Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 23 JUL.-AUG.- SEP. 2014

CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
AB Block, Baid Metha Complex,
New No. 16, Little Mount, Anna Salai, Saidapet, Chennai - 600 015.
Ph: 044 - 22300992, 22200854 Fax : 044 - 22355864
e-mail : pictrust@hotmail.com Website : www.pictrust.com

EDITORIAL

Dear Readers,

We are happy to publish the 23rd issue of Pharma Web newsletter for July Sep 2014. We regret to inform all our readers about the sad demise of our past chairman Shri. G. Rangachari and also Shri. V. Janardanan, founder trustee of our Trust.

In the last newsletter we published the inaugural function of Pharma Knowledge and Training Institute (Finishing School) under the aegis of our Trust and also the details of first training programme on the subject of "Industrial Orientation Training for Quality Management Personnel". After successfully completion of the above said training programme, we conducted second training programme in the month of October 2014 on the subject of "Industrial Orientation Training for Production Management Personnel". We will be publishing the details of the second training programme in our next issue.

In this issue we have published two articles namely "Pharmacopoeia" and "Concept of DQ, IQ, OQ & PQ" authored by Dr. N. Murugesan, Director, CDTL, Chennai and Mr. S. Jayakumar, Head of Quality M/s. Apex Laboratories Pvt Ltd. We have also published various notifications issued by Ministry of Health and Family Welfare, Govt. of India. The notifications reveal the following facts

a. GSR 498(E) dated 11.07.2014 prohibits manufacture and sale of "Fixed Dose combination of Flupenthixol and Melitracen for human use".

b. GSR 502 (E) dated 14.07.2014 explain that all vaccines, recombinant DNA derived drugs and all new drug delivery systems are new drugs and every vaccine preparation shall bear on the label the permission number granted by DCGI.

c. GSR 503 (E) dated 14.07.2014 explain about intimation to DCGI about the change of manufacturing facility or any change I the process, shelf life etc., for the new drugs granted by him and also allowing the manufacture or sale of Diclofenac injection for human use in single unit dose pack only.

d. GSR 570 (E) dated 07.08.2014 explaining about grant of license to any drug formulation containing single active ingredient only in proper name.

e. GSR 690 (E) dated 25.09.2014 explaining about competent person for manufacture and testing of medical devices, labeling provision for medical devices.

f. GSR 701 (E) dated 29.09.2014 a draft notification asking for comments for banning of plastic containers or use polyethylene Terephthalate in liquid oral formulations for primary packaging.

g. GSR 718 (E) dated 13.10.2014 prohibiting import of cosmetic tested on animals.

We have also published parliament question answers pertaining to drugs, we have also published important many technical news items and events etc., in this issue. I hope the readers may be benefited by the newsletter and any comments are welcome.

With Best Regards,

R. NARAYANASWAMY

Chief Editor

ARTICLES

PHARMACOPOEIA

By

Dr. N. Murugesan

Director, CDTL, Chennai & Nodal Officer- CDTL, Hyderabad

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

STANDARDS FOR MEDICINES

- **AYURVEDIC & SIDDHA SYSTEM**
  Follow the first schedule part-A of drugs & cosmetics of 1940
- **For unani & TIBB system-part-B**
- **For other system of medicines follow second schedule**

CURRENT PHARMACOPOEIA

- **Indian pharmacopoeia 2014 (7th edition)**
- **BP Pharmacopoeia 2014**
- **USP 37 2014(NF 30)**
- **Japanese Pharmacopoeia JP 2006(15th edition)**
- **European Pharmacopoeia (7th edition)**

Indian Pharmacopoeia

As per the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is the legally recognized book of Standards for the quality of drug substances and preparations included therein.

Publications of IP (By IP Committee)

Edition	Year
I	1955
Supplement	1960
II	1966
Supplement	1975
III	1985
Addendum	1989 & 1991
IV	1996
Addendum	2000
Vet Supplement	2000
Addendum	2002

Publications of IP (By IP Commission)

Edition	Year
Addendum	2005
V	2007
Addendum	2008
VI	2010
Addendum	2012
VII (Current Edition)	2014

Publication and Printing

Published by :

Indian Pharmacopoeia Commission, Ghaziabad

Printed by : National Institute of Science Communication And Information Resources (NISCAIR) near Pusa Gate, New Delhi.

Introduction

- This new edition of the IP entitled Indian Pharmacopoeia 2014 has been prepared by the Indian Pharmacopoeia Commission (IPC) in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.
- This is the seventh edition of the Indian Pharmacopoeia after Independence.

Introduction

- It supersedes the 2010 edition but any monograph of the earlier edition that does not figure in this edition continues to be official as stipulated in the Second Schedule of the Drugs and Cosmetics Act, 1940.

Presentation of IP 2014

IP 2014 is presented in four volumes:

Volume I
Volume II
Volume III
Volume IV

Contents of Volume I

- Notices
- Preface
- Indian Pharmacopoeia Commission
- Acknowledgements
- Introduction
- General Chapters

Contents of Volume II

- General Notices
- General Monographs on Dosage Forms
- Monographs on Drug substances, Dosage forms and Pharmaceutical Aids Monographs A to M

Contents of Volume III

- General Notices
- Monographs on Drug substances, Dosage forms and Pharmaceutical aids Monographs N to Z
- Monographs on Vaccines and Immunosera for Human Use
- Monographs on Herbs and Herbal Products
- Monographs on Blood and Blood-related Products
- Monographs on Biotechnology Products
- Monographs on Radiopharmaceuticals

Contents of Volume IV

- Monographs on Veterinary Products

- Non-Biological
- Biological
- Diagnostics
- Index

Presentation

- The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, Veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations.

- Standards for new drugs and drugs used under National Health Programmes are added in this edition and drugs as well as their formulations not in use now a days are ommited from this edition.

Presentation

- The number of monographs of Excipients, Anticancer drugs, Herbal products and Antiretroviral drugs have been increased in this edition.

- Monographs of Vaccines and Immunosera are also upgraded in view of the latest development of the technology in the field.

- Many chapters have been revised in the Appendices.

Presentation

- The monographs on Water for Injections in Bulk and Purified Water are also upgraded to harmonise with prevailing international requirements.

Format

- In an effort to make the pharmacopoeia more user-friendly, design of the texts of the monographs and of the test methods are kept same however they are upgraded.

- Cross-referencing has been avoided to make each monograph complete in itself thus making it convenient to the analyst performing the tests and to the ones checking the results of analysis.

Basis of Pharmacopoeial Requirement

- As in the past, this compendium provides a publicly available statement concerning the quality of a product that can be expected and demonstrated at any time throughout the accepted shelf-life of the article.

- The standards laid down represent the minimum with which the article must comply and it is incumbent on the manufacturer to ensure that the article is manufactured in accordance with Good Manufacturing Practices (GMPs).

Basis of Pharmacopoeial Requirement

- It is essential that sufficiently stringent limits are applied at the time of release of a batch of a material or product so that the pharmacopoeial standards are met until its expiry date under the storage conditions specified.

Basis of Pharmacopoeial Requirement

- It must be noted that a valid interpretation of any requirement of the Pharmacopoeia should be done in the context of the monograph as a whole, the relevant general monograph, where appropriate, the specified tests and methods of analysis including any reference to the relevant General Notices.
- Familiarity with the General Notices will facilitate the correct application of the requirements.

20

Changes

- General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.
- The use of chromatographic methods has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.
- Most of existing Assays and Related substances tests are upgraded by liquid chromatographic method in view to harmonize with other international Pharmacopoeias

Changes

- In most of the parenteral preparation and other monographs, the test of pyrogens involving the use of animals has been almost eliminated and replaced with Bacterial Endotoxin test.
- In some blood and blood related monographs, the Bacterial Endotoxin test has been incorporated.
- The test for *Shigella* has been added along with *Salmonella* in the Microbial Contamination test of several monographs. Several new monographs on antibiotics have been added where the Assay is by microbiological methods.

Changes

- More essential oils monographs, crude herbal drugs and extracts have been incorporated and also some existing monographs have been revised under the section Herbs and Herbal Products in volume III.
- For the first time, 19 monographs on radiopharmaceutical preparations along with a chapter on Radiopharmaceuticals have been added in Volume III, of this edition.

Changes

- A separate volume for veterinary monographs as Volume IV of this edition of Indian Pharmacopoeia has been designed to provide comprehensive information to those concerned with the quality control of veterinary medicines.
- For the first time, a general chapter on cell cultures for the production of veterinary vaccines and other general monographs has been incorporated.

Changes

- Several monographs on chemicals along with a number of monographs on veterinary vaccines, diagnostic, immunosera and surgical materials have been given place in this volume.
- Many monographs just on the basis of usual strength and doses have been mentioned in this volume while complete monographs are mentioned in other volumes of IP.

General Chapters

- Volume I is devoted mainly to test methods that are applicable to all the articles of the pharmacopoeia and general information pertaining to the quality requirements of medicinal substances.
- It also includes reference data such as reference spectra, typical chromatograms etc.
- The test methods reflect the sophistication of analytical methodology and instrumentation.

General Chapters

- Analytical methods are in general in harmony with those adopted internationally for monitoring the quality of drugs.
- The steps taken for harmonization have been initiated by the need to cope with the increasing demand for drugs manufactured in the country to globally accepted standards.

General Chapters

- Accordingly we have introduced 19 new chapters based on current technologies used by the stakeholders and harmonized with other international pharmacopoieas; like mass spectroscopy, inductively coupled mass spectroscopy and polymorphism etc.

General Chapters

- The trend towards controlling the microbial quality of all medicinal products has been recognized and the requirement regarding limits of bacterial contamination even of products for oral administration and topical application so that adequate controls are exercised by manufacturers by the adoption of GMPs has been continued.

General Chapters

- General chapters on Bacterial Endotoxins, Microbial contamination of non-sterile products, Microbiological quality of pharmaceutical preparations, Microbilogical assay of antibiotics and Sterility has been extensively revised.
- The general chapters of Microbial contamination of non sterile products and Microbiological quality of pharmaceutical articles have been merged together.

General Chapters

- For the first time, a general chapter on maintenance, identification, preservation and disposal of microorganisms has been added.
- The two general chapters on (i) Transfusion and infusion assemblies and similar medical devices and (ii) Amino acid analysis have been also included first time.

General Chapters

- The general monographs on Purified Water and Water for Injections in bulk have been fully revised and a comprehensive note on Drinking Water has been incorporated in the general chapter of Water for pharmaceutical use.

General Chapters

- In the Herbs and herbal products section, the chapter on DNA based authentication techniques of herbal drugs and determination of flash point of essential oils has been incorporated.
- The chapter on biotechnology derived therapeutic products has been fully revised. Special emphasis has been given on monoclonal antibodies antisera.

General Monographs

- The General Monographs for dosage forms of active pharmaceutical ingredients (APIs) are grouped together at the beginning of Volume II.
- They are followed by the monographs for the APIs, pharmaceutical aids and individual dosage forms, all in alphabetical order.

General Monographs

- Monographs for other articles of a special nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products & biotechnology products are given in separate sections in Volume III.
- Special emphasis has been given to veterinary monographs adding & updating in Volume IV.

New Edition

Monographs on Drug substances, Dosage forms & Pharmaceutical aids (A to Z)	: 313	
NDS Monographs	: 43	366
Antibiotics Monographs	: 10	
Herbal Monographs	: 31	
Vaccines & immunosera for human use	: 05	
Insulin Products	: 06	
Biotechnology Products	: 07	

New Edition

Monographs on Veterinary products :

Non Biological	:	**122**
Biological	:	**08**
Diagnostics	:	**01**
Immunosera	:	**05**
Surgical materials	:	**07**
Vet. Appendices	:	**06**
Vet. General Chapter	:	**10**

Radiopharmaceutical Monographs: First time being introduced in this edition.

General Chapter	:	**01**
Monographs	:	**19**

Anticancer monographs

1. **Bortezomib**
2. **Carboplatin**
3. **Carboplatin Injection**
4. **Docetaxel Anhydrous**
5. **Gemicitabine Hydrochloride**
6. **Gemicitabine Injection**
7. **Imatinib Tablets**
8. **Lapatinib Ditosylate**
9. **Lapatinib Tablets**
10. **Mitomycin**
11. **Mitomycin Injection**
12. **Sorafenib Tosylate**

Specific Features

Adding:

(i) 577 new monographs

(ii) 19 new General Chapters

(iii) About 200 new IR spectra's

(iv) Introducing first time 19 Radiopharmaceutical Monographs & 1 General Chapter

(v) Separate Veterinary Volume for easy access

(vi) 19 New Anticancer monographs

(vii) 11 New Antiviral Monographs

(viii) 22 New Excipient Monographs

Anticancer monographs

13. Sorafenib Tablets
14. Premetrexed Disodium
15. Erlotinib Hydrochloride
16. Erlotinib Tablets
17. Fludarabine Phophate
18. Bicalutamide
19. Bicalutamide Tablets

Antiviral Monographs

1. **Famciclovir**
2. **Famciclovir Tablets**
3. **Aciclovir Cream**
4. **Aciclovir Eye Ointment**
5. **Aciclovir Dispersible Tablets**
6. **Aciclovir Oral Suspension**
7. **Adefovir Dipivoxil**
8. **Adefovir tablets**
9. **Saquinavir Capsules**
10. **Arbidol Hydrochloride**
11. **Tenofovir Fumarate, Lamivudine & Efavirenz Tablets**

Excipient Monographs

1. **Acesulphame Potassium**
2. **Adipic Acid**
3. **Alfacyclodextrin**
4. **Ascorbyl Palmitate**
5. **Betacyclodextrin**
6. **Carboxymethylcellulose Calcium**
7. **Corn Oil**
8. **Cottonseed Oil**
9. **Ethyl Paraben**
10. **Ethyl Vanilin**
11. **Hydrogenated Vegetable Oil**
12. **Hydroxyethyl Cellulose**

Excipient Monographs

13. Hydroxypropyl Methylcellulose Phthalate
14. Isopropyl rubbing Alcohol
15. Monobasic Sodium Phosphate
16. Octyl Dodecanol
17. Petrolatum
18. Phenylethyl Alcohol
19. Polacrillin Potassium
20. Polyvinyl Acetate Phthalate
21. Polyvinyl Alcohol
22. Soyabean Oil

Active Pharmaceutical

Description, Identification, Tests, Related Substances, Heavy Metals, Sulphated Ash, Loss on Drying and Assay.

Injectable preparations

Identification, Extracteble volume, Related substance, pH, Test for Sterility, Test for Pyrogens/Bacterial Endotoxin Test, Assay.

Loss on Drying- Dry the sample in an oval at 105 C to constant weight

Spectrophotomatric techniques- IR, UV-VIS, AAS

Chromatographic techniques- TLC, HPTLC, HPLC, GC

FTIR is used for Identification for drugs.

OBITUARY

SRI. G. RANGACHARI (Past Chariman, TNPSWT)

D.O.B: 09-10-1927 ● D.O.D: 19-09-2014

Shri. G. Rangachari popularly known as 'GR' was born on 09.10.1927. He joined TTK in 1945 worked in various capacities and rose to the position of Chief executive of TTK Pharma.

After 34 years of service in TTK group he started his own organization is known as “GR group of companies” and Chairman of Bhuvaneswari Pharmach Pvt Ltd., Bhuvaneswari & Co., GR International, which were involved Manufacturing, Marketing and Export of Pharmaceutical products and allied machinery.

He was founder Trustee of TNPSWT and Chairman of the Trust from 1989 to 2011. He was also involved various activities of Pharmaceutical profession and a member of IPA TN Branch, 48th IPC LOC Co-chairman in 1996. He was an active member of lions club and kind freemason, he was hard and devotee of srirangam andavan and took active part in the various activities of andavan ashram.

He survives by his wife, Son, Daughter-in-law, Two Daughters and Son-in-Law, Six grand children and Eight great grand children.

Concept of URS,DQ,IQ,OQ,PQ

By

Mr. S. Jayakumar

Head - Quality, M/s. Apex Laboratories Pvt. Ltd.,

(Lecture Delivered on 15th May 2014, during the Training Programme on Quality Control)

CONTENTS.

- ✓ **Introduction.**
- ✓ **Validation**
- ✓ **User Requirement Specification.(URS)**
- ✓ **Phase of validation**
  - ➢ **Design qualification (DQ)**
  - ➢ **Installation Qualification (IQ)**
  - ➢ **Operation Qualification (OQ)**
  - ➢ **Performance Qualification (PQ)**
  - ➢ **Maintenance Qualification (MQ)**
  - ➢ **Component Qualification (CQ)**
- ✓ **Instrument Re-Qualification**
- ✓ **References.**

What is Validation?

➢ Goal of validation is to:

"Establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes."

➢ It is a requirement for Good Manufacturing Practices and other regulatory requirements.

- What does this mean?
  - ➢ An quantitative approach is needed to prove quality, functionality, and performance of a pharmaceutical/biotechnological manufacturing process.
  - ➢ This approach will be applied to individual pieces of equipment as well as the manufacturing process as a whole.
  - ➢ Guidelines for validation are set by the FDA, but the specifications of validation are determined by the pharmaceutical/biotech company.

USER REQUIREMENTS SPECIFICATION.

- **User Requirements Specification** (URS), is the most critical of documents and yet, the most often bungled. Whether the system is purely mechanical, or a mix of electro-mechanical, or solely a software program, the successful compilation and execution of the Installation Qualification (IQ) (for installation), Operational Qualification (OQ) (for functionality) and the Performance / Product Qualification (PQ) (for operability), is dependent on an User Requirements Specification (URS) containing clear, concise and testable requirements.

Developing the URS to this level is unique in most industries, but is, standard practice in strictly regulated industries, as it is a major building block in the creation of quality software. The URS contains all the traceability which is deemed mandatory for software assessed to be critical to product quality, in the pharmaceutical regulated industries.

Structure and Content of URS

- The URS can contain a large number of requirements and should therefore be structured in a way that will permit easy access to information.
- The requirement specification must be formally reviewed and approved by the pharmaceutical manufacturer.

▸ **The following guidelines should be followed during the production of the URS :**

1. Each requirement statement to be uniquely referenced, and no longer than 250 words.
2. Requirement statements should not be duplicated nor contradicted.

3. The URS should express requirements and not design solutions.

4. Each requirement should be testable.

5. The URS must be understood by both user and supplier; ambiguity and jargon should be avoided.

6. The use of diagrams is often useful.

7. The scope for readers to make assumptions or misinterpret should be minimized.

8. Wherever possible, the URS should distinguish between mandatory/regulatory requirements and desirable features.

System Interfaces
Environmental conditions
Access security
Diagnostics
System availability
Safety
Test and calibration
Quality procedures
Software development life cycle
Documentation requirements
Training
Engineering/installation standards
Ongoing support
Warranty
Delivery/commercial requirements

URS provides the following key benefits for the validation program:

1. Clarifies technical, quality, and documentation requirements to the vendor(s).
2. Enables the pharmaceutical manufacturer to assess the technical, regulatory, and commercial compliance (or otherwise) of submitted bids against a formal specification.
3. Ensures the basis of a structured approach to the presentation of information.
4. Provides a basis for testing and test acceptance criteria.
5. Provide a baseline for validation and verification..

➢ Design Qualification(DQ) process then can be reduced to two key objectives:

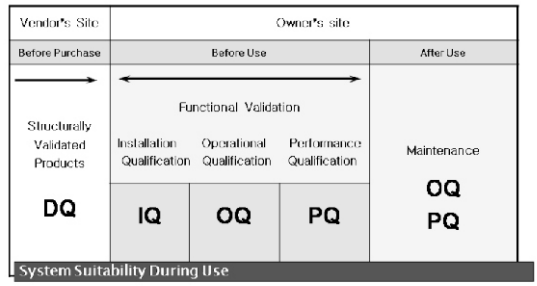
➢ Documented verification that the overall design appears to address, by some means, each and every **requirement** affecting the product and performance of the manufacturing process (or, in the case of unknown product or multi-product manufacturing facility, the required equipment/ system performance capabilities).

➢ Identification (and documentation) of the critical individual physical components, attributes, and operational features that directly support meeting each **requirement**.

Phases of Validation.

- Validation is broken down into 4 main phases,
- Design qualification (DQ).
- Installation qualification (IQ).
- Operational qualification (OQ).
- Performance qualification (PQ).

Validation Time Line.



Validation vs. Qualification.

- **Validation:**
  - Refers to the total life cycle of a product from development through use and maintenance.
  - **Owners** are responsible for **Validating their Processes** (personnel, equipment, methods, SOPs) to ensure compliance to cGMP/GLP regulations.
- **Qualification:** (Inspection, functional testing and documentation review)
  - Is a part of the validation process which verifies module and system functional performance prior to being placed on-line and thereafter according to a standard operating procedure.

Quality Management Equipment Qualification

Equipment Qualification

- It is a basic requirement of good analytical chemistry that balances and other analytical instruments must be suitable for the purpose for which they are used and that they must be appropriately calibrated. As a consequence, Equipment Qualification is gaining more and more importance in ensuring the validity of results.
- Manufacturers of analytical equipment are forced to play a significant role in the various steps of Equipment Qualification.

The 4 steps of Equipment Qualification

Step 1: Design Qualification (DQ) defines the functional and operational specifications of a balance or instrument.

