 list meant for countries whose patent protection laws are deemed inadequate by the US. The TRIPS agreement allows flexibilities such as countries deciding what is "new or innovative" in giving patent rights. That is why we have section 3(d) in our patent law, which defines what is new or innovative.

The US says its advice on patents will help India boost innovation. Is that true?

Actually, they, the US and EU, ought to learn from us. As UN special rapporteur on health, I had advised them to change their patent laws along the lines of the Indian one because we found that with their law, a majority of the drugs being patented were just new forms of existing drugs with no change in therapeutic efficacy. It is precisely to prevent this sort of tweaking of existing drugs to get patents that we have section 3(d). FDA's own data says 76% of drug patents in the US are for new forms of existing drugs. I pointed out to them that they were giving the same number of years under patent for an original new molecule as for new forms of an existing molecule. Companies make the same amount of money by tweaking existing molecules. So what's their incentive to discover new molecules? That's why the discovery of new molecules is grinding to a halt. If they had a law like ours, they would see how many new molecules and drugs would be discovered. But the pharma lobby that heavily funds US elections is too strong for the government to bring the necessary changes in patent laws.

Why has the Indian government's IP think tank generated controversy?

Health activists primarily have a problem with the composition of the think tank. Barring Prabha Sridevan, who is former chairperson of the Intellectual Property Appellate Board (IPAB) and has heard important patent cases as a high court judge in Chennai, what is the background of the other members? Do they have any research background or experience in policy-making?

Where are the academicians who have been advising the government on IP for so many years? We want to know from the government how the members of the think tank were picked. There has to be a transparent process. The BJP has come to power partly on the basis it is against nepotism. Who picked the members? The mandate of the think tank suggests that they will advise the government on IP policy forever. All this might just be window dressing, because some lobby within the government is pushing to change the IP law. Even the Confederation of Indian Industries (CII) and Federation of Indian Chambers of Commerce and Industry (FICCI) want the law changed. But they have always been part of the MNC conglomerate and will only think of their interests and about getting more investment. It will not be that easy. Our patent law was unanimously passed by Parliament. The whole government has backed the stance on section 3(d) so far. It will be a huge shift if they actually come out against it.

What should the government do about IP in the current circumstances?

The government seems to believe that by changing the IP law they will get more foreign investment. There is no evidence that will happen. India is known for its IT industry and in the developing world for its pharmaceuticals. If we change our laws to suit external interests, we could end up destroying our domestic industry. Creating a climate friendly for investment cannot be at the cost of your own industry.

'Make in India' should be made in India by Indians for Indians and for the whole of humanity. It should not become Make in India by foreigners, where they take over our industries.

As for being under pressure, this government is supposed to be a strong government so they should be able to withstand pressures from anywhere. If they buckle to US pressure despite being such a strong government, that will be a sad day. Let's see how strong they really are.

Source: *Times of India, 30th November 2014*

Scientists Devise $1 Injectable Contraceptive

A new one dollar easyto-use injectable contraceptive has been developed by researchers who plan to distribute it in 69 of the world's poorest countries by 2020.

The special device, with a smaller needle and no traditional syringe, will be sold at just $1 a unit.

An agreement has been signed which will make contraceptive injections available to women in 69 of the world's poorest countries, BBC News reported.

The deal has been reached between the Gates Foundation, the drug company Pfizer and the Children's Investment Fund Foundation.

The technology has been previously used for giving hepatitis B jabs in Indonesia. Burkina Faso was the first country to use it for contraception.

Using the prepackaged device, there is no need for health workers to prepare a syringe.

The drug is dispensed by simply squeezing a plastic bubble, giving users the protection they want for three months. With the design called Uniject there is no risk of spillages or dosing errors, and because the device cannot be re-used, it cuts out the risk of infection due to needle-sharing.

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

US Generic Drug Approval Delayed Despite An Act to Speed it Up

The process of approving generic drugs to be sold in the US has slowed critically to hit a 6-year low. According to international updates on FDA approvals, only 11 ANDAs (abbreviated new drug applications) were approved for November against a peak approval of 78 in September 2012.

The Generic Drug User Fee Act (GDUFA) in the US was proposed to expedite the approval of generic drugs on collecting higher fees to process applications. But since its implementation in September 2012, the average approval timeline of ANDA has increased to 27 to 30 months, from an average of 24 months. As part of the reforms process under GDUFA, the drug regulator, USFDA, targets to bring down the overall ANDA approval timeline to 10 months by 2017.

One of the major reasons for the delay is high number of drug applications being received by USFDA. The resources at FDA have not kept pace with the increased number of ANDAs received. For Indian drug makers, the ease of doing business in the US, the world's largest pharmaceutical market, has been considerably hit. On one hand, USFDA has become stringent in assessing the manufacturing practices of drug companies and beefed up inspection of facilities. On the other, the process of drug approvals has slowed considerably. This has thrown a spanner in the growth projections of most drug companies.

The uncertainty surrounding the time of approvals led to companies like Dr Reddy's Labs (DRL) putting a stop to offering growth guidance. The September quarter performance of companies like DRL and Glenmark Pharma was impacted on account of delayed approvals in the US. Likewise, companies like Sun Pharma and Lupin have not bagged any major drug approval in the last few months.

Analysts and industry players expect the pace of approval to pick up by the second half of the next year, thus potentially benefiting most large Indian companies. A speedier approval process will help companies like Cadila Healthcare, Sun Pharma and Lupin, which have one of the highest numbers of drug applications pending for approval with USFDA.

Source: *The Economic Times, 2nd December 2014*

Govt Plans To Make Quality Stamp Mandatory For New Clinical Trials

Starting early next year, the government is planning to make quality accreditation mandatory for new clinical trials in the country.

"Pharma companies or sponsors keen to conduct new clinical trials in India would have to seek accreditation from the Quality Council of India (QCI) for their sites, ethics committee and investigators before they apply for the drug regulator's clearance," said a government official aware of the proposal. For ongoing trials, it may not be made mandatory immediately but these will also be brought under the accreditation fold eventually, he confirmed. This proposal, initiated by the health ministry, is in the works and could be implemented as soon as next month, the official added.

Currently, National Accreditation Board for Hospitals & Healthcare Providers (NABH), an arm of QCI that offers quality certification to hospitals, clinics, blood banks, wellness centres, and dental clinics, is firming up standards that trials sites, ethics committees and doctors conducting such programmes need to maintain to get accreditation. However, the services of NABH have remained voluntary in nature in the past.

Clinical research in India has been in the eye of a storm in the last three years with public health activists accusing pharma companies and other stakeholders in the sector contract research organizations (CROs), doctors conducting trials, ethics panels of not sticking to global best practices and exploiting uninformed patients while testing experimental drugs.

They have accused pharma companies of skimping on compensation to trial victims in case of death and injuries, doctors of not taking proper informed consent of trial volunteers and the government of lax regulation in the space. The pharma companies argue that blaming the entire industry for wrongs committed by a few is not only unfair but also counterproductive for new drug research. The Supreme Court is currently hearing a public interest litigation on the matter.

"We wanted an independent third party to audit and certify the quality standards of trial sites, ethics panels and of doctors undertaking trials if they qualify. That is the reason we approached QCI to take up that responsibility," another government official said.

Of the 10 lakh trials conducted globally, India is home to only 15,000, estimates an expert panel headed by Ranjit Roy Chaudhury. This panel had also recommended accreditation of sites, investigators and ethics committees but by a central accreditation council, the constitution of which it had proposed. Industry experts said this demand will be a tall order till such time NABH is not staffed with specialised experts to carry out such technical audits.

"It is a well thought out plan but will be time consuming and demand substantial resource investment. While thrashing out the modalities, all stakeholders should be consulted to make it feasible," said Saurendra Das, executive director of Excel Life Sciences, a US-headquartered clinical site management firm.

Another CRO said it will be particularly onerous for standalone clinics and small hospital set-ups and new hospitals that are not already conducting trials.

" An audit can certify a trial site only if it has already conducted one or is conducting one but what about those sites which want to start but have no past record?" he said.

Source: *The Economic Times, 2nd December 2014*

Meda, Cipla Sue Apotex to Enforce Dymista Patents

Sweden-based drug firm Meda Pharmaceuticals Inc and Cipla Ltd have "sued" Apotex Inc and Apotex Corp in Federal District Court in Delaware in US to enforce patents of its allergy drug 'Dymista'. In a BSE filing, Cipla said "they sued Apotex Inc and Apotex Corp in Federal District Court in Delaware to enforce the Orange-Book listed patents covering 'Dymista' Nasal Spray."