Step 2 :Installation Qualification (IQ) ensures that a balance or instrument is received as designed and specified. It documents the installation in the selected user environment.

Step 3: Operational Qualification (OQ) demonstrates that a balance or instrument will function according to its operational specification in the selected environment.

Step 4: Performance Qualification (PQ) demonstrates that a balance or instrument consistently performs according to a specification appropriate to its routine use.

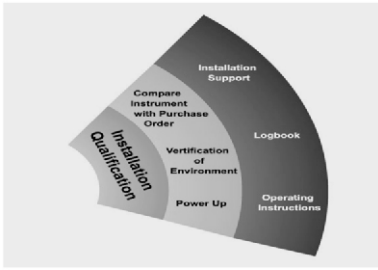
.

Design qualification (DQ)

Design qualification (DQ) is the process of completing and documenting design reviews to illustrate that all quality aspects have been fully considered at the design stage. The purpose is to ensure that all the requirements for the final systems have been clearly defined at the start.

Design Qualification (DQ) defines the functional and operational specifications of the instrument and details the conscious decisions made in the selection of the supplier. DQ should ensure that instruments have all the necessary functions and performance criteria that will enable them to be successfully implemented for the intended application and to meet user requirements.

Installation Qualification (IQ)



Installation qualification (IQ) is the process of checking the installation, to ensure that the components meet the approved specification and are installed correctly, and to see how that information is recorded. The purpose is to ensure that all aspects (static attributes) of the facility or equipment are installed correctly and comply with the original design.
all of the instrumentation components are identified and checked against the manufacturer's component listing.
The working environment conditions are documented and checked to ensure that they are suitable for the operation of the instrument.

Installation Qualification establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument.

Before installation:
- Obtain manufacturer's recommendations for installation site requirements.
- Check the site for the fulfillment of the manufacturer's recommendations (utilities such as electricity, water and gases plus environmental conditions such as humidity, temperature, vibration level and dust).
- Allow sufficient shelf space for the equipment itself, related SOPs, operating manuals, logbooks and software.

Operation Qualification (OQ)

Operational qualification (OQ) is the process of testing to ensure that the individual and combined systems function to meet agreed performance criteria and to check how the result of testing is recorded. The purpose is to ensure that all the dynamic attributes comply with the original design. Each of the instrument's function are checked to ensure that they conform to the manufacturer's specifications.
This includes the use of certified, traceable electrical simulators and standards to verify that the equipment is processing input signals correctly.

Performance Qualification (PQ)

Performance qualification (PQ), also called process qualification, is the process of testing to ensure that the individual and combined systems function to meet agreed performance criteria on a consistent basis and to check how the result of testing is recorded. The purpose is to ensure that the criteria specified can be achieved on a reliable basis over a period of time.

The performance of the equipment for its routine analytical use is checked to ensure that this complies with its specification.

The temperature sensor readings are compared with a certified reference thermometer. After calibration, the conductivity sensor readings are compared using certified, traceable control standards.

Control Standards of similar values to the intended test samples must be used for PQ.

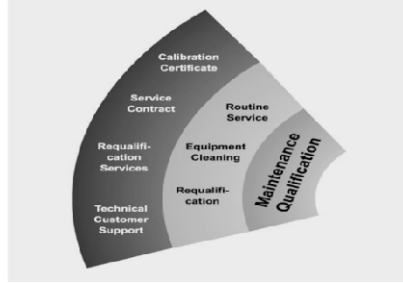
Performance Qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate to its routine use.

Important here is the word consistently. The test frequency is much higher than for OQ. Another difference is that PQ should always be performed under conditions that are similar to routine sample analysis.

PQ should be performed on a daily (or at least a weekly) basis, or whenever the instrument is used. The test frequency depends not only on the stability of the equipment but also on everything in the system that may contribute to the analysis results.

1. Define the performance criteria and test procedures.
2. Select critical parameters.
3. Define the test intervals.

Maintenance Qualification (MQ)



The MQ describes and documents any maintenance required on the equipment. This includes routine servicing and any repairs necessary. Details of any maintenance contracts are also documented in this section, together with a list of authorized service engineers. In addition, the MQ includes the routine cleaning of the equipment and also its ultimate disposal.

Instrument Re-Qualification

- Instrument Validation should not be viewed as a one-off event – confidence in analytical results is required for the whole of the instrument's working life.
- To ensure that this confidence is retained, the instrument validation process should be repeated at regular intervals during the instruments operational life.
- The difference between Installation Validation and Re-Qualification is that IQ is omitted for the Re-Qualification
- Re-Qualification should be performed at least annually and should be performed more frequently for applications whose test results have critical implications

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

By

Mr. D. Ashwin Kumar, Annai Veilankanni's Pharmacy College, Chennai

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

INTRODUCTION

Pharmacy ethics is a branch of medical ethics that provides a framework for pharmacists to use in resolving questions about what ought to be done in pharmacy practice.

ETHICAL THEORIES

Modern medical ethics has its roots in two classical theories known as deontology and utilitarianism. It is a gross over simplification to say that the deontological view is idealistic, while the utilitarian view is consequentialist, but that is an effective way of beginning to think of these two differing approaches to ethical theory. The deontologist is generally considered to be means and ends oriented, while the utilitarian is usually considered to be ends oriented only.

EHTICAL PRINCIPLES

Principle based has at times been criticized as too methodic and not sufficiently sensitive to the individual differences of ethical cases, but the study of pharmacy ethics would be incomplete without a description of the four basic ethical principles that apply in pharmacy ethics. The principle of nonmaleficence (doing no harm) requires that pharmacist refrain from acting in ways that will cause harm or injury to others. The Principle of beneficence (doing good) requires positive action to (1) prevent what is bad, (2) remove bad or evil, and (3) do or promote good. The principle of justice fairness requires that all benefits and burdens be distributed equally.

THE APhA CODE OF EHTICS

The American Pharmaceutical Association has adopted a code of ethics that is intended to present to the public the principles on which the pharmacy profession bases its professional duties.

CODE OF ETHICS FOR PHARMACIST

Pharmacists are health Professionals who assist individuals in making the best use of medications. This code, prepared and supported by pharmacist, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

A Pharmacist respects the covenantal relationship between the patient and pharmacist.

- A Pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.
- A Pharmacist respects the autonomy and dignity of each patient.
- A Pharmacist acts with honesty and integrity in professional relationship.
- A Pharmacist maintains professional competence.
- A Pharmacist respects the values and abilities of colleagues and other health professionals.
- A Pharmacist serves individual, community and societal needs.
- A Pharmacist seeks justice in the distribution of health resources.

PHARMACIST ROLE IN COMMON MAN

Pharmacist can play an important role as leaders to reduce patient safety risks, optimize the safe function of medication management systems, and align pharmacy services with national initiatives that measures and reward quality performances.

RESPONSIBILITIES OF MEDICATION SAFETY LEADERS:

LEADERSHIP: To provide leadership, the medication safety leader will

- Develop a vision of an ideal safe medication use system for the organization.
- Oversee the planning, creation, review and refinement of a medication safety plan.
- Proactively develop and lead implementation of error prevention strategies based on practice standards, literature review, medication safety tools, and analysis of the organization medication safety data.
- Participate in the planning, design, and implementation of the organization's medication use technology and automation systems.
- Build a culture of safety through “lesson learned” education and communication across the entire organization.

MEDICATION SAFETY EXPERTISE

In the role of authoritative safety expert, the medication safety leader will

- Serve as an authoritative resource on medication safety for the organization.
- Contribute the medication safety perspective for technology initiatives.
- Predict and prepare to manage medication safety issues caused by potential or actual drug product shortages and the use of replacement drug products. Participate at local and national levels in patients safety and medication safety organizations and initiatives.

RESEARCH AND EDUCATION

To further research and education regarding and medication safety, the medication safety leader will, share information about actual or potential medication errors or harm with safety organizations such as ISMP,FDA, drug or product manufacturers, and state error reporting programs.

- Conduct medication use safety research through well designed, externally validated studies and implement evidence based practices for medication safety.
- Contribute to the literature on medication safety.
- Provide medication safety education to pharmacy colleagues, students and residents, as well as other health care professionals.

CONCLUSION

ASHP believes that pharmacists, as experts on medication use, are uniquely qualified to serve as medication safety leaders. Medication safety leaders articulate the vision and direction for improving the safety of the medication- use system to prevent patient harm. The medication safety leaders role includes responsibility for leadership through direction and prioritization, medication safety expertise, influencing practice change, research and education. through analysis of the organizations medication safety data and literature review, the medication safety leader will lead development implementation of proactive error- prevention strategies and build a culture of safety across the organization.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th July, 2014

G.S.R. 498(E).—Whereas the Central Government was satisfied that the use of the drug 'fixed dose combination of Flupenthixol and Melitracen' for human use was likely to involve risk to human beings and whereas safer alternatives to the said drug are available;

Whereas, the Central Government was satisfied that it was necessary and expedient to regulate by way of suspension, the manufacture for sale, sale and distribution of the said drug in the country in public interest, and accordingly in exercise of the powers conferred by Section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government suspended the manufacture for sale, sale and distribution of fixed dose combination of Flupenthixol and Melitracen for human use through the notification number G.S.R. 377(E) dated 18th June, 2013;

Whereas the Hon'ble High Court of Karnataka in their order dated 14th August, 2013 in the case of WP No. 28354/2013 (GM-RES) quashed the notification and remanded the matter back to reconsider afresh by the respondents and take a decision one way or other in accordance with the Law.

Whereas, the Drugs Technical Advisory Board, a statutory body under the Drugs and Cosmetics Act, 1940, has examined the issue of suspension of manufacture and sale of the said drug in its 65th meeting on 25th November, 2013 and recommended that the use of the drug should be discontinued from the country.

Now, therefore, on the basis of the recommendations of the Drugs Technical Advisory Board and in exercise of the powers conferred by Section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution of the following drug with immediate effect :—

"Fixed dose combination of Flupenthixol and Melitracen for human use" .

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

ARUN K. PANDA, Jt. Secy.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi.110064
and Published by the Controller of Publications, Delhi.110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th July, 2014

G.S.R. 502(E).— The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public;

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

Objections and suggestions, if any, may be addressed to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

Draft rules

1. These rules may be called the Drugs and Cosmetics (8th Amendment) Rules, 2014.
2. In the Drugs and Cosmetics Rules, 1945,-
   (a) in rule 96, in sub-rule (1), after clause (xii), the following clause shall be inserted, namely:-
   "(xiii) Every vaccine preparation shall bear on its label the number of the new drug permission granted by the licensing authority as defined in clause (b) of rule 21".
   (b) in rule 122E, in the Explanation, for clause (i), the following shall be substituted, namely:-
   "(i) All vaccines, recombinant DNA (r-DNA) derived drugs and all New Drug Delivery Systems including modified release dosage forms of a drug formulation shall be deemed to be new drugs unless certified otherwise by the licensing authority as defined in clause (b) of rule 21".

[F. No. X-11014/1/2014-DFQC]

ARUN K. PANDA, Jt. Secy.

Note.- The principal rules were published in the Gazette of India, vide notification No. F. 28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number G.S.R. 346(E) dated 21st May, 2014.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th July, 2014

G.S.R. 503(E).—The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby, and the notice is hereby given that the said draft rules will be taken into consideration after the expiry of a period of forty-five days from the date on which the copies of the Official Gazette of India in which this notification is published, are made available to the public;

Any person interested in making any objection or suggestion on the proposed draft rules may do so in writing for consideration of the Central Government within the period so specified through post to the Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

Draft rules

1. These rules may be called the Drugs and Cosmetics (9th Amendment) Rules, 2014.

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

(a) in rule 105, in sub-rule (2),-

(i) in the second proviso, for the words "Provided also that", the words "Provided further that" shall be substituted;

(ii) in the third proviso, for the words "Provided further that", the words "Provided also that" shall be substituted;

(iii) after the third proviso, the following proviso shall be inserted namely:-

"Provided also that Diclofenac injection for human use shall be in single unit dose pack only." ;

(b) in rule 122A, after sub-rule (3), and before the proviso, the following sub-rule shall be inserted, namely:-

"(4) If there is a change, such as manufacturing process, manufacturing facility, site of manufacture, batch size, shelf life, presentation or any other change which may affect its identity, strength, quality, purity, after granting permission for importing a vaccine or biological product as a new drug, the importer shall submit application to the Licensing Authority, as referred to in clause (b) of rule 21, duly supported by technical data for the purpose of approval and accompanied by a fee of rupees fifteen thousand."

(c) in rule 122B, after sub-rule (3), and before the proviso, the following sub-rule shall be inserted, namely:-

"(4) If there is a change, such as manufacturing process, manufacturing facility, site of manufacture, batch size, shelf life, presentation or any other change which may affect its identity, strength, quality, purity, after granting permission for manufacturing a vaccine or biological product as a new drug, the manufacturer shall submit application to the Licensing Authority, as referred to in clause (b) of rule 21, duly supported by technical data for the purpose of approval and accompanied by a fee of rupees fifteen thousand."

[F. No. 18-6/2013-DC]

ARUN K. PANDA, Jt. Secy.

Note.—The principal rules were published in the Gazette of India, vide notification No. F. 28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide G.S.R. 346(E), dated the 21st May, 2014.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 7th August, 2014

G.S.R. 570(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), *vide* number G.S.R. 748(E), dated the 5th October, 2012, 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 containing the said notification were made available to the public;

And whereas the copies of the Gazette in which the said notification was published were made available to the public on the 5th October, 2012;

And whereas, the Drugs Technical Advisory Board has been consulted in the matter;

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

Now, therefore, in exercise of the powers conferred by Sections 12 and 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 (3rd Amendment) Rules, 2014.

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

   (3) Notwithstanding anything contained in sub-rule (2), the licensees who are manufacturing single active ingredient drug formulation on the commencement of these rules shall make application for grant of licence for the drug formulation containing single active ingredient in proper name within one year of the commencement of these rules.

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

   (a) in rule 71, after sub-rule (7), the following sub-rule shall be inserted, namely:—

   "(8) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient only in proper name.";

   (b) in rule 71A, after sub-rule (3), and before the proviso, the following sub-rule shall be inserted, namely:—

   "(4) The application for grant of licence for a drug formulation containing single active ingredient shall be made only in proper name.";

   (c) in rule 71B, after clause (iv), the following proviso shall be inserted, namely:—

"Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made only in proper name.";

(d) in rule 76, after sub-rule (8), the following sub-rule shall be inserted, namely:—

"(9) The applicant shall make application for grant of licence for a drug formulation containing single active ingredient only in proper name.";

(e) in rule 76A, the following proviso shall be inserted, namely:—

"Provided that the application for grant of a licence for a drug formulation containing single active ingredient shall be made only in proper name."

[F. No. X.-11014/5/2011-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 last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), *vide* number G.S.R. 346(E), dated the 21st May, 2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy)

NOTIFICATION

New Delhi, the 1st September, 2014

G.S.R. 633(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by Section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said section for the information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration after the expiry of the period of thirty days from the date on which copies of the Official Gazette in which this notification is published, are made available to public;

Objections or suggestions, if any, may be addressed to the Secretary (Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy)(AYUSH), Ministry of Health and Family Welfare, AYUSH Bhawan, 'B' Block, GPO Complex, INA, New Delhi-110023.

Any objections or suggestions, which may be received from any person with respect to the said draft rules, within the period specified above, will be taken into consideration by the Central Government.

DRAFT RULES

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

(2) They shall come into force after one year from the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in rule 157, for sub-rules (1B) and (1C), the following sub-rules shall be substituted, namely:—

"(1B) No manufacturer shall use any prefix or suffix with the name of any Ayurvedic, Siddha or Unani Tibb drug falling under clause (a) of Section 3 of the Act, except as described in the authoritative books specified in the First Schedule to the Act:

Provided that a formulation without any specific name, described in the authoritative books may be named on the basis of the ingredients of that formulation.

(1C) The names of any Ayurvedic, Siddha or Unani Tibb drug falling under clause (a) of section 3 of the Act shall not be used for naming any patent or proprietary medicine relating to Ayurvedic, Siddha or Unani Tibb systems of medicine referred to in sub-clause (i) of clause (h) of the said section.

(ID) Notwithstanding the period for renewal of licence provided in rules 156 and 156A, the licensee of the Ayurvedic, Siddha or Unani Tibb drug, which is not in conformity with sub-rules (1B) and (1C), shall seek renewal of the licence with appropriate name of the drug within a period of one year from the date of commencement of the Drugs and Cosmetics (Second Amendment) Rules, 2014:

Provided that this rule shall not be applicable to any batch of Ayurvedic, Siddha or Unani Tibb drugs manufactured prior to the date of commencement of the Drugs and Cosmetics (Second Amendment) Rules, 2014."

[No. K. 11020/06/2011-DCC (AYUSH)]

BALA PRASAD, Jt. Secy.

Note : The Principal rules were published in the Official Gazette *vide* Notification No. F. 28-10/45-H (I), dated 21-12-1945 and last amended *vide* No. G.S.R. 346 (E), dated 21.5.2014.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, 25th September, 2014

G.S.R. 690(E).—Where as the 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), number G.S.R. 703(E), dated the 24th October, 2013, in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i), dated the 24th October, 2013, 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 containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 24th October, 2013;

And whereas, the objections and suggestions received from the public in respect of the said draft rules were considered by the Central Government.

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

1. (1) These rules may be called the Drugs and Cosmetics (4th Amendment) Rules, 2014.

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

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 76, in sub-rule (1), for the third proviso, the following proviso shall be substituted, namely:—

"Provided also that for medical devices, the whole time employee under whose supervision the manufacture or testing is conducted shall be—

(i) a graduate in Pharmacy or Engineering (in appropriate branch) from a University recognised by the Central Government for such purposes and has had at least eighteen months practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(ii) a graduate in science, from a University recognised by the Central Government for such purposes, with Physics or Chemistry or Microbiology as one of the subject and has had at least three years practical experience in the manufacturing or testing of devices to which this licence applies after his graduation; or

(iii) a diploma in Pharmacy or Engineering(in appropriate branch) from a Board or Institute recognised by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or testing of devices to which this licence applies after his diploma; or

(iv) having a foreign qualification, the quality and content of training of which are comparable with those specified in clause (i), clause (ii) and clause (iii) and is permitted to work as competent technical staff under this rule by the Central Government.".

3. In the said rules, for rule 109A, the following rule shall be substituted, namely:—

'*109A. Labelling of medical devices.*—Subject to the other provisions of these rules, the following particulars shall be printed in indelible ink on the label or sticker on the shelf pack of the medical device or on the outer cover of such medical device and on every outer covering in which the medical device is packed, namely:—

(a) proper name of the medical device;

(b) the details necessary for the user to identify the device and its use;

(c) the name of the manufacturer and address of the manufacturing premises where the device has been manufactured;

(d) the correct statement of the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package shall be expressed in metric system; and

(e) the date of manufacture and date of expiry; alternately the label shall bear the shelf life of the product:

Provided that in the case of sterile devices the date of sterilisation may be given as date of the manufacture of the device:

Provided further that the device is made up of stable materials such as stainless steel or titanium, and supplied non-sterile, date of expiry may not be necessary;

(f) to provide, wherever required, an indication that the device contains medicinal or biological substance;

(g) to provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No.";

(h) to indicate, wherever required, any special storage or handling conditions applicable to the device;

(i) to indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method;

(j) to give, if considered relevant, warnings or precautions for the attention of the user of the medical device;

(k) to label the device, if the device is intended for single use;

(l) to overprint on the label of the container, the words "FOR CLINICAL INVESTIGATION ONLY", if the device is intended for clinical investigation;

(m) to overprint on the label of the device, the words "Physician's Sample—Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample;

(n) to provide, except for imported devices, the manufacturing licence number by preceding the words "Manufacturing Licence Number" or "Mfg. Lic. No." or "M. L";

(o) Devices or In-vitro diagnostics which are not sold to customer or patient directly and are sold for use by hospitals or diagnostic labs shall provide the information affixing additional label or sticker on outer shelf pack;

(p) to provide on the label, in case of imported devices, with the approval of the licensing authority mentioned in rule 21, the import licence number, name and address of the importer and address of the actual manufacturing premises, date of manufacture, (if not already printed at the time of import):

Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardisation (ISO) in lieu of text and the device safety is not compromised by a lack of understanding on the part of the user in case the meaning of the symbol is not obvious to the device user.'.

4. In the said rules, after rule 109A as so substituted, the following rules shall be inserted, namely:—

'109B. Exemption of certain labelling requirements for medical devices for export from India.— The labels on packages or container of devices for export shall be adopted to meet specific requirements of the law of the country to which the device is to be exported, but the following particulars shall appear in conspicuous manner on the label of the shelf pack of the medical device in which the device is packed and every other outer covering in which the container is packed-

(a) name of the Device;

(b) the distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B.No.";

(c) the date of expiry, if any;

(d) the name and address of the manufacturer and address of actual premises where the device has been manufactured;

(e) the manufacturing Licence No. preceded by the letters "M.L. No" or "Manufacturing Licence No";

(f) the internationally recognised symbols in lieu of text, wherever required:

Provided that where a device is required by the consignee not to be labeled with the name and address of the manufacturer, the label on the packages or container shall bear a code number as approved by the licensing authority and the code number shall bear the name of the State or Union territory, in abbreviation, followed by the word "Device" and "manufacturing licence number:

Provided further that where a device is required by the consignee not to be labeled with the code number also, the label on the packages or container shall bear a special code number, as requested by the consignee, and approved by the licensing authority under rule 21.

109C. Shelf life of the medical devices.— The shelf life of the medical devices shall not exceed sixty months from the date of manufacture:

Provided that this period may be extended by the licensing authority, in respect of any specified medical device, if satisfactory evidence is produced by the manufacturer to justify such an extension.'.

5. In the said rules, in Schedule D, after item number 6 and the entries relating thereto, the following item number and entries shall be inserted, namely:—

Class of drugs	Extent and conditions of exemptions
"7. Custom Made Devices	All provisions of Chapter III of the Act and the rules made thereunder, subject to the condition that the device is specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design characteristics and is intended for the sole use of a particular patient and the label should bear the word "custom made device." *Explanation.*—Mass produced devices which only need adoption to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom made devices.".

6. In the said rules, in Schedule K, after item number 34 and the entries relating thereto, the following item number and entries shall be inserted, namely:—

Class of Drugs	Extent and Condition of Exemptions
"35. Custom made devices	All provisions of Chapter IV of the Act and the rules made thereunder, subject to the condition that the device being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design characteristics and is intended for the sole use of a particular patient and the label should bear the word "custom made device." *Explanation.*— Mass produced devices which only need adoption to meet the specific requirements of the medical practitioner or any other professional user shall not be considered to be custom made devices.".

7. In the said rules, for Schedule R-1, the following Schedule shall be substituted, namely:—

"Schedule R-1

(See rules 109A, 109B, 109C and 125A)

The medical devices shall conform to the Indian Standards laid down from time to time by the Bureau of Indian Standards. If there are no Bureau of Indian Standards then it shall conform to the International Standards, like International Organisation for Standardisation, or other International Pharmacopeia Standards and such other standards as may be specified for this purpose. In case national or international standards are not available, the device shall conform to the manufacturer's validated standards.".

[F. No. X/11014/3/2013-DFQC]

K. L. SHARMA, Jt. Secy.

Foot Note:.—The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H (1), dated 21st December, 1945 and last amended *vide* notification number G.S.R. 570 (E), dated 07.08.2014.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th September, 2014

G.S.R. 701(E).—The following draft rules which the Central Government proposes to make, in exercise of the powers conferred by clause (i) of sub-section (2) of section 33 read with section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), on the recommendation of the Drugs Technical Advisory Board, is hereby published for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing this notification is made available to the public;

The objections and suggestions, if any, received from any person with respect to the said draft notification within the period so specified shall be taken into consideration by the Central Government;

The objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Room No. 523-A, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi – 110011.

Draft Rules

1. **Short title and commencement.**—(1) These rules may be called the Prohibition of Use of Polyethylene Terephthalate or Plastic containers for primary packaging of drug formulations for using in certain cases Rules, 2014.

(2) They shall come into force after a period of one hundred and eighty days from the date of its final publication in the Official Gazette.

2. **Prohibition of use of Polyethylene Terephthalate in liquid oral formulations for primary packaging of drug formulations.**—No manufacturer shall use the Polyethylene Terephthalate or Plastic containers in liquid oral formulations for primary packaging of drug formulations for paediatric use, geriatric use and for use in case of pregnant women and women of reproductive age group.

3. **Penalty for contravention.**—Any manufacturer who contravenes the provisions contained in rule 2 shall be liable to penalty under the provisions of the Drugs and Cosmetics Act, 1940.

[F. No. X.11014/10/2013-DFQC]

K. L. SHARMA, Jt. Secy.

OBITUARY

SHRI. V. JANARDANAN
Date of Demise: 29.10.2014

Shri. V. Janardanan, aged 82 was born in Valapad, Thrissur district, Kerala State. He graduated in Pharmacy from Madras Medical College in the year. After graduation he joined Orient Pharma (currently TTK Pharma) as a medical representative and rose to the level of Production Manager and Chief Executive at TTK Pharma. Soon after he left TTK Pharma, he founded Meridian Pharmaceuticals in 1982 in partnership with two of his close associates. He retired as the Vice Chairman of Meridian Pharmaceuticals in 2007. He served as the Secretary of Indian Drug Manufacturers Association and was also an active member of Indian Pharmaceutical Association. He is survived by his wife and a son and a daughter.

We pray for his soul rest in peace.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

Notification

New Delhi, the 13th October, 2014.

G.S.R. 718 (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. 311(E), dated the 5th May, 2014, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 5th May, 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 8th May, 2014;

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

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

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

(2) They shall come into force with effect from thirty days after the date of its publication in the official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, after rule 135-A, the following rule shall be inserted, namely:-

"135-B. *Prohibition of import of cosmetics tested on animals.*- No cosmetic that has been tested on animals after the commencement of the Drugs and Cosmetics (Fifth Amendment) Rules, 2014 shall be imported into the country.

[F.No. X.11014/11/2013-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 last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 690(E), dated the 25th September, 2014.

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054

INFORMATION

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

Profile of Third Rank Projects

PHARMACEUTICS

Name: Ms. Vianni Chopra
Project Title: Formulation & Characterisation of Zinc Albumin nanoparticles entrapped polymeric films/nanofiber patches for vaginal route as a novel platform for the treatment of cervical and ovarian cancer
College: J S S College of Pharmacy, Ooty
Guide's Name: Mr. G.N.K. Ganesh

PHARMACEUTICAL CHEMISTRY

Name: Mr. C. Sathiyaraj
Project Title: Design, Sythesis & Biological evaluation of novel pyrazole analogues from chalones as antitubercular agents
College: Madras Medical College, Chennai
Guide's Name: Dr. A. Jerald Suresh

PHARMACEUTICAL ANALYSIS

Name: Ms. Kota Saranya
Project Title: Method development and validation for the simultaneous estimation of irrational combination of drugs by HPTLC in Pharmaceutical formulation
College: SRM College of Pharmacy, Chennai
Guide's Name: Mr. K. Manikandan

PHARMACOLOGY

Name: Ms. Radhika Ramaswamy
Project Title: Study of insilico and invitro anticancer activities of traditional Indian medicinal plants- Reverse pharmacology work
College: Sri Ramachandra University, Chennai
Guide's Name: Dr. C. Uma Maheshwara Reddy

PHARMACOGNOSY

Name: Ms. S. Zaburuth Nisha
Project Title: Pharmacognostical, Phytochemical antioxidant and Hypolipidemic activity on leaves of *operculina turpethum*
College: Madras Medical College, Chennai
Guide's Name: Dr. N. Jayashree

PHARMACY PRACTICE

Name: Ms. Ritu Sebastian
Project Title: Herb- drug interaction of *Trigonella foenum graecum* on Pharmacokinetics of nateglinide in healthy subjects
College: J S S College of Pharmacy, Ooty
Guide's Name: Dr. S. Ponnusankar

PHARM D - PHARMACY PRACTICE

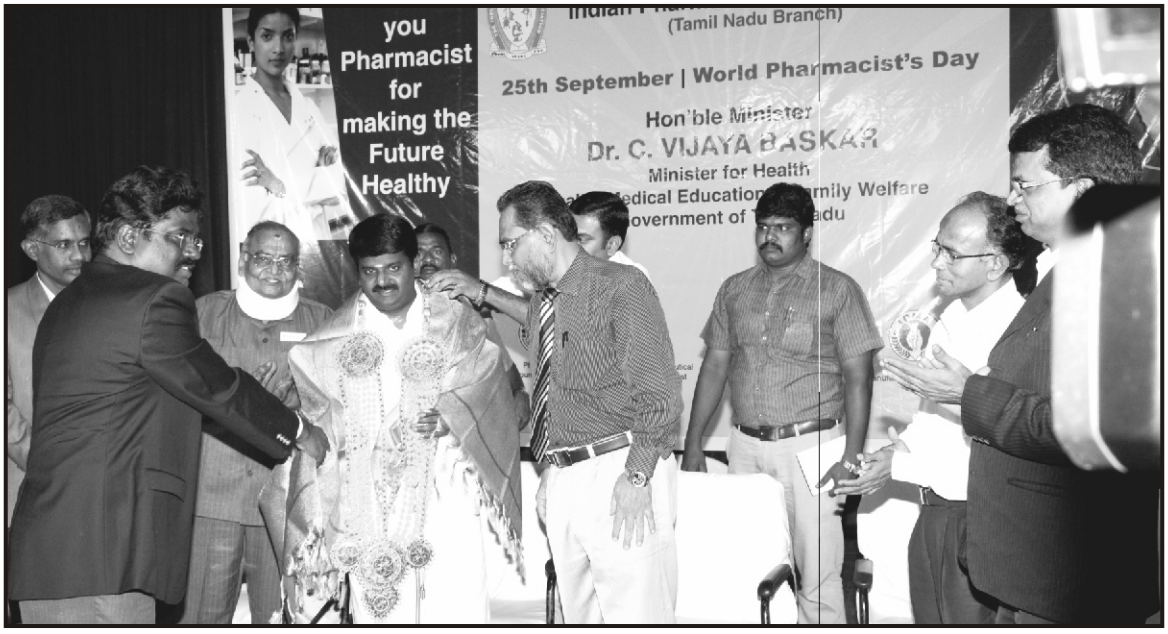
Name: Mr. P. Raja Mani Teja
Project Title: Effectiveness of omega 3 acid ethyl esters as an add on therapy to anti hyperlipidemic agents
College: SRM College of Pharmacy, Chennai
Guide's Name: Prof. M. S. UmaShankar

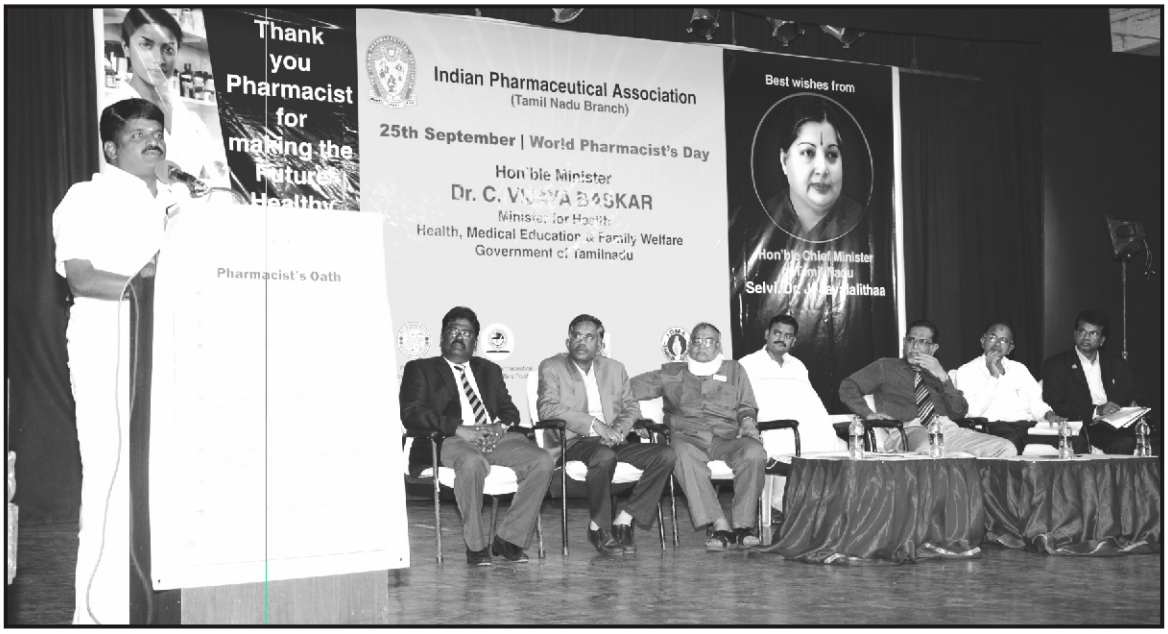
PHARM D- CLINCIAL PHARMACY

Name: Mr. G. Manas Kumar, Mr. K. S.Sechana & Mr.Anoop Santhosh Mathews
Project title: Therapeutic drug monitoring of vancomycin in various degrees of renal function
College: PSG College of Pharmacy, Coimbatore
Guide's Name: Mr. T. Tamilselvam

EVENTS

World Pharmacist's Day Celebration on 25th September 2014 by IPA, TN Branch





Indian Pharmaceutical Association, Tamilnadu Branch celebrated World Pharmacist's Day on 25th September 2014 at Raja Annamalai Mandram, Chennai. Many Pharmacy professionals and Pharmacy students of 1000 numbers attended the function.

Dr. C. Vijaya Baskar, Hon'ble Minister for Health, Medical Education and Family Welfare Government of Tamilnadu was the chief guest of the function. Mr. M. M. Yousuf, President, IPA, TN Branch welcomed the gathering. Thiru S. Abdul khader, Director of Drugs Control, Tamilnadu, Dr. S. Manivannan, Deputy Drugs Controller(i), CDSCO, South Zone, Chennai and Prof. K. Chinnaswamy, President, Tamilnadu Pharmacy Council, were guest of honours of the function. Mr. J. Jayaseelan, Secretary, IPA, TN Branch and Dr. V. Ravichandiran, Vice president IPA TN Brach spoke on the occasion. They requested Hon'ble Health Minister to set up a Pharma industrial park as well as to create a separate university for the Pharmacy education in Tamilnadu. They also requested the Hon'ble Health Minister to fill up all the vacancies in the Pharmacy department of Madras & Madurai medical college and also to fill up the vacant posts of pharmacist's in various hospitals in Tamilnadu. Further they requested to start B.Pharm courses in Thanjavur and Coimbatore government medical colleges. Hon'ble Health Minister assured the gathering to take up the issues with appropriate ministries and Hon'ble Chief Minister. The meeting ended with the vote of thanks by Dr. V. Ravichadran, Vice President, IPA, TN Branch.

World Pharmacist Day Celebration 2014 at Periyar College of Pharmaceutical Sciences, Trichy

World Pharmacists day was celebrated on 25th September at Periyar College of Pharmaceutical Sciences, Trichy. Mr. G. Sebastian, Correspondent presided over the function. Prof. Dr. R. Senthamarai, Principal, PCPS, Trichy delivered the welcome address and emphasized the role of Pharmacist and the spectacular development in the field of Pharmacy. Prof Dr. A. M. Ismail, Vice Principal and Mrs. K. Vasuki of Thiruvarur Medical College Hospital felicitated the programme.

Mr. K. Chandrasekaran, Assistant Director of Drugs Control, Trichy Zone, Trichy delivered the Special address and in his speech he highlighted that Pharmacists should continue to work towards a greater role in patient care and in safe medicines use. The Pharmacists oath was sworn by all the Pharmacists recited by Dr. T.Shri Vijaya Kirubha, Head, Department of Pharmacognosy.

World Pharmacist Day Celebration 2014 at PSG College of Pharmacy in Association with IPA-CPD, Mumbai

PSG College of Pharmacy celebrated World Pharmacist day on Sep 25th 2014. The International Pharmaceutical Federation (FIP) conferred the theme as “ACCESS TO PHARMACISTS IS ACCESS TO HEALTH”. This event encourages pharmacist to organize activities that promote and advocate for the role of the pharmacist in improving health in every corner of the world. On this day vibrant celebrations were held at PSG College of Pharmacy which includes variety of educational events such as poster presentation, pharmacy awareness campaign and awareness lecture as well as Counseling of patients in their Hospital and in rural areas.

World Pharmacist Day Celebration 2014 at Sri Ramachandra University, Chennai

Faculty of Pharmacy and Hospital Pharmacists of Sri Ramachandra University celebrated the world Pharmacist's day on 25th September 2014. Dr. D. Chamundeeswari, Principal, Faculty of Pharmacy welcomed the dignitaries, fellow pharmacists and budding pharmacists. Dr. T. K. Parthasarathy, Professor of Eminence and Chief Advisor Sri Ramachandra University felicitated Mr. R. Narayanaswamy; Deputy Drugs Controller (India) (Rtd.) the chief guest of the function and Mr. Jacob Nicolas, Diector-Training and Programmes, Acknova- Academy of Professional Excellence, British Columbia, Canada and addressed the gathering .He appreciated the services of pharmacists.

The chief guest Mr. R. Narayanaswamy unveiled the theme of the pharmacist's day as “I am a responsible Pharmacist”, The Future is Healthy”. He gave a presentation depicting the various challenging roles of pharmacists as manufacturer, counsellor, community pharmacist health care provider, discoverer of new medicines, documentation pharmacists, Pharmacovigilence i.e advisor to doctors, teacher, quality control analysts, patent officer, research pharmacist(both clinical and preclinical) etc. He finally conclude that as the president of Pharmacists welfare trust,he is encouraging the M.Pharmacy students to apply for financial aid for their projects.

Dr. A. Ravi, Medical Director, Sri Ramachandra University in his special address stressed that pharmacists should reach the community and spread awareness about the proper usage of medication in the community.

Dr. P. V. Vijayaraghavan, Dean Education and Director Academic Administration, in his address appreciated the Faculty of Pharmacy in conducting enrichment program in advanced Pharmacy practice for Pharm.D and M.Pharm (Pharmacy Practice) students. Dr. K. V. Somasundaram, the Dean of Faculties inaugurated the “Pharmacists day” and emphasised the pharmacy professionals to work hard to achieve their goals. He also distributed certificates to the students who have undergone value added course on 'Drug Regulatory Affairs'. The Vice Principal, Faculty of Pharmacy, Dr.K.Chitra proposed the vote of thanks.

Various competitions and cultural activities were conducted and the pharmacy students, research scholars and the hospital pharmacists took active part in it. Prizes were distributed for the deserving persons.

NEWS

Hospitals Make A Killing on Medical Devices Like Stents, Implants

The cost of medical devices like stents and pacemakers is enough to give anyone a heart attack. TOI found that patients were being forced to pay double or even triple the price for medical devices at hospitals. As most of these are not available in the open market, patients can't check prices and are held hostage by hospitals, which force them to buy at the price they quote.

Sources in the healthcare sector told TOI that in several hospitals, the margins on devices — ranging from stents, implants and pacemakers to artificial joints, titanium plates for fractures, and valves — could add up to as much as 30% of their profits. Hundreds of such devices are used in a hospital every day. Of course, it is the patient who pays for these handsome margins.

Take what happened to a lawyer whose father was admitted to a 'charitable' hospital in Kochi. The doctors advised that the patient needed three drug eluting stents at Rs 95,000 per stent. Since he knew the pharma and medical devices market reasonably well, the lawyer went directly to the hospital's supplier, who offered the same stents for about Rs 40,000 each, a rate much higher than would have been charged to a bulk buyer like a hospital. But the hospital refused to use a stent bought by him. He had no option but to take the stent provided by the hospital as his father could not be shifted. After much haggling, the hospital offered to give three stents for the price of two, charging him Rs 87,000 for each. The final price of each stent, including the 'free' one, was effectively Rs 58,000.

"The actual cost at which the hospital gets it is probably in the range of Rs 30,000 or even less. That's a mark-up of almost 300% on just one stent. And this was a top-of-the-line branded stent from one of the biggest multinationals. There were many patients there who were being charged the full amount. Even the supplier gets a cut from the company. Imagine what the actual price might be if directly sourced from the company, probably about Rs 20,000," said the lawyer.

Adding to the margin on devices is the profit hospitals make billing patients for medicines using the same principle of buying cheap in bulk and selling at a much higher price to the patient. In fact, devices, medicines and diagnostics could account for as much as 70% of a hospital's profit. Some very reputed doctors confirmed to TOI that this was the case, but asked not to be named.

Experts feel that making it mandatory to declare the maximum retail price on each device could help cap the price and make companies compete to offer lower prices. However, doctors point out that having an MRP has not prevented profiteering in medicines, with the MRP being fixed high enough to accommodate commissions since there is no limit on what the MRP can be. Moreover, while MRP is mandatory on everything manufactured in India, many devices are imported and escape this stipulation.

Another suggestion is that devices be prescribed by doctors but left to patients to buy from pharmacies where several brands could be stocked to allow patients to decide. "After all the sterility required of a medical device like an implant is of the same level as a syringe or bandage. If those can be bought in pharmacies, why not devices? This system of hospitals meant to sell services becoming peddlers of wares compromises the right of a patient as the consumer to choose," argued one expert in favour of open purchase. But not all patients would relish the extra hassle of having to purchase each item themselves. They might also feel they do not know enough to make an informed choice.

A surgeon in a corporate hospital narrated how a company offered him a stapling gun used in surgeries at Rs 20,000, which he found to be as good as the one he was using regularly but which cost about Rs 22,000. "Since it saved the patient Rs 2,000, I decided to use the cheaper one.

But I got a call from the purchasing section of the hospital to go back to using the earlier one since the company gave it to the hospital for Rs 14,000, which meant a mark-up of Rs 8,000, while the other company offered its gun to the hospital for Rs 16,000, which meant only Rs 4,000 for the hospital," said the surgeon. He went back to the one that cost Rs 22,000 since both were equally good. In most hospitals, if two devices are more or less equal, the choice of which one is used depends on which fetches the hospital a bigger cut.

"If the Telecom Regulatory Authority of India (TRAI) can regulate and prescribe ceiling rates for call charges or roaming charges, why is there no government regulation on what hospitals can charge for medical procedures and devices? Just as there is a National Pharmaceutical Pricing Authority (NPPA) for medicines, there ought to be an authority that regulates the price of devices. Why is the government allowing hospitals to loot patients like this?" asked the lawyer whose father had three stents implanted.