The company added that it has sued Apotex Inc and Apotex Corp "in response to Apotex's submission to the US FDA of an abbreviated new drug application (ANDA), and accompanying Paragraph IV certification, seeking approval to market a generic version of Meda's 'Dymista' prior to expiration of the 'Dymista' patents."

In June 2013, Cipla granted the global commercialisation rights for 'Dymista' to Meda AB except for certain geographies.

Commenting on the development, Meda CEO Dr J rg-Thomas Dierks said: "Meda will vigorously enforce the 'Dymista' patent rights against Apotex and any other company who challenges these patents.

"The Complaint was filed within 45 days of receiving Apotex's Paragraph IV certification notice, thus triggering an automatic stay preventing the FDA from approving Apotex's ANDA for 30 months from receipt of the notice, unless ordered otherwise by a district court, the Cipla said.

"Meda has the exclusive licenses to US Patent Nos. 8,163,723 and 8,168,620 covering the 'Dymista' composition and its approved uses, which does not expire until 2026'," it said.

Meda holds the New Drug Application (NDA) to manufacture and market Dymista in the US for the treatment of seasonal allergic rhinitis.

Meda and Cipla are jointly represented by attorneys from Sterne, Kessler, Goldstein & Fox P.L.L.C. And Ashby & Geddes, PA.

Source*: The Hindu, 4th December 2014*

Germany Bars Antibiotic Drug Form Ranbaxy's Plant

Ranbaxy Laboratories Ltd has been barred by from exporting the antibiotic cephalosporin to Germany from its plant in Madhya Pradesh for not complying with standard manufacturing practices.

Germany's regulator issued a "non-compliance" report for the plant where Ranbaxy made the antibiotic, after an inspection in June, the European Medicines Agency said on its website in a notice dated Nov. 26.

During the inspection, the German regulator found deficiencies related to operation of drug manufacturing rooms and procedures related to sterilisation of equipment at the Dewas site, the notice said.

The Dewas factory and Ranbaxy's other India-based plants are also barred from exporting to the United States after the U.S. Food and Drug Administration (FDA) inspections found those plants violated its standard manufacturing practices.

Ranbaxy, which has said it was working on resolving problems at its plants to get the regulatory bans lifted, did not respond to a request seeking comment on the observations made by the German regulator.

Ranbaxy gets more than half of its revenue from the United States. Germany accounted for 2 percent of global sales in the 15-months period ended March 2014, as per the company filings. The latest German sales data was not immediately available.

Source: *The Hindu, 4th December 2014*

All New Medicines to Come Under Price Control

The drug price regulator has mandated companies to seek its approval for every new medicine, including combinations of existing ones, to ensure that consumers are not overcharged. According to the National Pharmaceutical Pricing Authority (NPPA) all innovative launches like new combinations of price-controlled medicines as well as those with changed strengths and dosages will be treated as 'new medicines'.

The move is aimed at spanning the price regulation of essential medicines. while also keeping a check on innovative branding and marketing strategies of pharmaceutical companies to circumvent price control, an official, in the know of developments, told TOI.

Currently, prices of 374 medicines are directly capped by the government at the average price of those being sold with at least 1 per cent market share. This roughly accounts for 10-13% of the total domestic pharmaceutical market pegged at around Rs 79,000 crore.

In order to escape price regulation . companies often launch newer combinations by making minor changes to existing price-controlled medicines. Sometimes, firms also tweak the strengths and dosages to bypass the price ceiling.

While such products are launched as newer brands, companies benefit from such strategies because under the existing law, firms are free to fix the launch price of all medicines, other than the 374 that are directly under government control. Even for such medicines, companies are free to raise prices by up to 10% annually.

“Market launch and/or sale of a 'new drug', as defined under paragraph 2 (u) of the DPCO (Drugs Price Control Order) 2013 without prior approval of retail price by the NPPA or where such approval stands withdrawn shall not only attract recovery of overcharged amount along with interest and penalty but also prosecution under Section 7 of the Essential Commodities Act, 1955," NPPA said in a recent notice.

The regulator has also asked companies to submit a compliance certificate from Drug Controller General of India (DCGI), which monitors quality of medicines and gives approval to new products.

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

Europe Bars Imports From Antibiotic Injectables Unit : Ranbaxy

The European Union has banned imports from a Ranbaxy Laboratories Ltd factory unit that makes injectable antibotics after the unit failed an inspection, the latest in a series of quality-related setbacks for the Indian drugmaker.

European authorities inspected all units at Ranbaxy's Dewas plant, in central India, in June and did not approve the manufacturing practices at the unit that makes injectable cephalosporin antibiotics, Ranbaxy said in a stock market filing on Thursday.

All other units of the facility were approved, it said, adding the company had decided to stop producing cephalosporin injectables at Dewas before the inspection occurred.

"We wish to state that Ranbaxy's decision to discontinue manufacture of cephalosporin injectables would not have a significant impact on the business," Ranbaxy said.

All of Ranbaxy India-based factories, including Dewas, are already barred from exporting to the United States after the U.S. Food and Drug Administration said its inspections found manufacturing quality lapses.

The latest EU ban on the Dewas plant was enforced after German regulators also found quality lapses during an inspection of the site. The European Medicines Agency, in its statement dated Nov. 26, did not specify, however, if the ban was on the oral or injectable cephalosporin antibiotics units.

Source: *The Hindu, 5th December 2014*

Astrazeneca, Ranbaxy Prevail in Nexium Antitrust Trial

A Massachusetts jury has found that an agreement between AstraZeneca Plc and Ranbaxy Laboratories Ltd to delay the launch of a generic version of AstraZeneca's heartburn drug Nexium was not anticompetitive.

The verdict, handed down Friday in federal court in Boston, is the first time a jury has decided such a case since the US Supreme Court ruled last year that so-called "pay-for-delay" settlements may run afoul of antitrust laws.

The US Federal Trade Commission estimates that pay-for-delay deals, in which a branded drugmaker pays a generic rival to stay off the market, cost consumers $3.5 billion each year.

An attorney for the plaintiffs, which include drug wholesalers, retailers and insurers, could not be reached for comment. AstraZeneca and an attorney for Ranbaxy released statements saying they were pleased with the verdict.

The lawsuit, which began in 2012, challenged a 2008 settlement in a patent suit between AstraZeneca and Ranbaxy. The plaintiffs claim the settlement gave Ranbaxy nearly $1 billion to delay the launch of its generic Nexium.

The suit originally also targeted two other generic drugmakers that reached deals with AstraZeneca over Nexium, namely Teva Pharmaceutical Industries Ltd and Dr. Reddy's Laboratories Ltd, but both settled with the plaintiffs.

Two other cases against the same four companies over the Nexium settlements are pending in Pennsylvania state court. Those cases are not affected by Friday's verdict.

Ranbaxy had planned to launch generic Nexium this year, but the FDA recently revoked its approval, citing problems with the company's manufacturing process.

Source: *The Hindu, 7th December 2014*

CCI Clears Sun-Ranbaxy Deal With Riders

Sun Pharma and Ranbaxy on Monday got the Competition Commission of India's (CCI) approval for their long-pending $4-billion merger, but with a condition that they would have to modify the deal by divesting seven key products to address monopoly concerns.

The regulator, which has ordered Ranbaxy to sell six products and Sun to divest one, will also appoint a monitoring committee to oversee compliance to the conditions put forth by it to ensure that the merger does not hit competition.

The approval comes within days of clearance from the Foreign Investment Promotion Board (FIPB) for the deal that was announced in April, and would create India's largest and world's fifth biggest drug-maker.

Besides, this was the first case which the CCI subjected to a public scrutiny process as it had found the deal 'prima facie' in violation of the competition laws.

In its order, dated December 5 and made public on Monday, the CCI said, it “approves the proposed combination... subject to the parties carrying out the modification to the proposed combination.''

The CCI has directed Sun Pharma to divest all products containing 'Tamsulosin + Tolterodine', which are at present marketed and supplied under the Tamlet brand name.

Similarly, Ranbaxy would be required to divest all products containing Leuprorelin, which are marketed and supplied under the Eligard brand name.

Ranbaxy would also have to divest products such as Terlibax, Rosuvas EZ, Olanex F, Raciper L and Triolvance.