Behind the ballooning bills
·Whether it's drugs or devices, hospitals buy cheap in bulk and sell at a much higher price to patient
·If two devices are more or less equal, hospitals choose the one that gets them a bigger cut
·Experts suggest making MRP mandatory on devices or a price regulatory authority
·Another option is to let patients buy from market

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

Major Diabetes, Cardiac Drugs to Become Up to 35% Cheaper

In a move that has surprised and shaken the industry, prices of widely-used expensive anti-diabetic and cardiac medicines will reduce by as much as 35% over the next few weeks, with the drug pricing regulator, National Pharmaceutical Pricing Authority (NPPA), deciding to bring them under price control.

In a rare invocation of a lesser-used provision in the Drug Price Control Order (DPCO), NPPA has fixed the prices of 108 formulation packs of 50 anti-diabetic and cardiovascular medicines. What makes the development significant is that NPPA has fixed prices of those medicines which are not listed under the national list of essential medicines (NLEM). Prices of 652 drugs under NLEM were fixed by the government last year under DPCO 2013.

The drugs that will become cheaper include Gliclazide, Glimepiride, Sitagliptin, Voglibose, Amlodipine, Telmisartan and Rosuvastatin, Heparin and Ramipril.

The move will mean savings for patients prescribed expensive chronic therapies.

READ ALSO: Widely used drugs to cost up to 50% less

With this list, the total market of cardiac medicines under price control, including the earlier ones, stands at 58%, while 21% of the anti-diabetic market comes under the purview. Around Rs 5,500 crore of the pharma market will be impacted, with the range of prices being reduced from 10-15% to as high as 35%, with the average reduction around 12%.

The provision, Paragraph 19 of DPCO, 2013, authorizes the NPPA "in extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it deems fit".

The notification to fix prices of these medicines, which are non-scheduled formulations, was issued on July 10: "...wherever the maximum retail price (MRP) of the brand of a particular formulation exceeds 25% of the simple average price, the same

HOW NEW REGIME WILL PINCH PHARMA

COS THAT WILL FEEL THE IMPACT

Co	MAT* value (MRP)	Value loss (MRP)	% Impact (MRP)
Sanofi India	397	139	35
Astrazeneca	99	29	29
Merck	67	16	24
Zydus Cadila	211	40	19
Abbott	257	38	15
Ranbaxy	280	38	13
Pfizer	107	10	9
Cipla	219	19	9
Lupin	401	32	8
Dr Reddy's	174	14	8
Torrent	356	27	8
Glenmark	271	18	7
Sun Pharma	449	25	5
New DPCO Mkt Value**	**5,484**	**641**	**11**

TOP BRANDS IN AFFECTED CATEGORIES

Brand	Company	Molecule	Therapy
Telma	Glenmark	Telmisartan	Cardiac
Januvia	MSD	Sitagliptin	Anti-diabetic
Minipress xl	Pfizer	Prazosin	Cardiac
Cardace	Sanofi India	Ramipril	Cardiac
Nitrocontin	Modi Mundi	Glyceryl Trinitrate	Cardiac
Nikoran	Torrent	Nicorandil	Cardiac
Cardace	Sanofi India	Ramipril	Cardiac
Clexane	Sanofi India	Enoxaparin	Cardiac
Rosuvas	Ranbaxy	Rosuvastatin	Cardiac
Atorva	Zydus Cadila	Atorvastatin	Cardiac
Clexane	Sanofi India	Enoxaparin	Cardiac
Istavel	Sun Pharma	Sitagliptin	Anti-diabetic
Aten	Zydus Cadila	Atenolol	Cardiac
Rosuvas	Ranbaxy	Rosuvastatin	Cardiac
Volibo	Sun Pharma	Voglibose	Anti-diabetic

*Moving annual total value in Rs cr for affected categories; **New Drug Price Control Order; Source: AIOCD AWACS

Simply put, if the price of a drug brand exceeds the simple average price in that therapy group by 25%, or the price at which a new drug is launched for the first time is higher than the most expensive brand existing in the group, NPPA would initiate the process of fixing a price cap.

The move which surprised many in the pharma industry, has "shaken its confidence" and it is "examining all options". When contacted, the industry body Indian Pharma Alliance's secretary general D G Shah said the NPPA has "gone beyond essentiality as a criterion, and into policy-making and price fixation, making the NLEM redundant".

According to the notification, NPPA has also acted on drugs where there is a "huge inter-brand price difference in branded-generics/off-patent drugs, which is indicative of a severe market failure, as different brands of the same drug formulation, including the off-patent drug, which are identical to each other in terms of active ingredient(s), strength, dosage, route of administration, quality, product characteristics, and intended use, vary disproportionately in terms of price".

"And whereas market failure alone may not constitute sufficient grounds for government intervention, but when such failure is considered in the context of the essential role that pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing makes medicines unaffordable and beyond the reach of most and also puts huge financial burden in terms of out-of-pocket expenditure on healthcare", the notification says.

The regulator says that the new law allows NPPA to fix and revise price caps of drugs in public interest and this clause applies to both drugs which are part of the NLEM and those outside of it.

Recently, NPPA, under its newly-appointed chairman Injeti Srinivas, decided to monitor prices of all drug brands in critical therapies like cancer, HIV, diabetes, cardiovascular diseases, and tuberculosis. These could be also medicines which are part of chronic treatments and exorbitantly-priced brands.

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

India is the World's Largest Consumer of Antibiotics

India has emerged as the world's largest consumer of antibiotics, with a 62% increase in use over the past decade.

'Global Trends in Antibiotic Consumption, 2000-2010', a study by scientists from Princeton University, has found that worldwide antibiotic use has risen by 36% over those 10 years, with five countries — Brazil, Russia, India, China and South Africa (BRICS) — responsible for more than three-quarters of that surge. Among the 16 groups of antibiotics studied, cephalosporins, broad-spectrum penicillins and fluoroquinolones accounted for more than half of that increase, with consumption rising 55% from 2000 to 2010.

During this period, India's antibiotic use went up from eight billion units (2001) to 12.9 billion units (2010).

The study quantifies the growing alarm surrounding antibiotic-resistant pathogens and a loss of efficacy among antibiotics used to combat the most common illnesses. It confirms an increasing resistance to carbapenems and polymixins, two classes of drugs long considered the last resort antibiotics for illnesses without any other known treatment.

“Indians consume around 11 antibiotic tablets per year," Ramanan Laxminarayan, one of the authors of the study, told TOI. "That's five days of antibiotics for every person in the country, which is more than the Chinese or Brazilians. An average Chinese popped seven antibiotic pills a year. However, both India and China's numbers are lesser than the Americans who on average pop 22 antibiotic pills a year. The paper confirms that global use of antibiotics is surging and specially in India."

Laxminarayan said that was both good news and bad news. "It means that more Indians are able to access antibiotics, which are particularly important for those who previously died of easily treatable infections," he said. "However, the massive increase in use, both appropriate and inappropriate, is leading to increases in drug resistance. Antibiotic use is the single most important reason for resistance. Also use of last resort drugs like carbapenems has gone up significantly in India, and it is difficult to justify why such powerful antibiotics are being use so much more frequently.”

Laxminarayan said it had to be remembered that before we had antibiotics, it was pretty easy to die of a bacterial infection. "And we're choosing to go back into a world where you won't necessarily get better from a bacterial infection," he said. "It's not happening at a mass scale, but we're starting to see the beginning of when the antibiotics are not working as well."

Professor Dame Sally Davies, chief medical officer for England and chief scientific adviser for the Department of Health, London, said: "This paper breaks new ground with the comparative antibiotic consumption data by country of the first decade of

the 21st century. There is a direct relationship between consumption and development of antibiotic resistance, so the data is key for us all developing a 'National Action Plans Against Antimicrobial Resistance' as set out in the World Health Assembly Resolution in May."

The study noted that the use of antibiotics tended to peak at different times of the year, corresponding in almost every case with the onset of the flu season. In the northern hemisphere, for example, consumption peaked between January and March, while in the southern hemisphere it peaked between July and November. One notable exception was India, for which usage peaked between July and September, correlating with the end of the monsoon season.

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

Sun Pharma Ranbaxy $ 4 billion Deal Gets BSE, NSE Approval

India's top two stock exchanges have approved the merger of Ranbaxy Laboratories with Sun Pharmaceutical, clearing at least one regulatory hurdle facing consummation of the country's largest inbound Pharma deal inked four months ago.
The approval of the BSE and the National Stock Exchange will allow Sun to delist Ranbaxy shares from the two exchanges, two people familiar with the matter told ET. The exchanges approved the $ 4 billion merger deal last week, one of these people said.

This marks the first big milestone in a series of regulatory approvals that Sun and Ranbaxy need to conclude the deal. The two companies will still need clearances of the high courts of Gujarat and Punjab & Harayana, besides the Competition Commission of India to close the deal by the end of year as planned.

Spokespersons of Sun Pharma and Ranbaxy Laboratories said they have no comments to offer.
Sun had, in April, announced its plan to acquire rival Ranbaxy from its Japanese parent, Dalichi Sankyo, in an all-stock deal valued at $ 4 billion, including $800 million of debt. The transaction valued Ranbaxy at 2.2 times its $ 1.8 billion revenue for 2013 or about Rs 457 per share.

Shareholders of Ranbaxy, including Dalichi, which owns a 63.5% stake will get 0.8shares of Sun for every share they hold. Post deal, Dalichi will become Sun's largest shareholder after founder and MD Dilip S Shanghvi, with 9% stake and a seat on the company's board.

Soon after the deal was announced, two retail investors filed a petition before the Andhra Pradesh High Court, alleging that Silver Street, a limited liability partnership firm owned by subsidiaries of Sun Pharma, was involved in insider trading of Ranbaxy shares. In the six trading days preceding the announcement of the deal, Ranbaxy shares had jumped on the bourses.

In late April, the high court asked the stock exchanges to put the transaction on hold while serving notices on the Securities and Exchange Board of India (Sebi), BSE, NSE and Silver Street, Sun challenged the order in the Supreme court and in May, the high court vacated the interim stay.
After the closure of the deal, Ranbaxy will be subsumed under Sun. But a person familiar with the matter said that Sun may preserve the Ranbaxy brand in select geographies where it has perceived value, Details on this front are still being worked out he said.

After the takeover is complete, the combined entity will be fifth-largest generic firm globally with annual sales of over $2 billion. The post-deal entity would also become the undisputed leader in the Rs 75,000 crore domestic drug market and command a leadership position in the prescription market in almost 13 specialities that include psychological, cardiological and neurological therapies.

Ranbaxy's strength in acute drugs and its strong presence in emerging markets and Europe makes it a great fit for Sun in terms of therapy and geography as it focuses on chronic therapies and concentrates on the US and India markets.

Sun with its track record of nine successful acquisitions in the last decade has demonstrated its ability to turn around acquired firms such as Israel based Taro and US based URL (where it recovered its investment in a year's time). It remains to be seen whether Sun can replicate the same in case of Ranbaxy, a much larger company, almost its own size, which has been reeling under prolonged US regulatory troubles.

Source: *The Economic Times, 21st July 2014*

Rajasthan Bans Pharma Firm for Wrong Labelling of Drugs

The Rajasthan government has banned the Himachal Pradesh-based Pushkar Pharma from supplying drugs to the State, Health Minister Rajendra Rathore announcing in the Assembly on Wednesday.

This company had supplied wrongly labelled life-saving Meropenem injections to the State last month which were distributed under the government's free medicine scheme to the patients. Meropenem is a strong antibiotic drug which is used for acute bacterial infection in the lungs, kidney and other vital organs. It is also used for veterinary purpose.

The matter came to light when the warning label which said only for animal use was noticed while a patient was being administered the injection at Mathura Das Mathur Hospital at Jodhpur. It was then realised that the hospital had procured 1000 Meropenem injections and close to 400 had been used in one week. The injections were procured under the Chief Minister's Free Medicine Scheme and given to patients free of cost.

Raising the matter in the Assembly during Question Hour, Congress MLA Govind Singh Dotasra said the government should take strong action against the manufacturer and the distributor for serious negligence. He was supported by members of the ruling Bharatiya Janata party as well.

In his reply, Mr Rathore said the government had already instituted an enquiry into the incident which had submitted its preliminary report.

The final report would come after laboratory test reports of the samples of the injections were received. There were no reports of any adverse effects on the patients who had received the shots.

The three-member probe committee had said that there was gross negligence right from manufacturer to the hospital staff.

The manufacturers erred while labelling but no one down the chain detected the label. Though the Pharma company had claimed that the injections were meant for human use and only label was wrongly put, it cold be charged under the Drugs and Cosmetics Act. Soon after the incident the store keeper and pharmacist were placed under suspension.

Source: *The Hindu, 24th July 2014*

A Drug to Treat HIV Can Prevent it, But India Is'nt Promoting it

Imagine there was a pill that could prevent you from getting an incurable disease. And imagine that it had relatively few side effects, was made up of existing drugs that don't need lengthy new certification, was not entirely unaffordable and was recommended by the World Health Organization. Would you take it if you were vulnerable to an illness?

While some people may be averse to taking strong medicines when they are healthy, the idea of preventive medicines is well established.

Travellers often take anti-malarial pills when heading to the tropics and women routinely pop in pills to prevent pregnancy. So why shouldn't someone, who is at high risk of a particular disease, not be told about a pill that would stop it? That's precisely what the Indian government is doing - not promoting Tenofovir, the most commonly prescribed HIV treatment drug that can also prevent the disease.

WHO made a revolutionary recommendation this month that could alter the debate in the fight against the Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS), the most advanced stage of HIV infection. For the first time, WHO recommended that gay men, who along with sex workers, people who inject drugs and transgender people are most at risk of contracting HIV, should use antiretroviral (ARV) medicines as a preventive drug.

"Rates of HIV infection among men who have sex with men remain high almost everywhere and new prevention options are urgently needed," WHO said in its guidelines on HIV prevention on July 11. It strongly recommended that gay men consider taking antiretroviral medicines (pre-exposure prophylaxis or PrEP) as an additional method of preventing HIV infection, alongside the use of condoms.

While issuing the guidelines, WHO said the failure to provide adequate services to highrisk groups has threatened global progress on the HIV response. Such groups are excluded from national HIV plans in several countries and discriminatory laws and policies are major barriers to access, it said.

PrEP taken consistently has been shown to cut the risk of HIV infection in high-risk groups by up to 92%, although it is much less effective when not taken consistently.

The recommendation opens up a new debate on the use of ARVs as a preventive drug and how it will be perceived among those who engage in unsafe sex. In the Indian context, the issue has been kept out of the public health debate due to the reluctance of healthcare providers, lack of awareness among doctors and the criminalisation of homosexuality. Despite the high success rate of ARVs, they are far from being promoted as preventive drugs in India, experts feel.

"There are many barriers -- social and legal -- that make it difficult to market preventive treatment in India," said Dr Sanjay Pujari, Director of the Institute of Infectious Diseases in Pune. "You cannot publicly start promoting this among gay men in India, when you have a law that criminalises homosexuality."

There was no immediate response to an e-mail sent to the National AIDS Control Organisation, a division of the Ministry of Health and Family Welfare.

Pujari said most physicians are unaware that such an intervention exists and the lack of guidelines on PrEP complicates the issue further. Although he has prescribed ARV as a preventive drug to couples where one partner is HIV-positive, he still finds there is a reluctance to use the drug.

"It's a double-edged sword. People sometimes feel guilty that they are being promiscuous by popping the pill," Pujari said.

Rakesh (name changed), who tested HIVpositive eight years ago, said it is high time that India at least opens a dialogue on this issue.

"There are a lot of people who are having unsafe sex. So we are at a stage where the least that we can do is give people the information that such preventive treatment exists, and the liberty to choose," he said.

While Tenofovir has been hailed by some as the next big medical revolution after the morning-after pill, others have dismissed it as a "party drug" that may increase the risk of infection.

A key factor that may have dampened the promotion of ARVs for prevention is the fear that irregular use of the drugs and the non-use of condoms would lead to a return to the dark days of the AIDS epidemic. Pujari said that in the high-risk gay population, the sustained use of ARVs was only 30% and even during clinical trials, it was inconsistent.

"Unscientific advice is being given even by physicians to HIV-positive men to take PrEP before their weddings for say, six months, so they become incapable of transmitting HIV to their new brides after marriage nuptials. Rich gay men have been taking OTC (over the counter) ARV as prevention measures without medical advice or supervision," said Askok Row Kavi, activist and founder of the Humsafar Trust, an organisation that fights for the rights of the LGBT community in India. He said as a country, we are still not ready to promote preventive ARVs because of our patriarchal set-up.

Doctors including Pujari are clear that India needs a comprehensive debate in both the academic and public spaces on the introduction of preventive ARVs. Though globally the number of people dying of HIV/AIDS has fallen, renewed intervention and inclusive policies are still needed for those at risk.

"Bold policies can deliver bold results," said Dr Rachel Baggaley of WHO's HIV Department.

There's no better time to start than now.

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

50 Essential Drugs Free by Year-end

The Narendra Modi government will roll out the first instalment of its ambitious 'health assurance for all' promise by providing 50 essential drugs free by year end. As a first step, the Union health ministry has sent a proposal to the Prime Minister's Office seeking Rs 500 crore for the programme this year. Although the ministry is yet to finalise the list of 50 essential drugs to be covered under the programme, officials aware of its details told ET it could include antibiotics, anti-hypertensives and anti-diabetes drugs.

"It's a work in progress and it will be difficult to name the medicines at present. A group of experts will draw up the list, but it will definitely include drugs that can cure fever, cough, cold, rabies etc," said a senior ministry official, who didn't want to be named as he's not authorised to speak to the media. The free medicines will be available to those who access public healthcare facilities.

The ministry is planning to formulate the Free Drugs Scheme by August 10, receive proposals from the states by November and roll out the scheme in December provided it gets budgetary approval. According to a high-level expert group of the Planning Commission, the government needs rs 6,000 crore annually to provide free medicines at public health facilities.

The free drugs programme is one part of the National Health Assurance Mission announced by the president recently. The health ministry has constituted a task force headed by clinical pharmacologist Ranjit Roy Choudhury to recommend "actionable points" for the mission.

"The mission will essentially have three components — free drugs, free diagnostics and free health services. We plan to start with providing free medicines and once the broad contours of the mission are finalised the Free Drugs Scheme will become a part of the mission," the above official added.

Ex-Prime Minister Manmohan Singh had launched a similar plan about two years ago but that didn't gain traction because of lack of funding. The idea has been revived by the Modi government, which has promised to double government spending on healthcare.

The health ministry hopes the free medicines scheme will go a long way toward fulfilling the promise of reducing out-of-pocket expenditure on healthcare, which is defined as any direct expense incurred by households on doctors, hospitals and pharmacies.

With abysmally low levels of health insurance coverage, India is among countries with the highest out-of-pocket expenses, as a result of which move 2% of the population falls below the below poverty line every year, according to government statistics

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

NPPA Axe Threatens Life of Crucial Drugs

Drug manufacturers may cut back on production of several life saving medicines after the government decided earlier this month to expand the list of drugs whose price it controls.

The national Pharmaceutical Pricing Authority on July 10 announced cuts to prices of 108 cardiac and diabetes medicines by as much as 35%. Many of these drugs were not part of what is called the National List of Essential Medicines (NLEM). However the pricing authority said it excercised powers under the Drug Price Control Order that allows it to fix the maximum price of any drug under 'extraordinary' circumstances in 'public interest'.
The latest list of 108 medicines is in addition to 652 drugs under NLEM whose price is regulated to make chronic therapies affordable.

According to analysts, the latest list of medicines brought under price regulation have a market sales value of around Rs 5,500 crore, constituting nearly 6% of the Indian pharmaceutical market size. The most impacted drugs include cardiac drug enoxaparin, diabetes medicine glimepiride and anti-cholesterol agent atorvastatin.

The most affected drug manufacturers include Sanofi India, AstraZeneca, ZydusCadila, Abott Healthcare and Ranbaxy.
“Shocked and disappointed”, drug producers are weighing their options, including legally challenging the price cuts and scaling down production to minimize impact on profitability. Dilip G Shah, director general of trade body Indian Pharmaceutical alliance, pointed out that many developing and developed countries importing medicines from India benchmark their procurement price with Indian domestic prices.

“This may either lead to loss of exports or encourage companies not to supply price controlled products in the domestic market for better realization abroad.

In either case, it is a loss to the country, he told ET. India's pharmaceutical exports grew by just 1% to $ 15 billion (Rs 90,000 crore) during 2013-14. Domestic sales fell by 20% to Rs 76,000 crore during this period. Senior executives at drug manufacturers affected by the latest price cuts said they will be left with no option but to reduce output and supply of the medicines. " We may have to operate on very thin margins if we have to sell these drugs at such low prices, " said a top executive at a large Hyderabad-headquartered drug firm who sought anonymity.

Alok Dalal, a healthcare analyst at Motilal Oswal Securities, said that when the price controls were brought in place in 1995, of 74 moleculs, 36 were discontinued by Pharma companies over a period of time. "If the companies do not find it viable to continue selling the product due to the revised price structure, they may consider the option of withdrawing it from the market,"Dalal said.

The chief executive of a midsized drug firm that is at present not affected by the price cut said that the formula adopted by NPPA for cardiac and diabetes therapies will definitely affect profit margins at many pharmaceutical companies".The growing fear among the industry players is over the uncertainties involved in the Indian regulatory environment and over the NPPA's arbitrary decision making style. What is the guarantee that NPPA may not bring more therapies under price control?'

Utkarsh Palnitkar of KPMG India said it will be difficult for pharmaceutical companies to sustain their presence in what is already a highly competititve market. "There are multiple manufacturers across a wide range of price points. Brand creation requires extensive and sustained investments and without a reasonable return, being present in these segments may prove difficult for some".

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

First Malaria Vaccine May be Ready Next Year

The world's first malaria vaccine will be available in the market by next year. Pharma company GSK has submitted a regulatory application to the European Medicines Agency (EMA) for its malaria vaccine candidate, RTS,S.

It will be exclusively for use against the Plasmodium falciparum malaria parasite, which is most prevalent in sub-Saharan Africa (SSA). Around 90% of estimated deaths from malaria occur in SSA, and 77% of these are children under the age of 5.

Data from the phase III vaccine trial programme conducted at 13 African research centres in eight African countries (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, Nigeria, and Tanzania) including over 16,000 infants and young children have also been included to support the filing.

Results from a large-scale Phase III trial showed that over 18 months of follow-up, children aged 5-17 months at first vaccination with RTS,S experienced 46% fewer cases of clinical malaria, compared to children immunized with a control vaccine.

An average of 941 cases of clinical malaria were prevented over 18 months of follow-up for every 1,000 children vaccinated in this age group. Severe malaria cases were reduced by 36%; 21 cases of severe malaria were prevented over 18 months of follow-up for every 1,000 c hildren vaccinated. Malaria hospitalizations were reduced by 42%.

Source: *The Times of India, 31st July 2014*

IPV Offers Better Protection from Polio Virus

Inactivated poliovirus vaccine does not induce an intestinal mucosal immune response, but boosts protection in those primed with OPV

Within days of the government announcing inclusion of injectable inactivated poliovirus vaccine (IPV) in the immunisation programme, a study done in India has shown that a dose of injectable inactivated poliovirus vaccine (IPV) given to children aged between 1-4 years who had been vaccinated with oral poliovirus vaccine (OPV) boosts intestinal immunity to poliovrius offering substantially greater benefit compared to an additional dose of OPV.

Stool samples

This conclusion was drawn by researchers on 450 children of two groups with 225 children receiving IPV and 225 no vaccine.

Both the groups had stool samples available for primary analysis seven days after bivalent OPV challenge. In the IPV group, 27 (12 per cent) children shed serotype 1 poliovirus and 17 (eight per cent) shed serotype three poliovirus compared with 43 (19 per cent) and 57 (26 per cent) in the no vaccine group, suggesting those given IPV did not allow poliovirus to multiply in the gut, hence was better immunised as compared to those who did not receive this.

The finding backs the use of IPV vaccine included in the national immunisation programme on July 3 to accelerate polio eradication by boosting herd immunity in endemic regions, prevent international spread by travellers, and minimise the risk of poliomyelitis outbreaks due to imported wildtype or vaccine-derived polioviruses.

In a paper published in *The Lancet*, the team of authors led by Jacob John and Sidhartha Giri and others conclude that intestinal immunity induced by OPV is imperfect and wanes with time, permitting transmission of infection by immunised children.

Inactivated poliovirus vaccine (IPV) does not induce an intestinal mucosal immune response, but could boost protection in children who are mucosally (oral or gut) primed through previous exposure to OPV.

The authors did a randomised controlled trial that was not blinded in 450 children between August and September last year in Chinnallapuram, Vellore.

These children were healthy, had not received IPV before, and had had their last dose of OPV at least six months before enrolment.

The substantial boost in intestinal immunity conferred by a supplementary dose of IPV given to children younger than five years who had previously received OPV shows a potential role for this vaccine in immunisation activities to accelerate eradication and prevent outbreaks of poliomyelitis, the authors point out.

OPV has been the vaccine of choice for the Global Polio Eradication Initiative (GPEI) because of its ease of administration in mass campaigns, low cost, and ability to induce strong intestinal mucosal immunity against poliovirus shedding and transmission.

Although children and adults vaccinated with oral polio vaccine are protected against poliomyelitis if they mount a neutralising antibody response to all three serotypes they might still be susceptible to infection and transmit wild poliovirus.

The injected inactivated poliovirus vaccine has excellent immunogenicity that does not vary between populations.

However, “it does not induce an effective mucosal immune response poliovirus-specific IgA is undetectable in serum or saliva in most children

after administration of IPV and offers restricted protection against poliovirus shedding in the intestine after challenge with OPV," the paper states.

As a result, IPV's ability to prevent transmission in areas where faecal-oral transmission is efficient stands compromised.

"I believe pulse polio campaigns were critical to the polio eradication strategy, in that short period of time mucosal immunity was raised across the nation - this possibly helped decrease transmission of poliovirus in the environment by creating an immune barrier for long enough to decrease environmental transmission," Jacob John, Department of Community Health, Christian Medical College, Vellore, told this Correspondent.

"However, mass campaigns for immunisation in general are an admission that we are not reaching people through routine public health services and, therefore, is not the first choice for getting things done. Having said that, campaigns with IPV would be targeted in communities that have poor immune response to oral vaccines and as a VDPV (vaccine derived poliovirus) or circulating VDPV response measure. Injectable IPV should ideally be used in the UIP [universal immunisation programme] and slowly replace OPV."

The inclusion of IPV in the immunisation programme was more of a "risk mitigation effort" as part of the polio end game.

"Giving vaccines via a mucosal route would be preferable as it is less likely to cause discomfort and because it mimics natural route of infection.

However, not all vaccines can be delivered this way and even those that can be delivered thus appear to perform poorly in settings that require the vaccines most," Dr. John said while citing the example of Indian children who require up to 15 doses of OPV to be protected against poliovirus whereas only two or three doses are needed in high income countries.

Human gut complex

On why IPV is unable to cut transmission in areas where faecal-oral transmission is high, he said: "We are trying to understand why this is the case but the human gut is a fascinatingly complex environment and it is likely to be a while till we decipher it sufficiently to optimise oral vaccines."

IPV could be used as a complement to OPV in several ways: to prevent international spread by boosting intestinal immunity among travellers, to accelerate eradication in infected areas with poor OPV immunogenicity through use in campaigns, and to maximise herd immunity in advance of the planned global withdrawal of serotype 2 OPV in 2016.

Source: *The Hindu, 31st July 2014*

Clinical Trial Approval Process May Go Online

The Drug Controller General of India's office is planning to shift the process of approving clinical trial applications online. Every trial would be accorded a unique identity number and pharmaceutical companies, ethics committees, doctors or investigators conducting trials would be asked to regularly update information in the online database, including patients' personal details, serious adverse effects that they may suffer and compensation paid out to them by companies, according to a draft proposal firmed up by the drug regulator earlier this week.

This is in addition to other details which the regulator may seek before considering an application. The information around investigational product such as the medical condition it seeks to

Address, the profile of that disease in India, would have to be uploaded. So also the specifics of the investigator or doctor conducting the trial such as his team, site and whether parts of clinical trials are being conducted in other parts of the world.

The proposed comprehensive database would also contain information about the targeted patient population, whether any high risk or vulnerable patients' groups such as infants, children, women of childbearing potential, lactating women are participating in the trial.

Also, detailed disclosures may be sought not only on the composition of the ethics committee and how frequently they meet but also the proceedings of their meeting may have to be uploaded once the trial begins, according to the draft. This move comes after the Union health minister Harsh Vardhan, during a recent briefing, asked officials from the regulator's office to ensure complete transparency in their functioning.

Industry representatives ET spoke to however expressed misgivings about revealing patient's identity citing confidentiality norms. "I see a major concern regarding patient confidentiality. The security level of this database has not been specified, and it's unclear how the regulator will keep patient identifiers secure," said Shoibal Mukherjee, former vice president at Quintiles, a US-headquartered contract research organization.

He said patients and relatives of patients suffering from diseases such as AIDS, tuberculosis, venereal disease, skin disease or psychiatric illness, would hate to see their names and addresses on a database that is accessible to a wide variety of people.

Officials at the drug regulator's office maintain that consultations with stakeholders are on and all legitimate concerns around patients' confidentiality would be taken care of.

Mukherjee also said that unless the submission and approval system is made completely paperless like the one run by the Income Tax Department for income tax payment and returns submission, the process will result in massive duplication of effort.

"It is work in progress and the idea is to eventually graduate to a paperless system," the official at the drug regulator's office said. The Supreme Court is currently hearing a public interest litigation on whether existing rules and regulation of the country adequately protect clinical trials subjects, particularly those participating in trials of new chemical entities.

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

Sun-Ranbaxy Combine to Hold Over 40% Market Share in 25 Drugs

Sun Pharma will have a market share of over 40% in 25 drugs once it takes control of Ranbaxy, according to an ET analysis, that may be reason for a close look at the deal by the competition watchdog that has begun to examine the biggest deal in the Indian pharma industry.

For nine drugs its market share will be more than 65% and in another 15 it will be 40-60%, revealed an analysis of the latest data from market research firm AIOCD Awacs.

Sun-Ranbaxy combined market share to be 9.5%

In addition, there are 11 drugs in which the Sun-Ranbaxy combine will enjoy a 33-40% market share. In all, the two companies have 128 common formulations.

The Competition Commission of India, the country's anti-trust regulator, recently issued show-cause notices to both companies asking them to explain how the takeover won't result in the

domination of India's Rs 76,000-crore drug market by the merged entity.The combined share of the two companies in the total drug market is 9.5%, which in itself is not a significant or threatening figure.

But it's the substantial market share in several popular medicines that's likely to be scrutinised by the regulator. A Sun Pharma spokesperson refused comment on ET's emailed queries.Legal experts said CCI can insist that some brands or facilities be divested before the merger goes through if it establishes that the combined entity can dictate prices because of its dominant position in these categories.
It could also insist on undertakings that the merged entity will not raise prices and maintain production at a specified level. Sun-Ranbaxy combine will have a share of more than 57% in the Rs 430-crore market for common anti-inflammation drug diclofenac; a 78% market share in somastostatin, which is used to treat gastrointestinal hemorrhage and which has annual sales of Rs 50 crore; 76% of the Rs 80-crore market in prostate cancer drug leuprorelin; and 55% of the Rs 48-crore market in quetiapine, a drug used to manage dementia in the elderly.

The proposed entity will also have a 92% market share in the combination of rosuvastatin and ezetimibe, used to treat high cholesterol. Even though this drug has annual sales of just Rs 4 crore, CCI may still comb through the category to study the impact on the entire family of rosuvastatin and its combinations with fenofibrate, which stands at Rs 524 crore, as the entity will account for a little less than a third of the market.

The ET analysis showed that for at least eight-nine drugs, where Sun-Ranbaxy could control a disproportionate share of more than half the market, the total market size is very small, and the regulator may not pay much notice. On the other hand, there are some categories where the duo's combined market share may be less, but the size of the market is big.

For instance, it will control 23-27% of the Rs 800-crore market for cholesterol-lowering drug atorvastatin and some of its combinations. The fragmented nature of the market and availability of molecules that can be substitutes will be a positive factor in CCI's assessment of this deal, said Gautam Shahi, senior associate at J Sagar Associates, a law firm.

“If significant market power or dominant position is finally established in a few categories, CCI can resort to two possible approaches: structural remedies, such as asking the players to divest brands or facilities making concerned products or behavioural remedies like imposing an output and product line maintenance condition," he said.

A senior executive at a rival drug firm said it would be interesting to see the position the competition watchdog adopts for drugs that are under price control. "The companies could argue that once price caps have been set by the government, they have no room to abuse their leadership position in pricing," he said.

Source: *The Economic Times, 5th August 2014*

Aspirin Cuts Digestive Tract Cancer Risk

Popping an aspirin can significantly reduce the risk of developing and dying from the major cancers of the digestive tract- bowel, stomach and oesophageal cancer.

Scientists from Queen Mary University of London came to this conclusion which was published on Wednesday after reviewing evidence from many studies and clinical trials assessing both the benefits and harms of preventive use of aspirin.

The study which was funded by Cancer Research UK among others found taking aspirin for 10 years could cut bowel cancer cases by around 35% and deaths y 40%. Rates of oesophageal and stomach cancers were cut by 30% and deaths from these cancers by 35-50%.

But researchers led by head of QMUL's Centre for Cancer Prevention Jack Cuzick also warns taking aspirin long term increases the risk of digestive tract bleeding. The study confirmed if every one aged between 50-65 started taking aspirin daily for at least 10 years there would be a 9% reduction in the number of cancers, strokes and heart attacks overall in men and around 7% in women.

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

Kerala Doctor Imprisoned For A Day for Giving Drug Sans Licence

For the first time in Kerala, a doctor was found guilty of running a pharmacy without having a licence from the state drugs control department.

Kollam additional sessions judge on Thursday issued a sentence of one-day imprisonment and slapped a fine of Rs 1.20 lakh on Dr P Kamalasanan (67), who runs a single-doctor clinic, Nava Bharat Hospital, in Sasthamkotta in Kollam district. Appearing before the court on Thursday, Kamalasanan served the sentence by remaining there till the rising of the court.

Qualified Private Medical Practitioners Association (QPMPA), which has been fighting the case on behalf of Kamalasanan, said the association would appeal to the high court against the verdict.

The Indian Medical Association's Kerala chapter has stepped up to defend the doctor. Dr A Jayakrishnan, state secretary, IMA, said the state drugs control department is misinterpreting the Act. "A doctor has the right to prescribe and dispense drugs of his choice to his patients but under his supervision," said Jayakrishnan.

The court gave the verdict based on a Kerala high court order that all private hospitals should obtain drug licence for running pharmacies.

Public prosecutor A M Azim said the case was registered in 2010 and the doctor failed to produce purchase bills and drug licence for the drugs stocked and sold at the pharmacy attached to his clinic.

Dr Kishore Kumar, secretary, (QPMPA) said as per the Drugs and Cosmetics Act, 1940 (schedule K, item 5) allows registered medical practitioners to give drugs to his own patients without a drug licence. He added that the clause has been extended to clinics, hospitals owned and maintained by single registered medical practitioners or hospitals owned and maintained by husband and wife as a single entity.

But deputy drugs controller Ravi Menon said as per the Drugs Control Act doctors themselves should prescribe and dispense drugs.

Source: *The Times of India, 8th August 2014*

Sun Plans to Rise in Japan's Pharma Market

Sun Pharmaceutical Industries, which is in the process of acquiring control of Ranbaxy Laboratories from Daiichi Sankyo, will soon put its purchase to work through the exclusive marketing opportunity offered by two drugs in the US, rationalising research and other costs and eventually using its association with the seller to crack the Japanese market.

Sun Pharma's Japan entry will take place three to four years after it closes its deal to acquire Ranbaxy and once basic issues at the company have been fixed, said people familiar with the plans. The $4-billion deal, announced in April, is currently awaiting various regulatory clearances. Spokespersons at Sun Pharma and Ranbaxy declined to comment.

JAPAN MARKET: TEMPTING BUT TRICKY

Japan, the world's largest drug market after the US and Europe, has proved tough for Indian players to succeed. The penetration of generic drugs is less than 25 per cent compared with more 80 per cent in the US drug market. But the Japanese government's intent to raise this share to 60 per cent by 2017 has prompted analysts to dub it as the next big frontier for Indian drugmakers.

"In Japan, Indian players cannot simply succeed by replicating the strategies that have paid off in the US of launching at the lowest price, garnering high market share and playing a volumes game," said Amit Chander, partner at Baring Private Equity. "That is because Japan is an acutely brand-conscious market, where the dominant perception is that high quality and low prices do not go together," said Chander, who heads the pharma and healthcare vertical at the private equity fund.

In this context, Sun Pharma's strategy of partnering Daiichi, a top local drugmaker, seems to be a prudent strategy, he added.

Thus far, Indian drugmakers have adopted two models to enter Japan. While most have begun by manufacturing raw materials for a Japanese partner in the hope of entering into formulations later, some, like Lupin, have taken over local companies.

"For a company of Sun's size and scale, selling just raw materials in Japan wouldn't move the needle. The Daiichi platform has the potential to offer a sure-footed entry in this tricky market," Chander said.

RANBAXY TURNAROUND PLAN

Within a year of deal closure, Sun Pharma hopes to have brought to the US market two of Ranbaxy's pending exclusive marketing opportunities generic versions of Nexium and Valcyte. The latter earns its parents Astra Zeneca and Rochemore than $5 billion in annual US sales.

"Also within a year of closing the deal, Sun could assess R&D project overlaps between the two companies and cut costs by scrapping duplications, keeping only best projects alive," said one of the people cited earlier. This is in addition to reining in corporate expenses and general administration expenses in overlapping markets.

"Ranbaxy's R&D expense has been to the tune of 9 per cent of sales in the past, a low-hanging fruit for Sun Pharma to cut costs. If you look at the areas where R&D spend of India's top five drugmakers go, you will not find significant difference, barring a few therapy preferences here and there," said Chander. "Beyond access to the ANDAs (abbreviated new drug applications) filings of Ranbaxy, there would not be much to gain from the capabilities, different from what it already has in-house."

Between the first and third year of acquisition, Sun Pharma plans to focus on realigning Ranbaxy's sales division and reap benefits flowing from integrating procurement and supply chains.

During this period, it also aims to boost efficiencies in key markets, such as India and the US, to deliver $250 million of operational synergies it has promised by the third year.

Sun Pharma believes that about 60 per cent of synergies would accrue in the third year and aims to improve Ranbaxy's EBITDA margins to 15-16 per cent by then, up from the single-digit figure at present, another person aware of Sun's plans said.

Between the third and fifth year, Sun plans to use Ranbaxy's infrastructure in emerging markets in many of which it is not present to launch its own products. By the end of this period, Sun hopes to have sorted out Ranbaxy's prolonged regulatory troubles with the USFDA, the person aware of the company's plan said.

By 2017-18, Sun aims to have improved Ranbaxy's EBITDA margins to 20-21% at par with industry standards.

Source: *The Economic Times, 11th August 2014*

SC Seeks Records of Cancer Vaccine's Clinical Trials

Taking serious note of alleged death of seven tribal girls in Andhra Pradesh, Telangana and Gujarat during clinical trials of a cervical cancer vaccine, the Supreme Court on Tuesday asked the central drug control authority and Indian Council for Medical Research to tell how permission for human trial of the drug was given.

A bench of Justices Dipak Misra and V Gopala Gowda summoned the files relating to grant of permission for conducting clinical trial of a cervical cancer prevention vaccine in 2012.

The bench also asked the Centre to produce all files relating to grant of licence for trial of the vaccine to prevent human papyloma virus (HPV) which causes cervical cancer. The drug is produced by pharma majors Glaxo Smithkline and Merck. The court asked relevant files to be produced on October 28.

Dealing with a set of two PILs on clinical trials, the court wondered how a drug was licensed to be sold in India by the Drug Controller General of India (DCGI) and ICMR, even though it had allegedly caused death and severe ailments to tribal girls.

It said, "We are concerned whether before drug was accepted to be used in India and whether DCGI and ICMR had followed procedure for its introduction." Counsel for petitioner, senior advocate Colin Gonsalves and Anand Grover, referred to an August 30, 2013 report by the parliamentary standing committee that painted a dismal picture of drug trials in India.

The bench asked the Centre to detail an action taken report on the recommendations by the parliamentary standing committee.

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

Random Decisions in Pharma Pricing Bad For India's Health

The National Pharmaceutical Pricing Authority(NPPA) arbitrarily fixed prices for all anti-diabetic and cardiovascular drugs outside the scope of the Drug Price Control Order (DPCO) 2013, with no warning to manufacturers.

This action transgressed the mandate of DPCO 2013, which addressed pharmaceutical pricing based on the 'essentiality' criteria and clearly stated that the "intention of the policy is to bring essential medicines under price control and not to control the Indian pharmaceutical industry" a position that has been enunciated by the Department of Pharmaceuticals in an affidavit before the Supreme Court. The drug pricing regulator invoked paragraph 19 of the DPCO 2013 which authorises it "in case of extraordinary circumstances" to fix the ceiling price or retail price of any drug in public interest "for such period" as it deems fit. Clearly, para 19 is a special power to be used only when an extraordinary circumstance arises and for a temporary period of time.

Notably, the decision goes against the National Pharmaceutical Pricing Policy (NPPP) 2012, which was deliberated by a group of ministers and approved by the nation's highest policymaking body, the Cabinet. NPPP 2012 clearly rules that all essential drugs are under price control while those outside the National List of Essential Medicines (NLEM) 2011 should not be under a controlled regime and their prices should be fixed by market forces.

Less than a year after the new DPCO, and its stiff price cuts on 348 medicines, the drug control regulator's move brings many more drugs, outside the NLEM, under price control, making NLEM redundant and potentially exposing every drug to price control.

Today, India is the most competitive pharmaceutical market in the world, with a flourishing generics industry and multiple alternatives for each drug, available at different price points. The regulator's arbitrary and unexpected move threatens the structure and long-term health of this industry. It harms the investment climate, hampers employment generation and mars India's image as a business-friendly country.