According to the fair trade watchdog, the modification to the proposed deal aims “to maintain the existing level of competition in the relevant markets in India.''

The merged entity would have operations in 65 nations, 47 manufacturing facilities.

Source: *The Hindu, 9th December 2014*

Cadila Launches Cheaper Version Of World's Top-Selling Drug

The company will launch it under the name Exemptia at a fifth of its U.S.Price
Drugmaker Cadila Healthcare Ltd said on Tuesday it launched in India the first biosimilar version of the anti-inflammatory medicine adalimumab, the world's top-selling drug, at a fifth of its U.S. Price.

The drug's branded version is sold under the name Humira by U.S. firm AbbVie Inc, and costs $1,000 for a vial in the United States. Humira had sales of $3.26 billion in the quarter ended September, accounting for 65 percent of AbbVie's total revenue.

A price of $200 a vial would still keep the drug out of reach for most people in India, where more than 70 percent of the population lives on less than $2 a day and health insurance is scarce.

Biosimilars are cheaper copies of biotech drugs - medicines made from proteins and other large molecules.

Cadila expects sales of between 1 billion rupees ($16.16 million) and 2 billion rupees from its biosimilar of Humira in the Indian market, Deputy Managing Director Sharvil Patel told Reuters.

The company will launch its version under the name Exemptia for treating diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, and ankylosing spondylitis.

About 12 million people in India suffer from these disorders, Cadila said in a statement.

"We are working towards being among the first wave of the launch of this drug's biosimilars globally," Patel said, adding he does not expect any domestic competition on the drug "in short term."

The company expects to launch the medicine in the United States in 2019, he said.

Humira's U.S. patent will expire in late 2016 and AbbVie has said it will take years for other drugmakers to develop and win approval for their own generic versions.

Cadila has meetings scheduled with the U.S. and Europe regulators next year, Patel said. "It's a very attractive market, there are many, many companies working on this product."

Biosimilars are expected to account for about one quarter of the $100 billion worth of sales stemming from off-patent biological drugs by the end of the decade, a study compiled by Thomson Reuters BioWorld said in September.

Several hundred companies around the world are chasing the biosimilars market, including Indian generic drugmakers Dr Reddy's Laboratories Ltd, Cipla Ltd and Lupin Ltd.

Source: *The Hindu, 10th December 2014*

WHO : India Has 12.8cr Suspected Malaria Cases

India has recorded only 8.81 lakh confirmed malaria cases. This means that only 7% of total number of cases are being confirmed in the country.

As many as 111 crore Indians are at risk of getting infected with malaria of which 28 crore have been found to be at highest risk.

The World Health Organization on Tuesday said India has 12.8 crore suspected malaria cases. However, India recorded 8.81 lakh confirmed cases of the world's most dangerous vector borne disease.

This means that only 7% of malaria cases are being confirmed in the country.

The country also faces the most deadly threat of the malaria strain becoming resistant to the most advanced drugs available till date, thanks to unregulated selling of banned malaria therapies. The most dangerous malaria carrying vector P falciparum has been found to have become resistant to the wonder drug artemisinin in five countries Cambodia, Lao, Myanmar, Thailand and Vietnam.

WHO has banned the sale of oral artemisinin based monotherapy medicines and replaced them with artemisinin combination therapies. The use of monotherapy medicines threaten the long-term usefulness of ACTs, because it fosters the spread of resistance to artemisinin.

The number of countries that allow the marketing of oral artemisinin-based monotherapies has dropped tremendously since the World Health Assembly adopted a resolution supporting the ban in 2007.

But as of December 2014 the WHO confirmed that 24 pharmaceutical companies continued to market oral artemisinin monotherapies, half of them located in India. WHO also said India and Thailand are on track to achieve a decrease of 50-75%in malaria cases.

Source: *The Times of India, 10th December 2014*

Soon 100% FDI In Medical Devices

The department of industrial policy and promotion (DIPP) has moved a Cabinet note to allow 100% foreign direct investment in medical devices as part of a strategy to not only reduce imports but also promote local manufacturing for the global market, which will be worth over $400 billion next year.

Over the past few months, the government has eased FDI rules in defence and construction to promote domestic manufacturing as PM Narendra Modi made a pitch for 'Make in India' and boost investment and economic activity. The proposal on medical devices will be a carve-out of the FDI policy in pharmaceuticals, said an official, adding that there will be no need for government approval in this segment. Currently, India imports over 70% of medical devices used here.

At present, medical devices come under the purview of the Drugs and Cosmetics Act and FDI in the sector is governed by the same rules as that for pharmaceuticals or medicines. Though the government allows 100% FDI in pharmaceuticals, companies are required to comply with certain conditions. For instance, in case of pharmaceuticals, 'non-compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board (FIPB). Similarly, in case of FDI in existing Pharma manufacturing units, the government may in corporate the conditions while granting approval.

Now, the proposal, moved by DIPP, suggests medical devices are different from medicines and, therefore, FDI for manufacturing of medical devices can be allowed under the automatic route without any such conditions as are applicable for pharmaceuticals.

The FDI norms, in case of drugs, are also stringent because there were concerns due to increasing presence of multinationals through acquisitions of domestic Pharma companies, which may adversely impact prices of medicines in India. This was the reason the government differentiated between the FDI policy for setting up a new drug facility and the acquisition of an existing one. FDI is allowed through the automatic route for setting up a new drug facility while for FDI in existing facilities approvals are need by the FIPB and Competition Commission of India.

The latest proposal, which has received consent during inter-ministerial consultation, is expected to be tabled in the Cabinet this month, official sources said. The healthcare and diagnostic segment is growing rapidly, creating a major market for manufacturing of medical equipment and devices in India.

The medical technology sector in India was estimated at $6.3 billion in 2013, growing 10-12% per annum.

Source: *The Times of India, 10th December 2014*

Zydus Rolls Out New Biosimilar Drug

Drug firm Zydus Cadila on Tuesday launched biosimilar of Adalimumab, used for treatment of auto immune disorders, at a price much lower than the innovator drug in India.

Developed by Zydus Research Centre, the biosimilar has been approved by the Drug Controller General of India and will be marketed under the brand name 'Exemptia' at a cost that will be one-fifth of the innovator product Humira by AbbVie.

The company has got approval for the product for four areas at present -- rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis and ankylosing spondylitis.

"The cost of the innovator product by AbbVie is $1,000 per vial. Our Exemptia will be available at one-fifth of its cost in India. It is the first biosimilar of Adalimumab," Zydus Cadila deputy managing director Sharvil P Patel told PTI.

The company is also looking for approvals for three large indications - Crohn's disease, ulcerative colitis and plaque psoriasis, he added.

When asked about the global sales of Adalimumab, Patel said: "The sales were around $12 billion worldwide."

Though the innovator drug is under patent protection but the therapy was not available to patients in India.

"This therapy will offer a new lease of life to millions in India who did not have access to it so far. Patel said.

Source: *The Times of India, 10th December 2014*

Medical Device Firms Asked to Reveal MRP

Medical device companies are for the first time being asked to reveal the maximum retail price (MRP) of the devices they sell in India. The National Pharmaceutical Pricing Authority (NPPA) has written to about a dozen top medical device companies asking for a list of devices they manufacture or import along with their current prices citing "media reports" about huge trade and profit margins on devices like cardiac stents, orthopaedic implants and other devices, leading to patients being charged exorbitant prices.

The move is significant also because the NPPA letter dated December 5 stated that this information was being sought to examine if there was any price violation in notified medical devices.

"While it is laudable that the NPPA is looking into the pricing of medical devices, seeking the MRP of a device or basing any regulation on the MRP is a totally useless exercise. There is no regulation on how much MRP can be marked for any device. The companies mark whatever inflated price they want," said a senior cardiologist.

This is known to the NPPA, as the Maharashtra Food and Drug Administration (FDA) had sent a report to it over a year back giving details of how companies were overcharging for medical devices. The FDA report gave several examples of drug eluting stents being imported by manufacturers for about Rs 40,000 but with the MRP shown as approximately Rs 1.5 lakh, a mark-up of more than 250%.

The FDA report had sought control on prices of devices like stents and orthopaedic implants. Medical devices including drug eluting stents, orthopaedic implants, disposable syringes, ocular lens and heart valves are notified as drugs under the Drugs and Cosmetics Act, 1940 but not included under the Drug Price Control Order (DPCO). Hence, their prices are neither monitored nor controlled.

Source: *The Times of India,10th December 2014*

Stem Cells in Eye Can Restore Vision, Say Scientists

In what promises to be an alternative to corneal transplantation in treating blindness caused from damage to cornea, scientists from city-based L.V. Prasad Eye Institute (LVPEI) in collaboration with U.S. scientists claimed to have discovered potent stem cells in the eye that possess the ability to restore lost sight.

The findings have been published in the journal, *Science Translational Medicine* on Thursday. Speaking to journalists, Sayan Basu, LVPEI consultant corneal surgeon and scientist, said he along with other scientists at the laboratory of Prof.James L.Funderburgh, Professor of Ophthalmology, University of Pittsburgh School of Medicine, tested stem cells obtained from human eyes on an experimental model of corneal scarring.

Source: *The Hindu, 12th December 2014*

Pick-Up in Local Market Boosts Pharma MNC's

A pick-up in the local pharma market augurs well for MNCs which are still recovering from the adverse impact of drug price control on high-priced, top selling brands. After a two-year slump, the domestic market is recording higher volumes in the last six months. The resolution of the dispute between stockists and drug companies in the aftermath of the drug price control order resulted in volumes gradually picking up in the local market.

For the quarter ended November, the volumes grew 4.6 per cent against a 1.6 per cent drop in the year-ago period.The top five MNCs -GSK Pharma, Abbott Healthcare, Pfizer, Sanofi and Abbott India - together command 14 per cent share in the ` . 82,000crore Indian pharma market.

According to data released by pharma market research body AIOCD, since the last two months, MNCs have clocked higher growth than their domestic market counterparts. Among the top-ten players, Pfizer grew 34 per cent in November when the overall market growth was 11 per cent. In October, the fastest growth was by GSK Pharma at 13 per cent.

For MNCs, the portfolio of products under price control -which figure in the National List of Essential Medicines (NLEM) -has not been growing since the past two years.

The growth of NLEM portfolio of MNCs this year has dropped by over 5 per cent as against 1.7 per cent growth posted by domestic companies.Even the growth of the non-NLEM portfolio of MNCs has been lower than that of the domestic drug companies. To make matters worse, the volumes in the domestic pharma market was growing in single digits. All this led to underperformance of MNCs in the overall Indian pharma market as well as on bourses.

Now, with volumes picking up and the effect of price control getting normalised, MNCs may show better earnings.But, the Street has been discounting this with stocks of most MNC drug firms like Abbott India, GSK Pharma, Pfizer, Sanofi and Merck outperforming the BSE Healthcare Index in the past three months. Shares of Abbott India have more than doubled in the past six months.

GSK Pharma, the largest drug MNCs in India, has surged 24 per cent in three months.

In a report on the company, Rakesh Nayudu, an analyst with Espirito Santo Securities has listed factors like impact of NLEM portfolio weighing on profitability and market share loss over the years amidst competitive intensity to indicate that GSK pharma is not out of woods.

Source: *The Economic Times, 12th December 2014*

NPPA Extends Price Caps to 52 More Essential Drugs

The National Pharmaceutical Pricing Authority (NPPA) has extended the price caps to 52 drugs deemed essential by the government, including painkillers and antibiotics, in its latest move to improve the affordability of medicines.

The additional drugs join a list of nearly 400 essential treatments under price control. In a notice issued in September, the NPPA had fixed the prices of 36 drugs, including those to treat infections and diabetes.

The wide-ranging price cuts have hit both local and foreign drugmakers and have been opposed by many industry officials, who have said drug prices in the country were already among the lowest in the world.

In the latest pricing move, the drugs added include commonly-used antibiotics and painkillers as well as medicines used to treat cancer and skin disorders, a notice on the NPPA website said.

The price caps on some of these drugs only apply to specific companies, it added.

Companies, including Lupin, Cadila Healthcare and Merck, the Indian arm of Germany's Merck KGaA, are among those selling drugs mentioned in the latest notice, the authority said.

Cadila and Lupin did not immediately respond to a request for comment. Merck was not immediately reachable.

NPPA Deputy Director Naresh Arya said the regulator continued to look at other disease areas where the prices of drugs might need to be fixed. The domestic pharmaceutical industry bodies filed two separate lawsuits against the NPPA in July over its notice to cap the prices of 108 drugs that were not on the national list of essential medicines.

Source: *The Hindu, 13th December 2014*

Prices of 25 More Drugs Now Capped

There's good news for patients. Drug pricing regulator NPPA announced cap on prices of over 25 drugs, including painkillers and antibiotics, which will lead to reduction in their costs over the next few weeks.

The price regulator in a notification issued on December 10, fixed prices of formulations which join a list of 348 essential medicines that were placed under price control. The new drugs on which caps were issued include commonly-used antibiotics and painkillers, as well as medicines used for treating cancer and skin disorders.

The NPPA notification mentions a total of 52 drugs, including those with specific dosage strengths which were till now not under the purview. The latest addition brings the total market size of medicines

under price control to nearly Rs 125 crore, according to market research firm AIOCD AWACS. The wide-ranging price cuts will impact both domestic and foreign companies.

The NPPA notification, an industry expert explained, also includes price changes which will be extended on dosage strengths of molecules which were till now not under price control. It said it has fixed/revised the prices in respect of 52 formulation packs both ceiling and retail price packs under DPCO, 2013. Price caps on some of these drugs only apply to specific companies, it added

Earlier efforts by the NPPA to bring down prices of essential drugs for diseases like cancer, have been strongly opposed. In July, the NPPA in a rare invocation of the lesser-used provision had fixed prices of 50 antidiabetic and cardiovascular medicines. This was the first time that the government had brought drugs, outside the national list of essential medicines, under price control.

The move had triggered of a series of protests and lawsuits from the industry against the drug pricing regulator, as they feared more such action.

Finally, in September this year the government had withdrawn certain powers of the drug pricing regulator that allowed it to cap prices of widely-prescribed anti-diabetes, cancer, HIV, tuberculosis and cardiac medicines.

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

After Price Cap, Drugs in Short Supply

The government's price control measure for essential medicines has had an unexpected fallout several of these drugs, including those for treatment of chronic ailments such as high uric acid levels, diabetes and acne, are either in short supply or have gone missing from chemist shops.

Among the drugs facing shortage are Zyloric (prescribed for uric acid control), Ocid (acidity), CCM (calcium supplement) and Etroxin (a thyroid medicine) among others. Albumin, a lifesaving protein, has been in short supply for nearly four months now.

Druggists claim the pharmaceutical companies have reduced the production of these vital drugs because their profit margins have gone down a charge denied by manufacturers. Kailash Gupta, head of a federation of chemists, said while controlling the price of essential medicines the government should also ensure their regular supply.

Kailash Gupta, president of All India Chemists and Distributor's Federation, said several vital medicines went into short supply right after their prices were controlled by the government.

“Ten capsules of Zyloric used to cost Rs 37.40. But after price control measures announced by the government, it now costs Rs 23.30. Similarly, the MRP of Eltroxin (25mg) went down from Rs 76 to Rs 69. Ocid's price was cut by nearly Rs 30 for a sachet containing 15 tablets," said Gupta.

In September this year, the government curbed the power of regulator to cap HIV and cancer drug prices.

"We get many patients who are suffering from chronic ailments and dependent on some of these medicines. They are desperate to get these medicines," he said.

According to Dr Anoop Misra, chairman, Fortis-CDOC Centre of Excellence for Diabetes, Metabolic Diseases, and Endocrinology, Zyloric is one of the standard drugs prescribed to kidney patients, those suffering from gout and even diabetics to control uric acid. "The substitutes available in the market for this medicine are costlier," he said.

Dr Sujeet Jha, head of the endocrinology department at Max hospital, Saket also confirmed the absence of Zyloric at the hospital's pharmacy.

The spokesperson of GlaxoSmithKline, which manufactures the drug, told TOI: "We are currently facing some issues across our manufacturing network that is impacting our ability to supply a number of products. We are doing our utmost to bring supply back to normal as soon as possible." The spokesperson added that restoring normal supply may take a few months.

According to IMS Health's latest market data, pharmaceutical sales in the domestic market during November grew 11.6% from the previous month.

A senior official from Cadila Healthcare said there was no shortage of any drug manufactured by the company. "We continue to produce at our previous levels. There is no cut in either production or supply. I am surprised to hear that you have found shortage. From our end, the supply situation is fine and we have not received any complaints," a senior executive of the company said.