The pharmaceutical industry is an integral part of the healthcare system and its growth and sustainability is critical to a robust healthcare environment. The government needs to help build a more collaborative environment, partnering and engaging with all stakeholders to find sustainable solutions to India's healthcare challenges.

There is no question the industry needs to make quality medicines available to the most vulnerable populations. But instead of arbitrary pricing decisions, it would like the focus to be on enhancing the patients' ability to pay and actions to actualise the new health minister's commitment that health insurance for all would be a top priority of the Modi government.

The industry is committed to a consultative process and expects the government to take into consideration the views of all stakeholders. It seeks stability and predictability in the regulatory environment and its expectation has been reinforced by assurances from departments and officials in the ministry of chemicals and fertiliers. The industry was assured there would be no volatility in pricing, that government would work in close consultation with industry and that the intent was to build trust and cooperation. The NPPA's arbitrary and unilateral action runs contrary to all these sentiment and has shocked the industry.

Importantly, the assumption that patients will have increased access to medicines as a result of this price reduction is unfounded. On the contrary, this action could have a negative impact on the market, compromising quality and perhaps availability. Surely the subsidy of medicines for the poor must be primarily the responsibility of the government? Industry would be very willing to engage in dialogue to emerge with collaborative and sustainable solutions and step forward to play its part.

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

It's Ethical to Use Untested Drugs to Fight Virus : WHO

The World Health Organisation said that it is ethical to use untested Ebola drugs to help contain the current outbreak.

The Geneva based international health agency, however, said that countries which use experimental treatments have a moral obligation to collect data on those treated so the world can learn what works against Ebola. The statement comes following a meeting on Monday of an expert panel which had asked to assess the ethics of using untested medical interventions.

WHO said, " In the circumstances of this outbreak and provided certain conditions are met, the panel reached a consensus that it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention."

WHO said the ethical criteria will include transparency about all care aspects, freedom of choice, confidentiality, respect for the person, preservation of dignity and community involvement.

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

Gold Particles Can Help Fight Cancer

A novel treatment for an aggressive form of brain cancer, which involves using tiny nanoparticles of gold to kill tumour cells, has been successfully tested by scientists in the UK.

The groundbreaking technique could eventually be used to treat glioblastoma multiforme the commonest and most aggressive brain tumour in adults that is also notoriously difficult to treat, University of Cambridge researchers said. Most patients die within a few months of diagnosis and just six in every 100 patients with the condition are alive after five years.

The research involved engineering nanostructures containing both gold and cisplatin, a conventional chemotherapy drug. These were released into tumour cells that had been taken from glioblastoma patients and grown in the lab. Once inside, these 'nanospheres' were exposed to radiotherapy. This caused the gold to release electrons that damaged the cancer cell's DNA and its overall structure, thereby enhancing the impact of the chemotherapy drug.

The process was so effective that 20 days later, the cell culture showed no evidence of any revival, suggesting that the tumour cells had been destroyed.

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

Higher BMI Increases Risk of Developing Common Cancers

A first of its kind study by a team of doctors, including one of Indian-origin, has revealed that a higher body mass index (BMI) increases the risk of developing 10 of the most common cancers. This is the largest study of its kind on BMI and cancer, involving more than five million adults in the UK.

UK researchers at the London School of Hygiene &Tropical Medicine and the Farr Institute of Health Informatics estimate that over 12,000 cases of these 10 cancers each year are attributable to being overweight or obese and calculate that if average BMI in the population continues to increase, there could be over 3,500 extra cancers every year as a result.

A total of 1,66,955 people developed one of the 22 cancers studied over the follow-up period. BMI was associated with 17 out of the 22 specific types of cancer examined.

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

FMCG Cos Seek Speedy Approvals at Lunch With Food Regulator

Concerned at the alleged slow pace of new product approval by food safety regulator Food Safety and Standards Authority of India (FSSAI) a high profile group of CEOs of leading food companies, including GlaxoSmithkline Consumer Healthcare MD Zubair Ahmed, Coca-Cola President Venkatesh Kini, Kellogg MD Sangeeta Pendurkar, Cargill India MD Siraj Chaudhry, Mother Dairy MD S Nagarajan, Ferrero Group India head Luigi Oddone and McCain Foods MD Vikas Mittal, together met FSSAI chairman K Chandramouli, along with the other top brass of the food regulator last week, in what was strictly under-wraps.

The unprecedented meet, which got together India's heads of leading foods firms, indicates the importance of product approval at a time when foods firms are barely returning to higher growth after two years of slump.

Given the sensitivity of the matter; none of the company heads who met were willing to be quoted on record.

Confirming to ET that the CEOs had met him last week, Chandramouli said, We are implementing the food safety standards on a huge scale for the first time in the country. It is a big challenge, but ultimately, it is for the benefit of the consumer.

Many of the country heads were meeting Chandramouli for the first time, because the usual practices is time, because the usual practices is that it is the corporate affairs representatives of firms who meet FSSAI officials to iron out issues.
Chandramouli added:"It was an exchange of ideas and information everyone of them had suggestions and points of view. I had not met many of the CEOs earlier,so they came to meet me. Product approval was one of the issue discussed."

One of the officials directly aware of the developments said "While various aspects were discussed, emphasis was on speed to market for innovations.

The India heads also wanted to assure FSSAI that they are aligned with the food regulator in addressing food safety and quality".
Another official also privy to developments said," There's an urgent need for quick approvals at a time when product innovation gives a huge competitive

edge. A lot of investment goes in research and development which companies want to fast track, but are stuck at the regulator because clearances are taking too long". The equation between food and drug firms and FSSAI hasn't always been smooth, with frequent skirmishes involving new product approval, imports and new labeling norms.

In April this year, FSSAI had blocked a consignment of syrups meant for coffee chain Tata Star bucks which led the coffee chain to approach the Bombay High Court for relief.
Last year on the eve of Diwali consignments of leading gourmet chocolate importers such as Mars, Godiva, Guylian and Lindt were stopped by the food safety regulator; FSSAI had said that the imported products did not contain India-specific labeling norms and that the importers had merely pasted local stickers on products that were supposed to sell in overseas markets.

Earlier this year, the Indian Drug Manufacturers Association (IDMA) and a Maharashtra based firm Vital Nutraceuticals had filed a petition against FSSAI in the to take approval for a broad spectrum of food products including "novel foods, functional foods, food supplements and special dietary foods already licensed or existing.

The Bombay High Court called the advisory unlawful and gave a verdict in favour of the drug firm, which FSSAI has challenged in the Supreme court.

Chandramouli added that product approval is under litigation and that the regulator was awaiting the Supreme Court judgement on the matter.
A couple of months back, importers of Canola oil were told by the FSSAI not to import the edible oil under the brand name, stating that every container of Canola oil must be labeled "imported rapeseed low erucic acid oil".

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

Sun Pharma Unit Recalls Multiple Lots of Capsules From U S

Caraco Pharmaceutical Laboratories Ltd, a unit of Sun Pharmaceutical Industries Ltd, has initiated a recall of multiple lots of Cephalexin capsules from the US market.

According to a notification by the US Food Drug and Administration (FDA), the recall of the 3,40,553 units of 500 mg and 1,13,677 units of 250 mg bottles is voluntarily initiated by the company through a letter to the regulator in June under 'Class-II' classification.

Cephalexin is an antibiotic that belongs to the family of medications known as cephalosporins. It is used to treat certain types of bacterial infections. "CGMP Deviations: These products are being recalled because they were manufactured with active pharmaceutical ingredients (APIs) that were not manufactured with good manufacturing practices," FDA's website said citing the reason for recall.
When contacted, a Sun Pharma spokesperson offered no comments.

The recalled drug bottles were distributed by Caraco Pharmaceutical in the US while manufactured in India by Sun Pharma. According to American health regulator FDA, Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where

The probability of serious adverse health consequences is remote.

Recently Caraco Pharmaceutical had said that it initiated a recall of some lots of Venlafaxine Hydrochloride extended-release tablets from the US market for not meeting the drug release dissolution specifications under Class-II classification.

Meanwhile, in another notification, FDA said Wockhardt USA has initiated a recall of 840 bottles of Bupropion hydrochloride extended-release tablets USP (SR), 100 mg, (500-count bottle) from USA market.

Source: *The Hindu, 16th August 2014*

Pharma Stocks Buck Trend, Hit New Highs

Shares of pharmaceutical companies continued their good run on Wednesday in an otherwise weak market as investors and traders placed their faith in such stocks, expecting the rally to go on for a while on steady earnings growth. On Wednesday, 19 pharma stocks such as Sun Pharma, Cipla, Lupin and Aurobindo Pharma hit life-time highs while 30 stocks touched 52-week highs.

Market participants have turned bullish on leading pharma companies in recent times as they continued to gain share in existing products, new product launches, and drug exclusivity in US markets. Analysts expect the growth story to turn more broad-based with the domestic pharma market recovering.

The BSE Healthcare Index has been on a roll for the past eight trading sessions; the index has outperformed the market by gaining 8.7 per cent, against Sensex's gain of 2.8 per cent. Consistent performance and preference of investors for stocks in the defensive space helped the sector outshine the broader markets. BSE Healthcare has surged 373 points, or 2.9 per cent, at 13,139 points to close at a life-time high on Wednesday, against Sensex's fall of 106 points, or 0.4 per cent, at 26,314 points. Within the mid-cap space, companies such as Jenburkt Pharma, Shasun Pharma, Amrutanjan Healthcare, Indoco Remedies, Orchid Chem and others have rallied up to 20 per cent.

“We are very positive on Indian pharma companies such as Sun Pharma, Dr Reddy's and Lupin, and within the MNC space, Abbott Labs and Merck, on impressive earnings performance," said Mehraboon Irani, principal and head-private client group business at Nirmal Bang Securities. "However, I would like to advise investors to be careful about pharma names as there's froth in some stocks." Analysts believe Indian pharma firms will continue to experience strong growth in the US over the medium-term. This will be driven by sizeable generic opportunity over the next three years and a strong product pipeline of pending new drug applications.

"Big US drug wholesalers have reported generic price inflation. In our opinion, the key beneficiaries of the price increases would be Lupin, Dr Reddy's, and Sun-Ranbaxy," said Abhishek Sharma, analyst at IIFL Institutional Equities. "We believe that some of the positive impact would continue over the next few years." Sun Pharma's recent announcement to acquire Ranbaxy for $4 billion has been a sentiment booster for market participants, and analysts expect this trend to continue as companies would scout for technological capabilities in select therapy areas and look for market entry-led acquisitions.

Source: *The Economic Times, 21st August 2014*

Chikungunya Vaccine Shows Promise

An experimental chikungunya vaccine has shown promising results in a small-scale trial carried out in humans.

Developed by scientists at the National Institute of Allergy and Infectious Diseases in the U.S., the vaccine is made by using human cells grown in culture to produce three proteins found on the surface of the chikungunya virus. These proteins then self-assemble to form 'virus-like particles,' which are not infectious but can elicit a protective immune response when given as an injection.

In the trial, the vaccine was administered as three injections at different doses to 25 healthy volunteers. It produced protective antibodies in those individuals and was found to be safe and well tolerated, the scientists reported in a paper published online last week by *The Lancet*.

Moreover, the vaccine appeared to generate durable immunity. Eleven months after vaccination, the antibody levels in the volunteers "were comparable to those reported after natural chikungunya virus infection, which have been inferred to be protective," the paper noted.

Previously, in tests carried out on monkeys, the vaccine proved capable of protecting the animals from high doses of the infectious virus.

Larger studies of the vaccine in diverse populations, including those at risk of chikungunya virus infection, were needed to confirm the initial human data, the scientists observed in their paper.

"Development of vaccines for orphan agents is challenging because the market might not be large enough to justify the investment," remarked Ann Powers of the Centers for Disease Control and Prevention in the U.S. in a commentary published in the same journal.

Work on an earlier chikungunya vaccine developed in America was discontinued after early clinical trials because of an absence of funding and questions over the eventual marketing of the vaccine.

Meanwhile in India, vaccine manufacturer Bharat Biotech is preparing to secure regulatory approval for the clinical trial of its chikungunya vaccine. The vaccine was developed entirely in-house and utilised the inactivated form of the chikungunya virus, Krishna M. Ella, the company's chairman and managing director, told this correspondent.

The virus strain used for the vaccine had been isolated in 2005 during an outbreak in this country. Another Indian vaccine maker, Indian Immunologicals Ltd., is also working on a chikungunya vaccine.

Based on technology from the U.S. Army Medical Research Institute of Infectious Diseases, this vaccine too will use the inactivated virus. The company hoped to begin pre-clinical toxicity studies of the vaccine in animals next year, according to a senior executive.

Source: *The Hindu, 21st August 2014*

A Feel Good Order for Consumers, but A Pain for the Pharma Industry

The latest government order to control prices of certain drugs in the cardiovascular and anti-diabetic segments may only cause some near-term growth wobbles in the affected therapies but the larger fear that it has ignited within the pharma industry is that of similar such interventions in future in non-essential drugs.

We believe multinational companies such as Sanofi, AstraZeneca and Merck will be the worst affected because of their higher exposure to the drugs covered under the new notification and the premium pricing they enjoy. As a result, the revenue loss for these companies could be in the range of 8-10 per cent of their domestic pharmaceutical market in 2014-15.

On the other hand, revenue losses for domestic pharmaceutical companies such as Lupin, Zydus Cadila, Ranbaxy, and Emcure could be lower at 2-5 per cent of their domestic market sales during the year. However, the impact of the price reduction on their overall revenues is likely to be limited as a large proportion of their revenues come from exports.

Traditionally, the Drug Price Control Order (DPCO) has sought to impose price controls on essential medicines that are listed in the National List of Essential Medicines (NLEM). A total of 348 of these NLEM drugs were brought under DPCO beginning May last year. Thus, drugs used to treat diseases such as bacterial infection, viral infection, pain, and allergies were mainly targeted for price controls. These fall under the category of acute disease therapies; acute diseases have rapid onset of symptoms but are cured within a short time duration; for example, common cold.

However, what caught the industry completely off-guard was the July 2014 DPCO order. For the first time, the government brought drugs for chronic diseases under price control. Thus drugs used for treating high blood pressure and diabetes were targeted for price control.

The new order brings under DPCO's purview 108 anti-diabetic and cardiovascular drugs worth Rs.5,800 crore, which is nearly 44 per cent of the total market for these drugs. These two drug segments, used for treating lifestyle related diseases, are the fastest growing segments of the pharma industry and account for close to 20 per cent of India's pharmaceutical market of Rs.66,100 crore.

The World Health Organisation estimates that the per capita expenditure on healthcare in India was close to $61 in 2012. This represents a 13 per cent (in rupee terms) average annual increase over the 10-year period to 2012. Although overall healthcare spends are increasing, the overall penetration of healthcare services continues to remain low compared to other developing countries in the world.

The new order is expected to lead to an average price decline of close to 12 per cent for the 108 formulations during the year. This is expected to help improve affordability of these chronic care medicines. Going forward, improved affordability is expected to help increase healthcare penetration in these two drug categories.

From the consumer's point of view, of course, this is all for the good. The new DPCO could result in decline in a patient's medication bill across highly popular drugs in the chronic care category. For example, there will be savings of 8-10 per cent for a patient suffering from blood pressure and advised a popular combination therapy of Telmisartan with Amlodipine.

Given the high correlation between the expenditure on healthcare and growth in overall domestic drug consumption, this will be a key factor in driving

overall drug consumption volumes in the country in the years ahead. However, near-term challenges remain for the pharmaceutical companies most exposed to the current price control order.

Based on the expected implementation timelines of the new order and the existing stocks that are available with the distribution channels and companies, we expect the impact of the current price control to be felt in another 2-3 months' time.

Consequently, as per our estimates, revenue growth in the two chronic segments will be lower by 3-5 percentage points from our earlier forecast of close to 12-14 per cent for 2014-15. However, the impact on overall industry growth will be less than 1 per cent for 2014-15, with the industry sales projected to be close to Rs.73,000 crore for 2014-15.

Though this will be an inflection point for these therapies in the short term, the domestic pharmaceutical industry is expected to reap benefits of higher volumes growth in the chronic care category. Companies, especially large domestic players, could look to push for higher volume growth as many of their drugs enjoy good brand recognition. Overall, pharmaceutical sales in the country is expected to cross Rs.1-lakh crore by 2018-19.

Source: *The Hindu, 25th August 2014*

Gates Wide Open in Maradona Land for Indian Pharma Companies

Argentina has fully opened its $6-billion drug market to Indian companies, increasing the scope of exports to finished pharmaceuticals formulations from just raw materials earlier.India was not allowed to do so earlier due to local laws.

PV Appaji, director general of Indian Pharmaceuticals Export Promotion Council, said that with effect from August 8, the Latin American nation has included India on the list of countries that can supply medicines to it.

Argentina's pharmaceuticals market is expected to touch $15 billion by 2020. Eight key markets of the Latin American region are now valued at over $30 billion, reporting a compound annual growth rate (CAGR) of over 10%.

Of the nearly $15 billion worth of drugs that India ships overseas every year, nearly 8 per cent is to Latin American countries. In 2012-13, India sold $44.85 million worth of bulk drugs to Argentina.

"Our companies can supply generic drugs at nearly half the price of Argentina's locally made drugs, enabling the Latin American country procure quality drugs at affordable costs," PV Appaji said, adding the move will help Indian drug companies access one of the largest pharmaceutical markets in the Latin American region." The development will especially boost exports of Indian companies that have globally approved manufacturing facilities.

However, Aurobindo Pharma's formulations business chief executive Arvind Vasudeva said, "We need to wait for the kind of regulations Argentina will come out with and the time it would consume for product registrations. At present, it takes 24-30 months in Mexico and 4-7 years in Brazil for product registrations and approvals." Aurobindo Pharma, which exports medicines to Brazil, Mexico and Columbia in the Latin American region, considers Argentina as an important market.

Alok Dalal, pharma analyst with Motilal Oswal, said that Indian firms may have to wait for at least two-three years after investing on product registrations and approvals to generate returns.

According to him, companies that are currently operating in Brazil would be better placed to explore Argentina.

These include Torrent Pharma, Glenmark Pharma and Cadila Healthcare among others.

Source: *The Economic times, 25th August 2014*

ICMR Model Research Unit Coming Up in Tirunelveli

A model rural health research unit is being established in the Kallur primary health centre attached to the Tirunelveli Medical College.

T.S. Jawahar, Senior Deputy Director-General, Indian Council of Medical Research (ICMR), who will lay the foundation for the centre in the coming week, said the Union government had chosen rural areas to build the capacity of peripheral medical colleges. Kallur was one of the five locations in the country where such units were being established by the Union Health Ministry on an outlay of Rs.5 crore over five years.

"Until recently, research was mostly concentrated in Delhi, Mumbai, Kolkata and Chennai. In rural areas, we have talented doctors who can provide rich information on local diseases, but they do not have an opportunity to take part in research. The project has been sanctioned to the Tirunelveli Medical College because of the backwardness of the region and the high disease burden in the area," Mr. Jawahar said.

He said the ICMR planned to provide the research centres with laboratories for molecular, microbiology, biochemistry and pathological investigations.The faculty from the local medical colleges would develop research proposals with support from ICMR scientists and laboratories like the National Institute of Epidemiology. Scientists from the National Insitutute of Epidemiology had already been training the faculty members of the Tirunelveli Medical College in writing out research reports.

Though the Kallur centre will be attached to the Tirunelveli college, ICMR officials say that they expect the Tuticorin and Kanyakumari medical colleges also to use the laboratories.

Source: *The Hindu, 26th August 2014*

Soon, An Opioid Painkiller Without Opium

There is good news for terminally ill patients of cancer and HIV suffering from acute and chronic pain.

Morphine the world's cheapest and most effective pain killer whose free availability is barred by many countries, including India, because it is made from opium, may soon be available for every one.
Stanford University bioengineers are close to brewing opioid painkillers without using opium from poppies.

A decade- long effort in generic engineering is now close to reprogramming yeast cells to make palliative medicines in stainless steel vats.

For centuries, poppy plants have been grown to provide opium, the compound from which morphine

And other important medicines such as oxycodone are derived.

Now, bio-engineers at Stanford have hacked the DNA of yeast, reprogramming these simple cells to make opioid based medicines via a sophisticated extension of the basic brewing process that is used to make beer.

Led by associate professor of bioengineering Christina Smolke, the Stanford team has already spent a decade genetically engineering yeast cells to reproduce the biochemistry of poppies with the ultimate goal of producing opium-based medicines, from start to finish, in fermentation vats.

Smolke and her collaborators, Kate Thodey, a post-doctoral scholar in bioengineering and Stephanie Galanie, a doctoral student in chemistry, detail how they added five genes from two different organisms to yeast cells. Three of these genes came from the poppy itself and the others from a bacterium that lives on poppy plant stalks. This multi-species gene mash-up was required to turn yeast into cellular factories that replicate two, now separate, processes: how nature produces opium in poppies and then how pharmacologists use chemical processes to further refine opium derivatives into modern opioid drugs such as hydrocodone.

Source: *The Times of India, 26th August 2014*

Pharma Players Gear Up to Cash in on Overseas Opportunities

The Indian pharmaceutical industry can benefit significantly from the huge emerging export opportunity. For long acknowledged as the generic drug manufacturing capital of the world, India with its several low cost generic manufacturers, can exploit the fact that over the next few years, a large number of drugs will be going off-patent.