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

52 Drugs to Get Cheaper

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The latest addition brings the total market size of medicines under price control to nearly Rs 125 crore, according to market research firm AIOCD AWACS.

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

25 Drugs Tested at Hyd Lab Put on Hold in 4 Nations

Four European countries decided to suspend marketing authorization of 25 drugs, which had undergone tests at the GVK Bio sciences facility here before they were introduced.

European Medicines Agency (EMA) said in a statement that it is reviewing the findings of non-compliance with good clinical practice at the GVK facility and determining its impact on medicines authorized on the basis of studies performed there. Germany, France, Luxembourg and Belgium have already decided to suspend marketing authorizations of these drugs.

“EMA will issue a recommendation on whether the marketing authorizations of the concerned medicines should be maintained, varied, suspended or withdrawn across the EU. The recommendation is expected in January, “ the regulator said.

When contacted, GVK Bio spokesperson refused to comment, saying the news was not communicated to the company.

EMA started the review in September 2014 following an inspection carried out by the French medicines' agency at the GVK Biosciences, which raised concerns on the 'reliability of studies' conducted at the facility between 2008 and 2014.

EMA's Committee for Medicinal Products for Human Use (CHMP) is now identifying, together with member states of the EU, the medicines covered by the inspection findings.

French drug regulator ANSM said on its website that Belgium, Germany, Luxembourg and France decided to suspend the marketing authorizations for the medicinal products concerned.

Source: *The Times of India, 7th December 2014*

CCI Approves Tie-Up of Sun, Ranbaxy, But Conditions Apply

The long-pending $4 billion merger between Sun Pharma and Ranbaxy on Monday got a conditional approval from fair trade watchdog CCI, which asked the two companies to divest some key products along with other changes to the deal to address the anti-competitive issues.

The fair trade regulator's approval comes after the first ever public scrutiny carried out by it for a merger, which was announced in April and would create India's largest and world's fifth biggest drug maker.

In an order released on Monday, the Competition Commission of India (CCI) said that it “approves the proposed combination..subject to the parties carrying out the modification to the proposed combination”. CCI has directed Sun Pharma to divest all products containing Tamsulosin + Tolterodine' which are at present marketed and

supplied under the Tamlet brand name.

Similarly, Ranbaxy would be required to divest all products containing Leuproprelin which are marketed and supplied under the Eligard brand name, among others.

In all, six products will have to be divested by Ranbaxy and one by Sun. According to the fair trade watchdog, the modification to the proposed deal aims "to maintain the existing level of competition in the relevant markets in India". This would need to be done through creation of a viable, effective, independent and long term competitor in the relevant markets pertaining to the divestment products, CCI said in the order.

"Ensuring that the approved purchaser of divestment product(s) has the necessary components, including transitional support arrangements to compete effectively with the merged entity in the relevant markets in India.

The combined entity would have operations in 65 countries, 47 manufacturing facilities across 5 continents, and a significant platform of speciality and generic products marketed globally.

Source: *The Economic Times, 9th December 2014*

India Can Insure its Health

Reforms and choosing the right pathway towards universal health coverage can be transformative

India has made extraordinary economic progress over the last few decades. Progress on human development, however, has not kept pace with its economic development.

While progress has been visible on health outcomes, with a 60 % reduction in child mortality and a two third reduction in maternal mortality, the country continues to reflect some of the world's poorest health statistics. India reflects among the highest number of infant deaths: 48 per 1,000 live births, which is three times that of China and four times that of Thailand or Sri Lanka.

It spends just over 1% of its GDP on publicly-funded healthcare, and almost 7 in 10 people pay for their own healthcare, with 60 million Indians pushed into poverty every year as a result. In comparison, China's public health investments in 2011 were 2.9 % of GDP and Brazil's 4.1 %.

The Narendra Modi government has promised to turn these statistics around with several reforms in the pipeline. It has been designing a National Health Assurance Mission aimed at providing affordable healthcare to all citizens. While conversations are underway on universal health coverage (UHC), there is inadequate clarity as yet on which diseases it will prioritise, or how much it will spend on public health.

If the reforms are to have a real impact, three lessons laid out in the Global Health 2035 report must be kept in mind:

India will have to increase its domestic health investments:

Currently, the government spends around $20 billion each year on health. This could be doubled to about $45 billion per year. And if the additional investments were spent on the highest impact interventions, India could achieve a "grand convergence" in global health. Which means India's rates of avertable infectious, maternal and child deaths could plummet to those seen in the bestperforming middle income countries like Chile, China, Cuba, or Costa Rica, or 'the 4C countries'.

To reach 4C levels, India needs to:

..Expand use of current medicines, vaccines and diagnostic tests..Build delivery systems that can efficiently distribute these life-saving tools..Ensure that new health technologies are used widely when they become available

The areas that will require the largest investments are maternal, newborn and child health; immunisations; aggressive malaria control; and health systems-strengthening. Since child death rates in India are higher in rural than urban areas, it will be particularly important to reach the rural poor.

Tackling drug-resistant tuberculosis must be another priority. The public health impacts would be profound with investments to achieve convergence, around one million deaths, including 660,000 child deaths, would be averted each year from 2035 onwards.

And the economic payoff would be enormous. From now until 2035, for every dollar that India invests in achieving convergence, there would be a return of around $10. In financial markets, investments with foreseeable returns of 10 to 1 over reasonable time horizons simply do not exist.

Address the growing challenge of non-communicable diseases (NCDs):

Research by the World Economic Forum and Harvard University suggests that unless India takes concerted action to turn the tide on NCDs such as heart and lung disease, it stands to lose $4.6 trillion before 2030.

The Global Health 2035 report found that innovative fiscal policies - taxing alcohol, sugar and all forms of tobacco and reducing fossil fuel subsidies - could be a powerful lever for curbing NCDs and raising new revenues for health.

A recent study led by Sanjay Basu at Stanford University concluded that tobacco taxation would be a potent measure to avert future cardiovascular deaths in India. If India increased the price of tobacco by 50% through a tax, this would prevent 4 million deaths and generate $2 billion in revenue annually over the next 50 years.

India has to expand the right health insurance coverage:

As we celebrate Universal Health Coverage (UCH) Day, it is encouraging to see that Prime Minister Modi wants to expand health insurance coverage. But choosing the right pathway towards UHC will be critical.

The Global Health 2035 report examined various approaches to expanding insurance, including publicly-financed 'pro-poor' insurance schemes, catastrophic coverage and private insurance. The report found that the pro-poor schemes would yield the highest health gains per dollar spent while ensuring that the poorest gain the most in terms of health and financial protection.

These pro-poor schemes initially focus on ensuring that everyone receives high-quality primary care. They benefit the poor because they are disproportionately affected by these health problems.

Once everyone in India is covered with primary care, these schemes then expand to cover higher cost services. With the right health investments today, by 2035 India could rise to become among the 'best-performing' middle income countries in the world.

Source: *The Economic Times, 12th December 2014*

370 Clinical Trail Deaths in 2 Years, But Kin of Only 21 Get Compensation

Despite clinical trials coming under scrutiny in various courts, little has changed on the ground. At least 370 deaths have been reported during clinical trials in India since February 2013, but compensation has been paid in only 21 cases, according to government data. The amount ranged from Rs 4 lakh to Rs 40 lakh, a senior official told TOI.

Of the 370 deaths, 222 (60%) cases have been examined so far by a regulatory panel on clinical trials. Of these, only 21 were eligible for compensation as the the drug under trial was found to have caused the deaths, the official said.

Medical experts, however, say there is lack of clarity on the norms on which eligibility for compensation is decided.

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compensation as the the drug under trial was found to have caused the deaths, the official said.

Medical experts, however, say there is lack of clarity on the norms on which eligibility for compensation is decided. It is largely subjective, they point out, and the basic data comes from the very investigators who are involved in conducting the trial. Hence, it is not only possible for them to influence or manipulate data, there is hardly any wherewithal with the regulatory agencies to check its authenticity .

"The investigator who reports adverse impacts of a drug under trial has conflict of interest because he is paid by the pharmaceutical company conducting the trial," says Dr C M Gulati, editor of the Monthly Index of Medical Specialities and an advocate of public health.

After a nudge by the Supreme Court, the government and Drug Controller General of India (DCGI), which monitors the quality of medicines as well as their testing, recently notified detailed guidelines for conducting clinical trials and reporting of data related to deaths. The regulator has also worked out a mechanism for paying compensation to the families of those who die during these trials.

As per the new rule put in place in January 2013, an independent expert committee examines the reported adverse events and makes recommendations to the licensing authority or DCGI, which will ultimately take a call on the quantum of compensation. However, health experts say the biggest draw for drug makers is the lax regulatory environment. "These expert committees evaluating registered deaths are in metros whereas companies pick up remote villages and small towns for conducting clinical trials," says a medical practitioner, pointing out that though companies insist they follow global best practices, participants in rural areas are often barely aware of the possible consequences of the trial.

The DCGI and other regulatory authorities claim there are adequate procedures in place to safeguard public interest. Of late, the regulator has started approving fresh trials.

The industry was faced with a slowdown since 2012 after repeated directives from the apex court for safety procedures for patients participating in the trials. The clinical trial industry in India is pegged at over `3,500 crore and is growing at 10-12% annually .

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

Medicine Import Scam : CBI Arrests 12 Customs Officials

Pharma distributors colluded with custom officials and imported drugs, especially those for treating cancer, from China and other countries.

CBI's anti-corruption wing sleuths on Monday arrested 12 customs officers in Chennai for letting some Pharma distributors import medicines without verifying license and other documents.

The arrested customs officials Ram Lal, Kannan, Karthik, Sanjay and eight others were produced before a CBI special court and remanded in judicial custody. The medicine import scam came to light in 2012 when CBI arrested a few customs officials.

When a drug is imported, the Pharma distributor or agency should produce a drug license before the drug control official deputed to the customs office. In this case, CBI officials said,Pharma distributors colluded with the customs officials and imported drugs, especially those for treating cancer; from China and other countries.

The agents did not produce the documents or other documents to import these drugs that arrived by air and sea.

"The customs officials did'nt bother to verify the license details submitted by these agencies based in Chennai. These drugs have been sold through medical shops across Tamilnadu and neighbouring states, " a source said. He added that the arrested customs officials were questioned and they confessed to having broken rules to benefit the drug distributors.

CBI court judge Krishnamurthy remanded the officials till December 29. Meanwhile, the counsel for the customs officials has filed a bail petition which will be heard on Tuesday.

Source: *The Times of India, 16th December 2014*

Novartis Drags Cipla to Court

After the bitter patent fights on HIV, cancer and diabetes drugs between MNCs and domestic companies, the focus is now shifting to non-communicable diseases like respiratory and lung ailments. Drug MNC Novartis has moved the Delhi high court seeking to restrain generic firm Cipla from selling an affordable version of its respiratory drug Onbrez in the domestic market.

Cipla too moved an application on Friday seeking the government's reply in the case, sources told TOI.

In a case where there is a clear implication on the right to health and access to treatment, Novartis aims to shut down an affordable version of the drug by a competitor, and has argued in its affidavit filed in the court that it will continue to import, and not locally manufacture, the drug.

Experts say that the MNC's stand is a clear violation of IP laws, which stipulate that the patent has to be 'locally worked' that is, be affordable and available to patients in the country.

Cipla recently launched its version of the drug at Rs 130 for 10 pills, at one-fifth of the price of the Novartis' Onbrez, which is sold at Rs 677 (for 10 pills).

There are 1.5 crore patients suffering from lung and respiratory diseases in India while Novartis has imported a negligible quantity, making it available to only 8,000 patients over a period of two years. The case was heard by Justice Manmohan Singh on Tuesday at the Delhi high court, and a final order is expected in January, sources told TOI. Both the sides are represented by high profile lawyers Novartis by Gopal Subramaniam and Cipla by P Chidambaram.

In its affidavit, of which TOI has a copy, while arguing that there is no requirement for the drug to be manufactured locally, Novartis has said that the "patent is worked" and the drug is made available to fulfil the requirement of patients in India. It has said that it will continue to import the drug from Switzerland, according to the demand, and the constitutional right to life, Article 21 (invoked by Cipa), is "misconceived and untenable". The company had filed for a patent on the drug in 2001.

After HIV drugs, domestic companies have been at the forefront of offering some of the most affordable treatments for asthma and chronic respiratory disease, industry experts say. This has been possible only because patents on these drugs or exclusive monopoly rights have been largely controlled till now.

Experts say that the MNC is looking at the patent laws "very narrowly", not having taken into account the key issue of pricing of the drug. They feel that the courts would look at the patent laws keeping in mind the larger issue of the right to health, and right to life, and how many patients in India cannot afford the Novartis medicine.

Source: *The Times of India, 17th December 2014*

Pharma Cos With Big Exposure to Russia Fall With The Rouble

Shares of Indian pharma companies with a significant exposure to the Russian market tanked on Tuesday's trade as concerns over the falling rouble led to panic-selling among traders. Rouble, which saw a steep fall since 1999, has raised fears that Russia might be heading towards difficult days, with the backdrop of a sharp drop in oil prices.

BSE Healthcare index fell by 2% at 14479 compared to its previous close of 14888 on Monday, the Sensexclosed at 26781, down by 1.97%. Dr Reddy's, which has close to 15% of its total revenues coming from Russia, fell by 6%, followed by Torrent and Glenmark. The Russian drug market is estimated to be $16 billion. According to analyst estimates companies like Glenmark, Torrent, Cadila and Ranbaxy have close to 15% of their revenues coming from Russian market. Though the rupee depreciation should help the companies to gain in markets like the US, in Russia most of these companies were trading in local currencies.

"I don't know if this is a long-term phenomena, as it can be best read by a currency or geopolitical expert. But if this fall continues and even if it

remains in these levels it will certainly erode the valuation of these companies," said Surjit Pal, an analyst with brokerage firm Prabhudas Liladher.

The fall in Russia's rouble is seen as a challenging time ahead for emerging markets that are faced with a fall in their own local currencies. The fall in capital markets of these emerging economies is further raising questions about how long would the "correction" last.

"It has yet to be seen whether this weakness is merely profit-taking or the downtrend might gain momentum in the weeks to come. But given the scale of the year-to-date rally, a period of correction and consolidation should not come as a surprise," said Radhika Rao of Singapore-based DBS bank in a research note "For now, triggers of this downshift are external. Concerns over growth in the G3 economies and China are weighing on sentiments."

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

Indian Pharma Cos Need A Cure to Beat Emerging Crisis

Depreciation of the Russian currency poses a risk to the profitability of Indian pharma companies such as Dr Reddy's, Glenmark and Ranbaxy. Russia, a key market for these companies, contributes 5% of overall Indian pharma exports.

RussiaCIS accounts for 10% of overall sales of companies like Dr Reddy's, Glenmark, Ranbaxy , IPCA and Torrent. In the September quarter, they began reporting that the Russian currency devaluation was hurting business. This could worsen.

Political crisis in Russia and weakening crude prices have resulted in sharp rouble depreciation against the US dollar (83% since March 2014). Analysts say an unchecked rouble slide would hurt profitability, especially if rupee holds stable (versus USD).

Dr Reddy's and Glenmark could take a hit as RussiaCIS constitutes 9-15% of their total revenues. But the impact on Torrent and IPCA would be nominal, owing to lower sales RussiaCIS, Rajat Rajgarhia, MD institutional equities, Motilal Oswal Securities said. Ranbaxy's 15-month earnings (Jan 2013-March 2014) from Russia was Rs 650 crore. But some compa nies may escape the rouble depreciation consequence net-net, as their loss will be offset by rupee depreciation (against the dollar).

But some analysts say the impact may not be large. "It's unlikely to impact Dr Reddy's profitability much as it earns only 15% of its sales (FY2014) from Russia, says Sarabjit Kour Nangra, VP research (pharma), Angel Broking.

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

Drug Firm Tweak Combo, Dosage to Evade Price Cap

From aggressively pushing new drug combinations to reducing supply, pharma bigwigs are coming up with various ways to circumvent the government's new pricing policy, even as the Centre has brought 52 more drugs under its price control mechanism.

Chemists say while supply of many essential drugs on the price control list ranging from painkillers and antibiotics to those treating cancer has reduced since the policy came into effect in 2013, newer and more expensive combinations are finding their way to doctors' prescriptions.

Medical representatives say companies have instructed them to "aggressively" market combination drugs. When TOI called pharmacies asking for amoxicillin, an antibiotic used to treat tonsillitis, bronchitis and pneumonia, many said it was unavailable. However, a combined version with antibiotic cloxacillin was available. While one strip (10 pills) of amoxicillin costs 68, six pills of the combined version cost 150.