Ratings agency Crisil said drugs worth $130-150 billion will be going off patent between 2012 and 2017. To capitalise on this, it expects that India's top 20 pharmaceutical companies will crank up capital expenditure by around 40 per cent to over Rs. 50,000 crore by 2017-18.

While the domestic industry was at about Rs. 77,000 crore in 2013, exports ranged around Rs. 90,000 crore, according to S. V. Veeramani, President, Indian Drug Manufacturers' Association (IDMA).

Pharmaceutical patent filings numbered around 2,500 in 2013, growing at around 11 per cent.

"We require robust patent laws in place as there are apprehensions about patent protection in India."

In India, the industry has been facing increasing regulatory restrictions. The last year saw headwinds from price cuts imposed on a wide range of essential drugs post the new drug pricing policy and higher research & development (R&D) costs.

But export-focused companies could benefit from recently announced government guidelines to evaluate applications for intellectual property rights (IPRs) in the industry.

"There has been some slowdown in granting patents and the guidelines to revise patent norms could be a response to the increase in number of patent filings in India," Anuj Sethi, Director, Crisil Ratings, told *The Hindu*.

"The revised guidelines could help lower the number of patent infringements and also ensure consistency and streamlining of the filing process."

Exports are volume driven, and even smaller players are eyeing emerging markets, said Mr. Veeramani.

The U.S. accounts for 29 per cent of India's pharma exports. and ratings agency ICRA expects companies to continue to experience strong growth there over the medium-term driven by the sizeable generic opportunity and the strong product pipeline of pending abbreviated new drug applications (ANDAs).

"In the U.S., the Affordable Care Act will ensure that the U.S. will seek to continue sourcing medicines at affordable rates and Indian generic manufacturers will stand to benefit, as more than 70 per cent of drugs sold in the U.S. are prescribed generics," Mr. Sethi said.

Source: *The Hindu, 30th August 2014*

Glenmark May be the Dark Horse in Domestic Pharma

Glenmark Pharmaceuticals may not have a very promising outlook in the near term but most analysts are bullish on its prospects in the medium-tolong term, making India's eighth largest drugmaker a likely dark horse in the sector.

A muted growth outlook for the current fiscal on account of subdued growth in its business in the United States, increase in research and development, or R&D spend, no prospects of major debt reduction and suspension of research on one of its chemical entities had built up a negative sentiment for the company's stock. However, analysts say it may be too early to dismiss the company's long-term prospects. The company has among the most diversified portfolios of markets outside India, with a particularly strong presence in the domestic and emerging markets.

The delay in new product approvals is likely to adversely impact its immediate business in the US. However, it has a few limited competition launches lined up for 2015-16 and 2016-17.
The drugmaker has a rich pipeline of 75 products awaiting approval. It has exclusive marketing rights for 31 of these, which are covered under the socalled para IV patent certifications in the US.

Add to this, it has a promising pipeline of molecules under innovative research and high expenditure on R&D. At a time when most pharma cos are shutting down their drug discovery units, glemark is investing serious money in R&D.

The company spends nearly 10% of its revenues on R&D, of which 40-45% is spent on innovative research. It has been able to monetise its R&D efforts time and again, lending support to its stock in the past.
It has six molecules under various stages of development. According to Harith Ahamed and Mohan Saraf of Spark Capital, Glenmark has the most diversified geographic mix among Indian pharma companies.

Over the years, the company has build strong franchises in several key emerging markets across Russia/CIS, South America and Africa. Glenmark's fast-growing domestic f ormulations business is its key strength.

With a strong presence in the fast-growing segments such as dermatology and limited exposure to drugs under price control list, Glenmark is expected to outpace domestic market growth. The company's management has guided for 16-

18% growth in the base business revenues in 2014-15.

Analysts expect the base business to grow at a similar CAGR betweenFY14 and FY16. The EBITDA margins are likely to be maintained at about 22% during this period. Glenmark Pharma's stock has been an underperformer over the past one year, gaining 39% while the ET Pharma Index went up 53%.

Analysts expect the stock to outperform over the next couple of years.

Source: *The Economic Times, 3rd September 2014*

Cosmetics Tested on Animals to Face Ban Soon

Almost six months after India first banned testing of cosmetics on animals, the government is now all but set to prohibit even the import of such products.

Speaking to ET, Health Minister Harsh Vardhan said the ban would soon be notified as a new rule under the Drug and Cosmetics Act, 1945, in the Gazette. The impending move, which would apply to shampoos, makeup, fragrances, hair, nail and skin-care products, concedes to the long-standing concerns raised by animal welfare organisations, but could face stiff opposition from cosmetics brands.

"The proposal just needs minister's nod. The file is with him and could be approved any day," said a senior health ministry official. The CEO of a top cosmetics firm said, "The impact will be huge since many firms will need to alter countries from where they import. IBHA is engaged in hectic lobbying with the ministry concerned."

The proposed ban drew a guarded response from the industry. An official at IBHA, the industry body representing 32 firms including Chanel, Unilever, P&G, L'Oreal, Oriflame and Avon, told ET, "We will comment only once the final notification comes. Right now, there's nothing to say."

"P&G does not test its products or ingredients on animals anywhere in the world unless required by law. We will continue to work with outside scientists, governments including India, policy makers and the industry to develop alternatives to animal research, which we believe is the only way to overcome the need for animal testing globally," a P&G spokesperson said.

"We do import some cosmetics into India, but as a global policy, Revlon doesn't do animal testing anywhere in the world," Revlon's sales & marketing director Rajiv Kumar said. As per industry estimates, the Indian cosmetics industry, currently valued at $950 million, is likely to treble to $2.68 billion by 2020, clocking an annual growth rate of 15-20%, twice as fast as that of the US and European markets.

Cosmetics testing is carried out from six months to two years to see if there are any health risks involved. Animals are usually killed after the procedure. All 28 countries under EU have banned import and sale of such products.

Source: *The Economic Times, 4th September 2014*

Govt Likely to Exempt Critical Drugs From Local Clinical Trials

The government has decided to draw up a list of serious and life-threatening diseases, and ailments that are particularly relevant to India, for which a new drug can be considered for exemption from local clinical trials if it has already been approved and marketed safely in developed countries such as the United States, UK, Canada, Japan and Australia.

The decision, officials said, was taken at a recent meeting of the technical committee set up under the health ministry to supervise clinical trials on experimental drugs - new chemical entities or new biological entities.
The ministry had on the basis of recommendations of an expert panel headed by Ranjit Roy Chaudhury earlier decided that such waiver of mandatory trials for new drugs might be considered only in cases of national emergency, extreme urgency, epidemics and so-called orphan drugs for rare diseases and drugs indicated for conditions for which no therapies exist.

Under the current norms, all new drugs which have not been used in India have to undergo trials on a specified minimum number of patients to get a marketing approval from the Drug Controller General of India (DCGI). However, the drug regulator can grant exemption from trial in 'public interest'.

The government has been reviewing the entire issue since May 2012, when a parliamentary panel alleged that over 30 new drugs had been approved without mandatory clinical trials.

Pharmaceuticals industry and drug regulatory experts have stressed the need for clarity in exemption criteria, particularly to address emergency situations. This will provide the health ministry with an enabling provision to introduce a new drug or vaccine in India without the bridging clinical trials, said pharma industry expert Ramesh Adige.

"And this provision can come in handy for meeting a public health emergency. Consider the latest Ebola virus epidemic in Africa which threatens to become a pandemic if appropriate steps are not taken. In such instances there is no time to waste, if the drug or vaccine has gone through clinical trials in the US, Europe or Japan," Adige said.

CM Gulhati, a drug regulatory expert, said, "The government's hands should not be tied in situations of grave emergency, where it needs to bring to the country a drug already approved in a developed country and so needs to waive mandatory trial for the drug. Proper guidelines need to be drawn to demarcate what constitutes these emergencies."

However, he added that the technical committee did not have the mandate to take a call on the issue.

Source: *The Economic Times, 4th September 2014*

Diabetes Triggering India's TB Burden, Says WHO Study

Diabetes has now been found to be fuelling India's tuberculosis burden.

India has the world's highest diabetes patients and is also referred to as the world's TB capital. Now, a study to be announced by the British medical journal Lancet on Thursday, reveal that India tops the list of countries with the highest estimated number of adult TB cases associated with diabetes.

New estimates produced reveal that the top 10 countries with the highest estimated number of adult TB cases associated with diabetes are India (302000), China (156000), South Africa (70 000), Indonesia (48000), Pakistan (43000), Bangladesh (36000), Philippines (29000), Russia (23000), Myanmar (21000) and Congo (19000). "These findings highlight the growing impact of diabetes on TB control in regions of the world where both diseases are prevalent," says author Dr Knut Lonnroth from the Global TB Programme at WHO in Geneva.

"TB control is being undermined by the growing number diabetes patients, which is expected to reach an astounding 592 million worldwide by 2035". The study indicates that 15% of adult TB cases worldwide are already attributable to diabetes. These diabetes-associated cases correspond to over 1 million cases a year, with more than 40% occurring in India and China alone. If diabetes continue to rise out of control, the downward trajectory in global TB cases could be offset by 8% or more by 2035, warn the authors.

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

Halal Cosmetics Brand Sets Up Shop in Gujarat

Ecotrail Personal Care, a company headed by two Ahmedabad-based Jain sisters, launched in the city on Wednesday Iba Halal Care-- India's first halal cosmetics brand.

Announcing the launch of Iba Halal Care, Mauli Teli, CEO of the company, said, "We are creating an entirely new category of cosmetic products halal cosmetic products. Halal (meaning lawful) cosmetic products are entirely hygienic, ethically manufactured products and meant for use by everyone."

Iba Halal Cosmetics range of around 60 products includes face creams, body lotions, hair oil, shampoo, conditioners, lipsticks, kajal, soap and perfumes. "These cosmetics products are free of alcohol and are popular in countries like Saudi Arabia, Canada, the UK, Turkey, Malaysia and Indonesia. They are known as mineral makeup products in European markets," Mauli said.

Grishma Teli, vice-president, research and development, Ecotrail, said only extracts from vegetables and fruits are used in the cosmetics products manufactured at the company's unit in Sanand. "The source of every ingredient is researched and it is ensured that products are 100% free of non-halal ingredients such as alcohol, chemicals like sulfate, paraben and mercury and animal-derived inputs," she said.

India is home to the world's second largest Muslim population but the community is still highly untapped as a consumer market for cosmetics products. Mauli Teli said that India's personal care

market is growing at 15-17% every year. "Ecotrail is currently focusing only on meeting the domestic demand," she said.

Muhamed Meeran, executive director of Halal India, apex body of halal certification, said the market for halal products, including food, pharmaceuticals, cosmetics and services, is expected to grow from $1.62 trillion in 2012 to $2.47 trillion in 2018. "Halal cosmetics sector is currently worth $26 billion and is expected to grow to $39 billion by 2018," Meeran said.

In Ahmedabad, the products will be available through two exclusive stores one in Mithakhali and the other in Juhapura from Sunday. The company has plans to expand its network through stores in cities like Surat, Bharuch and Vadodara (in Gujarat) as well as in Hyderabad, Bengaluru, Delhi, Mumbai, Jaipur, Lucknow, Kolkata and other cities.

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

US Approves Use of Novel Cancer Drug

The US Food and Drug Administration on Thursday approved the first of an eagerly awaited new class of cancer drugs that unleashes the immune system to fight tumours.

The drug, which Merck will sell under the name Keytruda, was approved for patients with advanced melanoma who have exhausted other therapies.

Cancer researchers have been almost giddy in the last couple of years about the potential of drugs like Keytruda, which seem to solve a century-old mystery of how cancerous cells manage to evade the body's immune system.

The answer is that tumors activate brakes on the immune system, preventing it from attacking them. Keytruda is the first drug approved that inhibits the action of one of those brakes, a protein known as PD-1, or programmed death receptor 1.

"This is really opening up a whole new avenue of effective therapies previously not available," said Dr. Louis M. Weiner, director of the Georgetown Lombardi Comprehensive Cancer Center in Washington and a spokesman for the American Association for Cancer Research. "It allows us to see a time when we can treat many dreaded cancers without resorting to cytotoxic chemotherapy."

This general approach might work for many types of cancer, though so far the main successes in clinical trials have come against the deadly skin cancer melanoma, lung cancer and kidney cancer.

But the treatments will not be inexpensive. Merck said Thursday that the drug, known generically as pembrolizumab, would cost about $12,500 a month, or about $150,000 a year. Merck said the price was in line with that of other cancer drugs, though it seemed to be a bit higher %than some. Many cancer doctors have already complained about the rapidly escalating prices of cancer drugs, %which they said could put treatments out of reach for some patients.

Source: *The Times of India, 6th September 2014*

Halol Unit of Sun Pharma Comes Under U S FDA Scrutiny

The share price of India's leading pharmaceutical player, Sun Pharmaceutical Industries (Sun) reacted on Thursday on reports of drug regulator, US Food and Drug Administration (FDA) conducting a surprise inspection of the company's manufacturing plant at Halol in Gujarat.

As against Wednesday's close of Rs 859.65 on the Bombay Stock Exchange, Sun fell to a low of Rs 808 in early trade on Thursday before closing at Rs 822.8, down 4.29 per cent.

The company refused comment on reports of the inspection, but sources indicate that the move may have been triggered by a number of recent recalls from the plant. In May, Sun Pharma's other manufacturing facility in Karkhadi, Gujarat had received a warning letter from the US FDA after investigators had identified violations of current good manufacturing practice (cGMP) and regulations for finished pharmaceuticals.

“Of late, Sun Pharma recalled three important medicines from the US market,” said Sarabjit Kour Nangra, VP Research, Angel Broking. It recalled 40,000 bottles fo Venlafaxine Hydrochloride extended release.

tablets after it failed the dissolution test, Gemcitabine for manufacturing issues and Metformin for packaging problems. While all recalls were limited to specific batches, all three products are manufactured at Halol.

The Halol plant was last inspected in September 2012 and reportedly contributes around 40 per cent of Sun's US sales and around 25 per cent of the consolidated profit of the company. “Results of the ongoing inspection at Sun Pharma's Halol plant would be significant given its importance to the company's US revenues as well as for its overall performance going forward,” Ms. Nangra said, adding that in 2013-14, US business accounted for 60 per cent of Sun's overall sales.

“Going forward, after the merger with Ranbaxy Labs, its dependence on the region would reduce to around 45 per cent of the expected sales in 2015-16. Thus, the share of the plant in the overall sales would reduce going forward (expected to be around 10 per cent of sales in 2015-16), while profitability could be impacted given the low profitability of Ranbaxy Labs in case of an adverse implication.”

Source: *The Hindu, 12th September 2014*

Bee Bacteria as Alternative to Antibiotics?

Honey has Broader Spectrum

London: Scientists now say that lactic acid bacteria found in honeybees have shown promising results as an alternative to antibiotics in a series of studies at Lund University in Sweden.

The group of bacteria counteracted antibiotic-resistant MRSA in lab experiments. The bacteria blend has already been tested on horses and healed persistent wounds. Raw honey was used to treat infections for millennia before it was processed and sold in stores.

Researchers identified a unique group of 13 lactic acid bacteria found in fresh honey, from the honey stomach of bees. The bacteria produce a myriad of active antimicrobial compounds. The bacteria were mixed with honey and applied to 10 horses whose owners had tried several other methods to no avail. All of the horses' wounds were healed by the mixture.

The researchers believe the secret to the strong results lie in the broad spectrum of active substances involved.

"Antibiotics are mostly one active substance, effective against only a narrow spectrum of bacteria. When used alive, these 13 lactic acid bacteria produce the right kind of antimicrobial compounds as needed.But since store-bought honey doesn't contain the living lactic acid bacteria many of its unique properties have been lost in recent times," said Tobias Olofsson, professor of Medical Microbiology.

The study said, "Today due to overuse of antibiotics and emerging antibiotic-resistant pathogens, we are facing a new era of searching for alternative tools against infectious diseases. Chronic wounds infected by pathogens are subjects for intensive research efforts because of the bacteria's ability to sustain antibiotic treatment and maintain chronic infections."

The findings could be vital both in developing countries, where fresh honey is easily available.

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

Self Medication : Boon or Bane

Pain is a blessing and also a curse: blessing because it is a warning sign for most of the diseases and thereby enabling easy diagnosis and cure. It is a curse when there is no medication or adequate management where the patient has to suffer infinitely. But one thing which is an absolute "no-no" is self-medication to relieve pain, which sadly most of the general population is not aware of, and some people keep on doing the same in spite of awareness. Self-,medication is nothing but selection and use of medicine by own to treat self-diagnosed condition or symptoms. Self-medication is increasing day by day. Common risk factors of self-medications include:-

Dangerous drug interactions

Rare but severe adverse reactions

Incorrect self-diagnosis, dosage and administration

Masking of a severe disease

Risk of dependence and abuses

Self-medication is available without medical prescription and sold to consumers directly, hence they are known as OTC (Over the Counter Drugs). OTC analgesics are painkillers such as Paracetamol, Aspirin and other non-steridal anti-inflammatory drugs used to get relief from pain can also cause gastro-intestinal bleeding and chronic renal failure. Even though self medication has several benefits such as better access to medication and quick relief for the patient it is not something to be followed as a matter of routine but in extraordinary situations where medical facility is not available or in emergencies warranting that.

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

Pfizer, Ranbaxy Win Dismissal of Lawsuit Over Generic Lipitor

REUTERS - Pfizer Inc (PFE.N) and India's Ranbaxy Laboratories Ltd (RANB.NS) on Friday won dismissal of a U.S. antitrust lawsuit accusing them of conspiring to delay sales of generic versions of the best-selling cholesterol drug Lipitor.

U.S. District Judge Peter Sheridan in Trenton, New Jersey, ruled that the plaintiffs, retailers and distribution companies that bought Lipitor directly from Pfizer, failed to plead their case with enough detail.

The lawsuit, filed in 2012, stems from a 2008 settlement of a patent lawsuit filed by Pfizer against Ranbaxy over Ranbaxy's plan to make generic Lipitor. Under the deal, Pfizer agreed to drop a claim for damages against Ranbaxy, and Ranbaxy agreed to stay out of the Lipitor market until November 2011.

Retailers and distribution companies claim that the settlement amounted to Pfizer paying Ranbaxy to stay out of the Lipitor market, violating antitrust laws. But Sheridan ruled Friday that their case failed because they did not offer any allegation of the settlement's dollar value.

Sheridan dismissed another version of the lawsuit last September.

A Pfizer spokesman said the company was pleased with the ruling.

"Pfizer has always believed that the procurement and enforcement of its Lipitor patents and the settlement of litigation relating thereto was at all times proper and lawful," the spokesman said in an email. "The company will continue to vigorously protect and defend its intellectual property, which is vital to developing new medicines like Lipitor that save and enhance patient lives."

Lawyers for the plaintiffs could not immediately be reached for comment.

Source: *The Hindu, 14th September 2014*

7 Indian Firms to Make Hepatitis C Drug

U.S. pharmaceutical major Gilead Sciences signs non-exclusive licensing agreements with these firms

In a move to make the treatment for Hepatitis C more affordable in developing markets, U.S. pharmaceutical major Gilead Sciences, on Monday, signed non-exclusive licensing agreements with seven Indian generic pharmaceutical companies to manufacture it.

Gilead signed agreements to make sofosbuvir and the investigational single tablet regimen of ledipasvir / sofosbuvir for distribution in 91 developing countries.

A statement from the company said it signed agreements with Cadila Healthcare, Cipla, Hetero Labs, Mylan Laboratories, Ranbaxy Laboratories, Sequent Scientific and Strides Arcolab.

The countries within the agreement account for more than 100 million people living with Hepatitis C, representing 54 per cent of the total global infected population.

According to World Health Organization, 130-150 million globally have Hepatitis C infection and in India alone, it is estimated that 10-20 million patients are infected with Hepatitis C which is several fold greater than those with HIV/AIDS.

A large number of patients develop liver cirrhosis and liver cancer.

Sofosbuvir is considered a breakthrough and in combination therapy has high cure rates. Sofosbuvir was approved under the trade name Sovaldi by the U.S. Food & Drug Administration (FDA) in December 2013 and by the European Commission in January 2014.

Technology transfer

Gilead said the FDA and European Medicines Agency were now reviewing the company's applications for a single tablet regimen of ledipasvir/sofosbuvir, an investigational agent and its safety and efficacy had not yet been established.

Under the licensing agreements, the Indian companies will receive a complete technology transfer of the Gilead manufacturing process to enable them to scale up production as quickly as possible.

"The licensees also set their own prices for the generic product they produce, paying a royalty on sales to Gilead to support product registrations, medical education and training, safety monitoring and other essential business activities," Gilead said. The licences also permit the manufacture of sofosbuvir or ledipasvir in combination with other chronic Hepatitis C medicines.

"In developing countries, large-volume generic manufacturing and distribution is widely regarded as a key component in expanding access to medicines. These agreements are essential to advancing the goals of our humanitarian programme in these countries,"

Gregg Alton, EVP, Corporate & Medical Affairs, Gilead Sciences, said in a statement.

Source: *The Hindu, 16th September 2014*

Generic Version of Life-Saving Drug Skip Tests, Government Looks Away

While the Indian government is pushing generic drugs as they are cheaper and, therefore, more affordable, there seems to inadequate attention on ensuring that the quality protocol of these drugs is properly observed.