The medical representatives said companies were also playing the trick of changing dosage.

Manufacturers are changing the dosage of the drug to evade DPCO. For example, 500mg of pain reliever paracetamol is in the price control list, so companies have increased the dosage to 650mg and are selling it as a higher price," said G Gopinath, working committee member of Federation of Medical Representatives Association of India (FMRAI).

And there is further tweaking of drugs. "In the list, a cap has been placed on 500mg of anti-diabetes drug metaformin. Now companies are pushing for metaformin sr (sustained relief), which, again, doesn't feature on the list," said H Sriram, who is also an FMRAI committee member.

More than 450 drug formulation packs are now under the price control mechanism of the National Pharmaceutical Pricing Authority. To meet the demand, chemists are stocking up more combination drugs. "While supply of essential drugs under the price control list has decreased, I wouldn't say there's a shortage. We do have most of these drugs, but demand for these combination drugs is more as doctors are increasingly prescribing them," said S Elangovan of Tamil Nadu Chemists and Druggists Association. When contacted by TOI, pharma majors Novartis and GlaxoSmithKline denied they were aggressively marketing combination drugs. While a Novartis spokesman denied the company's drugs that feature in drug price control order (DPCO) are in short supply, GlaxoSmithKline said the company had some issues in its manufacturing network, which would be rectified soon.

"We have been selling combination drugs for years and they are supplied based on the evolving demands. Besides, they are convenient for the patients as they can have one tablet instead of two," said a Glaxo SmithKline spokesman.

Experts say pharma companies are creating an artificial sense of shortage of essential medicines to push the more expensive version. "Their argument is that they are facing losses. We have done studies to show that only 17% of the market has been affected after the new drug pricing policy. And by 'affected', it just means reduction in profitability and not losses," said Sakthivel Selvaraj, a senior health economist with Public Health Foundation of India. He said 47% of the one lakh brands of drugs in the market are combination drugs. "The efficacy of these combination drugs is still ambiguous," he added.

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

From January 1, No Freebies For Doctors

Doling out freebies, cruise tickets, paid vacations and sponsorships to educational conferences and seminars for doctors by pharmaceutical companies has been banned from January.

The government has woken up belatedly to curb unethical marketing practices of pharma companies by spelling out a uniform code of conduct for the industry. The code will be voluntary to start with, and kicks in from January 1. It will be reviewed after six months; if not implemented "effectively", the government will "consider"' making it mandatory, sources told TOI.

At present, the pharma industry follows a "self-regulatory'' code that curbs unethical sales promotion and marketing expenses, bans personal gifts, and all-expenses paid junkets for doctors and their families, but there have been several instances where companies have violated the code, industry experts say. They say the code exists only on paper as companies try to influence prescriptions through several ways.

This is the first time in years that the code has been finalized by the government, as earlier attempts to do so got mired in bureaucratic red tape.

Concerned with the increase in unethical marketing practices and prescription drug promotions by

pharma companies, the government had first decided to ban these through a uniform code in 2008-2009, but the pharma associations did not agree to it.

When contacted, Indian Drug Manufacturers Association secretary general Daara Patel said, "The code seems to be strict. We are in consultations with the government. If we cannot educate about a particular medicine or disseminate information, how will doctors know about it?"

Industry body IDMA, representing certain domestic companies and OPPI, which represents MNCs, have their own "self-regulatory" codes in place, drawn up a couple of years back, and revised again in 2013.

Industry experts say that the government's Uniform Code of Pharmaceutical Marketing Practices has been modelled on the Medical Council of India (MCI) guidelines for doctors and healthcare professionals, which were further tightened in 2012.

The code - a copy of which is available with the TOI- talks about banning gifts, hospitality, medical samples, medical grants, and clarifies the relationship with healthcare professionals. Regarding gifts, it says "no gifts, pecuniary advantages, or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharma company, or any of it agents including retailers, distributors or wholesalers".

It says "in any seminar, conference or meeting organized by a pharma company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate, it will be on his/her own cost."

It further says that gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) such as tickets to entertainment events are also not to be offered or provided by pharma companies, nor cash or monetary grants for individual purposes. Hospitality should also not be extended to any doctor or their family members.

Referring to the earlier communication to industry associations sent out over two years back in March 2012, the department of pharmaceuticals says in the letter that the Uniform Code of Pharmaceutical Marketing Practices has been finalized after inputs by various stakeholders, and would be again reviewed six months after its implementation from January 1, 2015.

The industry associations have to upload the Uniform Code on their websites and will be responsible for informing its members, and the government in case of violations.

Source: *The Times of India, 23rd December 2014*

Cipla Bags Rs 1,100 Crore Order From South African Govt

Drug major Cipla's subsidiary has bagged an order worth 2 billion rand (around Rs 1,100 crore) for HIV drugs from the South African government.

Cipla Medpro, the South African subsidiary of the Indian firm, has bagged the order as part of the South African government's 2015-17 National ARV tender.

The contract is effective from April 1, 2015 and will run for a period of three years, Cipla Ltd said in a filing to the BSE.

"We are extremely proud to have won this tender which is not only testament to our high quality product portfolio, but is also in line with Cipla's ethos of advancing healthcare for all South Africans," Cipla Ltd MD and Global CEO Subhanu Saxena said.

Commenting on the development, Cipla Medpro CEO Paul Miller said Cipla is known as a pioneer of fixed dose combinations, following Yusuf Hamied's accomplishment of making AIDS medication available for a dollar a day in 2001.

"We intend to continue this proud tradition and build on the foundation laid to continue our quest of providing affordable healthcare to all," Miller added.

The medication will be produced at the company's 23,000 square meter manufacturing site in Kwazulu-Natal.

The latest government tender win is the third in the last one year for the company.

Cipla Medpro had earlier bagged a R280 million state therapeutic drug tender in August 2014 and a R345 million national respiratory tender in June 2014.

Cipla had completed the buyout of Cipla Medpro last year in July for an aggregate consideration of Rs 2,707 crore.

Source: *The Hindu, 24th December 2014*

Indian Immunologicals Makes Foray Into Bovine Serum Manufacture

Vaccine major Indian Immunologicals Ltd. (IIL) is making a foray into manufacture of bovine serum, a critical raw material for animal vaccines, by setting up a subsidiary in New Zealand.

A company in New Zealand had been acquired, and its plant, located 80 km from Auckland, has a capacity to make 300 tonnes, officials familiar with the development said on Tuesday.

Sets up subsidiary in New Zealand

Estimating the investment to be around Rs.10 crore, an official said production at the plant, under the ILL management, was expected to begin in April next. Pristine Biologicals (NZ) Ltd is a wholly-owned subsidiary, he added.

“The overseas venture will help in strengthening IIL's position as the leader in animal vaccines. It will help improving cost-competitiveness in manufacture of animal vaccines exported by us to over 50 countries in the Middle East, South America, Africa and CIS countries,” said Managing Director K. V. Balasubramaniam.

A release on the new venture said IIL is one of the major importers of bovine serum. It requires 200 tonnes and procures the same from New Zealand and Australia, two countries free of animal diseases listed by OIE (The World Organisation for Animal Health).

“With this new facility, we will be able to manufacture our own serum and become a robust player in animal vaccines with many value-added products,” Mr. Balasubramaniam said. A subsidiary of the National Dairy Development Board, IIL is the largest veterinary biological company and among the top three animal health companies in India.

Source: *The Hindu, 24th December 2014*

Young Medical Devices Cos Hail 100% Foreign Fund Injection

Young medical devices firms have welcomed the government's decision to allow full foreign direct investment (FDI) in the medical devices sector, saying this will encourage acquisitions and collaborations to develop new technologies.

The government has allowed 100 per cent FDI under automatic route in medical devices sector to encourage manufacturing of equipments, including diagnostic kits and other devices. Six-year-old Sofomo Embedded Solutions said this could pave way to more M&A activity for start-ups in India.

"It becomes easier for small companies such as ours to catch attention of the big guys, when they're physically present here," said Gautam Morey, 35-year-old founder of the company, which sells a device that can capture and transmit ECG to the

medic's fingertips within seconds.

The Pune-based company has so far sold 150 machines priced at a minimum value of Rs 40,000. The company, which is looking to raise Series A round, said a foreign-based investor would be best placed to take them to newer markets. Morey, however, added that other monetary benefits should be extended to large players if manufacturing in the space were to take off. Priyank Saxena, chief executive at Bengaluru-based InfraEyes, said he is open to mergers or acquisitions.

"Definitely. On the one hand, it gives avenues for potential M&As for early-stage start-ups like ours. At the same time, it will also increase the attractiveness of the industry," said Saxena. InfraEyes launched a non-invasive vein detection and location device named Veinus for doctors and nurses. The 2011 startup was reviewed by Healthstart, the country's first healthcare incubator and angel investment firm, and tested its pilot at St John's Hospital in Bengaluru.

Anand Madanagopal, founder of Cardiac Design Labs, said the government's decision on FDI opens new doors for companies like his. "It is a very good news. I am in talks with a foreign investor."

The Bengaluru-based start-up is making medical care more affordable by enabling cardiac patients in sub-urban and rural India to access advanced care through a device that brings in and alerts specialists in case of a problem. The device combines communications and proprietary algorithms technology and is designed for use in emerging markets where cardiologists and large hospitals are scarce.

"I am excited. The regulations becoming flexible will help start-ups like us attract capital," said Sairam Maduri, 24, founder of the Fournira Optime Diagnostics, a Hyderabad-based start-up, which has developed a technology to detect breast cancer at an early state using a simple blood test. Ramesh Radhakrishnan, partner at USbased venture capital firm Artiman Ventures, said the decision on FDI would encourage investors in Indian companies look for globally applicable products.

"A lot of innovative ideas on this sector die because of lack of investment at the angel and venture stage," he said.

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

New Drug Launches Drop 80% in 6 Years

Launches of new medicines in India have come down by over 87% during the last four-five years and drug manufacturers blame price regulations and policy uncertainty for making India an unattractive destination for both domestic as well as multinational pharmaceutical companies.

In 2008, 270 new drugs were approved for sale in India, whereas it dropped to 44 and 35 in 2012 and 2013, respectively. In 2014, only 56 new medicines were approved till November, government data shows.

"Most of the big pharmaceutical companies have knocked out India from their list of key markets. The reason is stricter policy measures cutting down on margins, making it less attractive as a business proposition for future growth," a senior executive in a leading domestic pharmaceutical company said.

A stricter regulatory regime, which not only brings down drug MRPs but also continuously expands span of price control, is cited as the main reason why drug manufacturers are losing their India focus. Industry officials also blame looming uncertainty in policy as another reason for companies to delay product launches. Apart from pricing, the pharma industry has been facing hiccups in foreign investment, new drug approvals, as well as clinical trials.

Government and regulators, however, brush aside such concerns. According to a senior official in the National Pharmaceutical Pricing Authority (NPPA), the price regulations are as per the policy and MRPs are fixed based on average price of

medicines in that segment. "There is no reason for a particular company to find it unviable when others are making the same drug at a lower price," the official said, adding that market surveys show a huge disparity in prices of similar medicines sold under different brands.

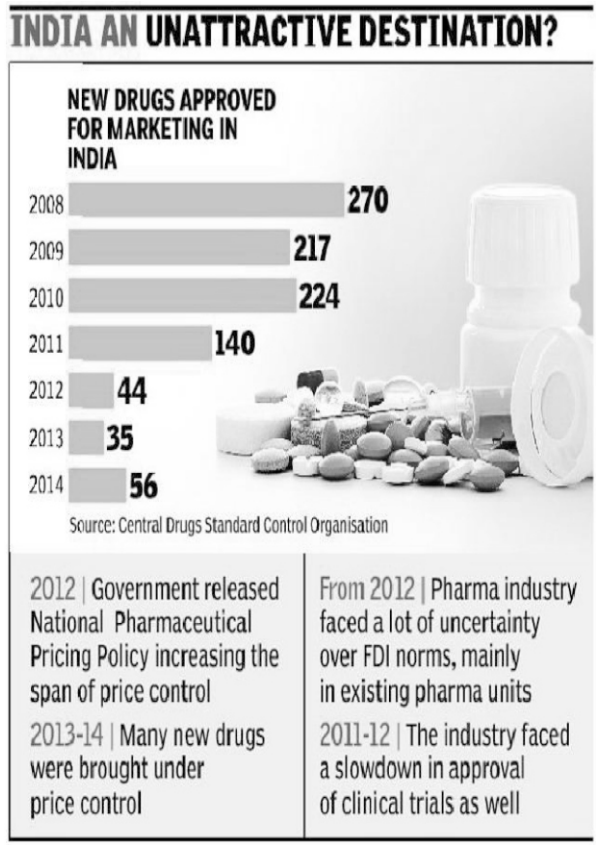
The number of drug approvals peaked in 2008, when as many as 270 new drugs were granted approval, followed by 217 in 2009, 224 in 2010, and 140 in 2011, the data shows.

However, since 2012, when the government released the National Pharmaceutical Pricing Policy bringing in 348 medicine formulations under price control, the new drug launches started reducing drastically.

"The role of NPPA is to implement the policy in letter and spirit and not create confusion leading to instability in the drug industry," another senior industry official said.

Recently, many medicines were also found missing from the market following stringent regulatory measures.

Source: *The Times of India, 27th December 2014*



Most Pharma Companies Earn USFDA Wrath Over Data Integrity Issues

Data integrity issues that include inappropriate manufacturing practices and overlooking results while testing medicines have taken centre stage this year, with several domestic pharma firms being hauled up by the US Food and Drug Administration (USFDA) over the issue.

Action against companies like Sun Pharma, Wockhardt, Cadila Pharma, Orchid Pharma and IPCA Labs this year has been on these issues, as reflected in the warning letters by the US regulatory agency. In some cases, when the issue was not resolved by the company satisfactorily, it resulted in a ban on the drugs exported to US from the plant (like Sun Pharma and Wockhardt), leading to loss of face as well as substantial revenues. The US is the largest market for domestic generic companies, contributing 25-55% of revenues for large companies, while India supplies around 40% of medicines (in volume terms) to that market.

The most high-profile case of data falsification and fudging of test results continues to be Ranbaxy, which is still not out of the woods with all its three USFDA-approved facilities having been banned from exporting drugs to the US. Sarabjit Kour Nangra, VP (research - pharma), Angel Broking, said, "As of now, the majority of the domestic companies under the USFDA glare are due to data integrity issues. The USFDA's warning letters and import alerts, if issued, are a huge setback to companies, given the example of Ranbaxy which is still not out of the mess completely. These issues have come to light only in the last decade when India's exports to US were ramped up. Domestic companies need to learn and gain experience in handling USFDA issues so that they avoid the misses."

The USFDA has strict checks and balances to maintain quality control at drug manufacturing facilities that have been approved after a rigorous process. These aspects include drug labelling, marketing, manufacturing and product quality, compliance, security and integrity. These form part of the current good manufacturing practices (CGMP) of active pharmaceutical ingredients (raw materials) and finished formulations. Any deviations from these draw flak from the US regulator.

When contacted, a Sun Pharma spokesperson said the USFDA observations about Karkhadi were taken very seriously and necessary changes to the relevant systems and equipment have been made, which will prevent data issues. "We are continuing to work hard on remediating balance issues at Karkhadi to ensure that the unit returns to compliance." On Halol plant, there have been no such observations.

Experts point out that there have been no instances where the medicines from any of the domestic facilities were harmful or had caused adverse events in the US. Global companies, too, come under USFDA scanner for manufacturing lapses.

Indian Pharmaceutical Alliance secretary general D G Shah told TOI: "This year, most companies under the USFDA glare are due to data integrity issues out of the industry's ignorance of the need to maintain and disclose abandoned tests, and partly because of lack of access to an organized set of guidance issued by the regulator. However, many of these practices are not intentional or deliberate, and are due to the ignorance of US requirements. Also, some of the companies facing regulatory action this year are those which were sent out warning letters last year."

In fact, companies are now becoming proactive as soon as they receive a warning letter, as in the case of IPCA Labs which voluntarily halted shipments to the US from its Ratlam plant in Madhya Pradesh after USFDA found violations at the facility. Some, like Lupin, were able to successfully resolve the FDA issues over a period of time.

The implications of FDA actions are huge, given the exposure of most domestic pharma companies to the US market (revenue contribution of 25-55% for large companies). A warning letter or import alert on any facility not only impacts the revenue stream from the unit, but also affects the drug maker's ability to make timely abbreviated new drug applications (ANDAs).

Source: *The Times of India, 29th December 2014*

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