A case in point is a life-saving drug, Liposomal Amphotericin B, which is used to treat fungal infections in critically-ill patients. Several doctors say while the need for the drug is obvious, the drug controller general of India (DCGI) has failed to ensure that pharmaceutical companies manufacturing the generic version of this drug carry out proper tests.

In fact, a government-appointed expert committee had recommended action against the erring pharma companies.

TOI also has a copy of a letter from VM Katoch, the director general of Indian Council of Medical Research (ICMR) to the DCGI on June 4, calling for action against companies manufacturing and marketing untested Liposomal Amphotericin B.

"The quality of these preparations will immensely affect the efficacy and toxicity," the letter states. Katoch told TOI that he wrote this letter in response to complaints received by him.

When contacted, DCGI GN Singh said the matter was forwarded to the state authorities for necessary action. "I am not aware of the present status of this particular case but licenses are given for the manufacture and marketing of generic drugs after detailed examination of the risk factors," he said.

Doctors say the obvious risk of Amphotericin B is its high toxicity, which can lead to kidney failure and death. However, given that it's a life-saving drug, used when patients are in terminal decline, they have little option but to use the generic version, especially for poor patients. "It's an unsatisfactory situation, but we monitor toxicity closely to see that it doesn't go out of control," said a doctor.

"Liposomal Amphotericin B was included in the Indian Pharmacopoeia the standards setting institution for drugs in India in the year 2010 and a number of licenses for the manufacture of generic versions of the same drug were granted without clinical trials. It was removed later when a senior official from the department of biotechnology raised objections. But the companies are still selling them," said one of the experts.

A generic medicine store in Bangalore. (TOI file photo)

TOI spoke to cancer specialists and transplant surgeons who use the anti-fungal medicine frequently. They said the current controversy is symptomatic of the real problem facing the health system. "The government is right in promoting generic drugs but where is quality control? There is no limit on the number of companies that can be allowed to manufacture the generic version of a drug and the amount they can charge. In case of Liposomal Amphotericin B, over a dozen pharma companies have been awarded the licenses," said a senior doctor.

Dr AS Soin, liver transplant surgeon at Medanta Medicity, Gurgaon, said fungal infections are common in terminally-ill patients and transplant cases. "Though there are advantages of a pioneering drug but we tend to use the generic ones because the former is simply unaffordable to many. The research molecule of Liposomal Amphotericin B is two to three times costlier as compared to the generic version," he said.

The All India Institute of Medical Sciences in New Delhi. (Getty Images file photo)

A senior AIIMS doctor, who did not want to be quoted, added: "Generic drugs are by definition as effective as branded ones. But the problem lies in poor regulatory mechanism that allows the manufacturing and marketing of spurious drugs in the name of generic versions."

Health ministry officials point out that while tests are conducted to check chemical composition of a generic drug, there are none to ensure "bioequivalence" or its efficacy compared to the pioneer drug.

Dr AK Dewan, medical director of Rajiv Gandhi Cancer Institute, regulators should allow limited branded generics of a particular compound and ensure quality. "The generic version costs Rs 7,000 per month. Another branded drug for lung cancer and head and neck cancer earlier cost Rs 80,000 per month for 100 tabs but with generic medicines available, it has come down to Rs 7,500. Even original manufacturers are forced to reduce prices to remain competitive," he says.

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

Epirus, Ranbaxy Win Nod for Arthritis Drug Copy

Boston-based biopharmaceutical company Epirus Biopharmaceuticals Inc said India's drug regulator has approved its copy of a top-selling arthritis treatment, paving the way for its launch in the country early next year.

The company's Indian partner, Ranbaxy Laboratories Ltd , will sell a copycat version of Johnson & Johnson's and Merck & Co Inc's infliximab, an anti-inflammatory drug with annual sales of about $6 billion.

The market for copycat biotech drugs, known as biosimilars, is becoming more lucrative as patents expire on older, high-priced antibody drugs that rank among the pharmaceutical industry's biggest sellers.

Infliximab, sold under the brand name Remicade, is used to treat rheumatoid arthritis, Crohn's Disease, psoriasis and other inflammatory conditions. In India, it sells at about Rs.70,000 ($1,150) a month. Like its main rivals, Amgen Inc's Enbrel and AbbVie Inc's Humira, the drug works by blocking a protein called tumour necrosis factor.

Epirus, which focuses on developing biosimilar drugs for sale, said it would launch the Remicade biosimilar in India under the name Infimab by the first quarter of 2015.

Chief Executive Amit Munshi, citing various estimates, said the Indian market for Remicade was worth $8 million to $10 million a year. He declined to say how much Infimab would cost or to estimate how many patients might use the drug.

The drug will be made in Mumbai by Reliance Life Sciences, part of billionaire Anil Ambani's Reliance Group Holdings.

Remicade copycats are already being sold elsewhere. South Korean drugmaker Celltrion Inc won approval in July for its version in Japan and is hoping for U.S. approval in 2015. Epirus is also in talks with Ranbaxy, as well as other Indian and international companies, about expanding sales of its biosimilar drugs in other regions, Mr. Munshi said.

Source: *The Hindu, 17th September 2014*

Court Asks Pharma Cos, Centre to Resolve Drug Pricing Issue

The Delhi High Court, on Thursday, asked the pharmaceutical companies, including Novartis India and Cipla, to hold a meeting with the Union Government and try to resolve the issue of implementing the revised drug pricing.

A bench of Justice B D Ahmed and Justice Vibhu Bakhru said representatives of the pharma companies hold a meeting with the Director of the National Pharmaceutical Pricing Authority (NPPA), the Ministry of Chemicals and Fertilizers, to settle the matter 'once and for ever'.

“You have meeting with the Director, NPPA, and come back in October. We expect the meeting shall take place and be concluded before the next date of hearing. You should try to resolve the issue once and forever. We are also tired of hearing it,” the court said.

The court has fixed the matter for hearing on October 30.

The court's suggestion came while hearing a bunch of petitions moved by the pharmaceutical companies and an association of medicine manufacturing companies challenging the government's new drug pricing order that asked them to slash prices of 348 medicines.

During the hearing, the pharma companies suggested that prominent boards of the revised drug prices could be displayed by retailers and chemists to inform the customers as calling back all the stocks and relabelling them was not feasible.

However, Additional Solicitor General Sanjay Jain was not in agreement with the proposal and suggested an alternative of shipping stickers of revised prices to retailers who can then affix the same on the drugs.

The pharma companies did not agree with the ASG's suggestion and termed it as impractical.

As both the parties were not agreeing with each other's suggestion, the court directed them to hold a meeting.

The firms have also challenged the provisions of the 2013 Drug Price Control Order (DPCO) of NPPA that had asked them to replace stocks in the market with those carrying reduced prices within 45 days of new price notification.

Besides Novartis, the Indian arm of Swiss firm Novartis AG, pharma firms Wockhardt, Lupin, Intas Pharmaceuticals, Alembic Pharma- ceuticals, Sandoz Private Limited and Chiron Behring Vaccines Private Limited had approached the court against the new drugs pricing order.

Earlier, Cipla and four other companies had moved the court against the 2013 DCPO. PTI

Source: *The Hindu, 19th September 2014*

Artificial Sweeteners Can Trigger Diabetes : Study

Artificial sweeteners may disrupt the body's ability to regulate blood sugar, causing metabolic changes that can be a precursor to diabetes, researchers are reporting. That is "the very same condition that we often aim to prevent" by consuming sweeteners instead of sugar, said Dr Eran Elinav, an immunologist at the Weizmann Institute of Science in Israel, at a news conference to discuss the findings. The scientists performed a multitude of experiments, mostly on mice, to back up their assertion that the sweeteners alter the microbiome, the population of bacteria that is in the digestive system.

The different mix of microbes, the researchers contend, changes the metabolism of glucose, causing levels to rise higher after eating and to decline more slowly than they otherwise would. The findings by Dr Elinav and his collaborators in Israel, including Eran Segal, a professor of computer science and applied mathematics at Weizmann, are being published Wednesday by the journal Nature.

Cathryn R Nagler, a professor of pathology at the University of Chicago who was not involved with the research but did write an accompanying commentary in Nature, called the results "very compelling." She noted that many conditions, including obesity and diabetes, had been linked to changes in the microbiome. "What the study suggests," she said, "is we should step back and reassess our extensive use of artificial sweeteners."

Previous studies on the health effects of artificial sweeteners have come to conflicting and confusing findings. Some found that they were associated with weight loss; others found the exact opposite, that people who drank diet soda actually weighed more. Some found a correlation between artificial sweeteners and diabetes, but those findings were

not entirely convincing: Those who switch to the products may already be overweight and prone to the disease.

While acknowledging that it is too early for broad or definitive conclusions, Dr Elinav said he had already changed his own behaviour.

"I've consumed very large amounts of coffee, and extensively used sweeteners, thinking like many other people that they are at least not harmful to me and perhaps even beneficial," he said. "Given the surprising results that we got in our study, I made a personal preference to stop using them."

In the initial set of experiments, the scientists added saccharin (the sweetener in the pink packets of Sweet'N Low), sucralose (the yellow packets of Splenda) or aspartame (the blue packets of Equal) to the drinking water of 10-week-old mice. Other mice drank plain water or water supplemented with glucose or with ordinary table sugar. After a week, there was little change in the mice who drank water or sugar water, but the group getting artificial sweeteners developed marked intolerance to glucose. Glucose intolerance, in which the body is less able to cope with large amounts of sugar, can lead to more serious illnesses like metabolic syndrome and Type 2 diabetes.

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

Price Cuts to Hit Ranbaxy, Cipla Most

Ranbaxy Labs and Cipla are among the companies which would face the maximum brunt of the new price cuts announced by National Pharma Pricing Authority (NPPA) early this week.

The drug pricing regulator capped prices of 43 formulations, including antibiotics Ciprofloxacin, and diabetes drug Metformin extended release tablets, among others.

The part of the domestic drug market which has been brought under price control is pegged at around Rs 450 crore, which is estimated to shrink by 39 per cent or Rs 179 crore, reckons Aiocd Awacs, a pharma marketing research agency.

"With this list, the scope increases predominantly in the anti-infective space. The major impact has come in the form of Ciprofloxacin 500 and 250 milligram which is 65 per cent of the market of the released ceiling price," said Hari Natarajan, vice president, Aiocd Awacs.

While Ranbaxy would take a Rs 55-crore hit, Cipla would face a loss of about Rs 46 crore, as a result of the new price cuts announced by the NPPA. Cadila Healthcare, Pfizer, Lupin, Torrent are some of the other companies, drugs of which will get covered by the new price cuts.

In July, the NPPA invoked a clause in the drug pricing order to cite extraordinary circumstances for more than 100 diabetes and heart disease drugs, which lie outside the scope of National List of Essential Medicines (NLEM) and fixed their price caps in 'public interest'.

The NLEM includes 652 formulations as essential. The drug pricing regulator invoked a special provision under the drug price control that gives it the right to fix the prices of any drug "in extraordinary circumstances, if it considers necessary to do so in public interest".

It cites huge inter-brand price differences in these drug categories as 'extraordinary'. The drug companies - both domestic and MNCs - are up in arms against the pricing regulator's move.

Industry bodies representing drug makers have challenged the decision in the high courts of Delhi and Bombay. Before moving the court, the Indian drug makers sought the intervention of Ananth Kumar, Union minister of chemicals and fertilizers, claiming that inter-brand differences cannot qualify as 'extraordinary' by any stretch.

"The inter-brand differences have always existed and were in existence when the NLEM was drawn up. Also, the inter-brand differences would be found in every single formulation which is manufactured by more than one formulator," the Indian Pharma Alliance's (a grouping of domestic drug makers) letter to minister said,

Source: *The Economic Times, 20th September 2014*

Pharma Fracas : Us Authors Call India's Move 'Overreaction'

The authors of a controversial report, which alleged that Indian drug makers sell inferior drugs in poor African countries, have called the Indian government's threat of legal action against them a 'shocking overreaction' to an academic work. "The government's threat of legal action is a shocking development, and if it proceeds, it will hurt India more than it hurts us," said Roger Bate and Aparna Mathur, research scholars at US think tank American Enterprise Institute (AEI), authors of the paper along with Ginger Jin, professor at the University of Maryland, and Amir Attaran, professor of law at the University of Ottawa.

Not even North Korea or Russia have taken the illiberal step of suing scholars for publishing academic research and India is poised to become the first government to do so, the authors told ET. The government, through the Indian Brand Equity Forum (IBEF), a trust under the ministry of commerce and industry, is exploring legal options against the authors and the US think tank for allegedly maligning the image of the country and its pharmaceutical industry.

The IBEF, miffed that the widely publicized paper pitted India against Africa on a sensitive issue such as public health through a "'sweeping generalisation', has already prepared a detailed report on the problems with the study, its sampling techniques and methodology and is currently in the process of readying its legal response. For instance, in an internal report, IBEF cites the time gap between data collection and publication of the study--a major handicap in getting companies to test whether the controversial allegations are correct.

"Most products would have crossed expiry dates," it said, wondering why it took the US researchers many years to release a report when the methods (mini-lab protocol) they employ lead to quick results, usually within hours. Bate and his colleagues maintain that everything about the studythe collection of data, the analysis, and the write-up and publicationwas conducted with proper academic rigour.

"The paper is a working paper, which means it has not yet been through extensive peer review and is disseminated for the purpose of idea sharing, discussion, comments, and suggestions. But the vast majority of the quality data have already

appeared previously in some of the top medical, scientific and socio-economic journals after extensive peer review," the authors said in the email. The study, which said it tested 1,470 samples of Indiamade drugs, found that a significantly higher fraction of them were of poorer quality if purchased from Africa than samples from India or from other middle-income countries such as China, Brazil, Turkey, Thailand and Russia.

It published the results just days before Prime Minister Narendra Modi's recent US visit and announced the findings at an event on Capitol Hill. The authors highlighted that the presence of Indian products in the unregistered African market---where drugs are sold illegally-- is worrying enough, but these medicines are of particularly poor quality and could be dangerous. The IBEF report counters this claim, asking how the authors could be sure that drugs labeled 'made-in-India' were actually manufactured in the country considering that only a few years back, the origin of many such products were finally traced to China.

“Anyone familiar with the pharmaceutical industry in India or Africa knows that a large number of Indian medicines are traded through poorly regulated channels where both compliance with the law and quality standards can be easily evaded. Our point is that if India wants to be regarded as a serious and ethical drug exporting country does it ? then this has to stop.” Bate and his co-authors said.

Source: *The Economic Times, 6th October 2014*

Untrained Pharmacists, A Deadly Menace

The number of complaints about medical shops operating without qualified pharmacists is alarming as it can impact public health. Regular sales staff without proper training can dispense the wrong drugs and end up endangering a patient's life.
Experts say qualified pharmacists not only counsel patients about dosage and relevance of taking a medicine at a particular hour but also serve as a line of defence against doctors prescribing wrong medicines.

Statistics from the food safety and drugs administration department shows there has been a gradual increase in the number of retail and wholesale drug stores in Chennai operating without a pharmacist. The number rose from 87 in 2011 to 125 in 2012 and to 108 in 2013. Till August this year : 138 medical shops were booked for not having a qualified pharmacist.

According to Section 18(c) of the Drugs and Cosmetics Act, 1940, a pharmacy is a shop where drugs are dispensed, measured or weighed and supplied. The drug administration department can suspend or cancel the licence of a store for functioning without the supervision of a registered pharmacist.

Dr C N Raja, honorary state secretary of Indian Medical Association, said only qualified pharmacists can understand the doctor's prescription and dispense medicines accordingly. There are chances that an incorrect medicine may be sold which can endanger the life of the patient because of the absence of a qualified pharmacist. Untrained sales staff have no knowledge about the medical terminology. Only educated patients crosscheck the drugs that they get from a medical store with the prescription”.

Sources said most drug stores don't employ qualified pharmacists to cut costs. The salary for a

Pharmacist is Rs 8,000 to Rs 15,000 a month. “I cannot afford to hire two qualified pharmacists for 12 to 13 hours a day. There are a large number of medical shops in the city and the competition is high. It is difficult to make a profit and hiring pharmacists is an added cost, “said a medical store owner.

Since shops operate without a pharmacist, a number of banned drugs continue to be sold across the counter. For instance, illegal sale of cough syrups containing codine phosphate without prescription continues in the city. Codeline phosphate should be sold only under prescription as teenagers easily become addicted to it.

Tamilnadu Chemists and Druggists Association president K K Selvan said most drug stores have qualified pharmacists. In response to a question on the growing number of cases, he said:”Sometimes they conduct inspections during lunch or dinner time when the pharmacist has gone out. That is why so many cases are recorded. We do ensure that drugs are not dispensed at that time”.

Sources said several drug stores have a pharmacist on paper to get the license to run a medical store. N Rajganesh, general secretary of Federation of Indian Pharmacists Organisation, said several medical stores run without qualified pharmacists. He said they had lodged several complaints but no action has been taken. “The drugs administration department struggles to conduct raids because of severe staff shortage. Only Maharashtra had managed to curtail this menace through stringent action” he said.

The drugs administration department has only 49 drug inspectors against the sanctioned strength of 59. They have to conduct inspections at more than 4500 medical shops in Chennai. Director of drugs control S Abdul Khader said “We conduct regular inspections across the state to find out if any shop violates rules”.

Source: *The Times of India, 6th October 2014*

A Steel Frame for Clinical Trials

The regulatory framework on clinical trials needs a coherent set of stand-alone rules. This will not only ensure adherence to the principles laid down by the Supreme Court but also give impetus to the clinical trials industry in India, currently languishing due to an uncertain regulatory environment.

In recent months, the quest for a safer, more transparent clinical trials regime has found new momentum. Fourteen notifications in July 2014, governing various aspects pertaining to a clinical trial ranging from placebo-controlled trials to compensation awards have been notified. Further, the Central Drugs Standard Control Organization (CDSCO) has proposed a forward-looking IT-enabled information system that will ensure transparency and protect the interests of trial subjects.

These developments are important steps for the clinical trials regime in India to satisfy the three principles laid down by the Supreme Court for approving trials assessment of risk versus benefit to patients, need for innovation *vis-à-vis* existing therapeutic option and the unmet medical needs in the country. But for satisfying these standards, much more remains to be done. The entire regulatory framework pertaining to clinical trials needs to be overhauled and a clear, coherent and

succinct set of stand-alone rules needs to be introduced for this purpose. This will not only ensure adherence to the principles laid down by the Supreme Court but also give impetus to the clinical trials industry in India, currently languishing due to an uncertain regulatory environment.

Accreditation and ethics

There are three key changes that are essential if the clinical trials regime in India is to be put on a firm foundation instituting a structured accreditation process accrediting investigators, trial sites and ethics committees, making ethics committees function effectively and ensuring diligent adherence to guidelines concerning informed consent from trial subjects. Each of these three aspects has been studied closely by the committee headed by one of us, the Ranjit Roy Chaudhury Committee, with detailed recommendations provided.

Accreditation must become the centrepiece of a new clinical trials regime founded on the principle of patient safety. Accreditation ensures adherence to certain quality standards thereby instilling confidence not only in patients who will be trial subjects but equally in the industry, which is responsible for conducting the trials. Thus, principal investigators of trials should be accredited depending on their qualifications, experience and training; trial sites should be accredited on the basis of infrastructure, personnel and systems; finally, institute ethics committees must be accredited keeping in mind the experience of their members and the standard operating processes for review which are used. Guidelines in this regard have been prepared recently by an expert committee; these must be implemented post-haste. If this is done, India would be the first country anywhere in the world to institute such a structured process of accreditation.

Conflicts of interest and consent

Accreditation of ethics committees is an especially central element towards making such committees effective custodians of the safety and probity of all clinical trials. Several cases of casualties in clinical trials have emerged in the past few years, where compliance with standard operating processes were shoddy or such processes themselves were absent. In an Indian Council of Medical Research (ICMR) publication, the independence of ethics committees and conflict of interest questions were highlighted. To correct this, it is not only essential that ethics committees are accredited but also develop standard operating procedures that are capable of effective implementation. To follow such procedures, members of ethics committees need to undergo high-quality mandatory training. This requires a combination of men and women of wisdom and experience and training protocols that are succinct and geared towards ensuring safe and effective trials where all norms are strictly followed.

A key positive spin-off of accredited ethics committees would be to prevent conflicts of interest. The Ranjit Roy Chaudhury Expert Committee Report pointed out gross malpractices and unscrupulous decisions in clinical trials caused owing to ethics committee members having an interest in the trial itself. To offset this, a key facet of accreditation would be a strict adherence to finding independent persons to serve on ethics committees. This can be achieved by a combination of randomised allocation of experts to particular ethics committees together with a supplementary check by the accrediting body. A hybrid process, part-automatic with a supplementary human element, would not only ensure independence of the ethics committee in fact, but also create a positive perception of such independence in the minds of trial subjects.

Such a positive perception of the independence of ethics committees, it is believed, would become a key facet of securing informed consent of trial subjects. The need for informed consent was a key norm that was recently found by the United States Office for Human Research Protections (OHRP) to be flouted in a cervical cancer study funded by the U.S. National Cancer Institute and the Bill & Melinda Gates Foundation. Till April 2014, 254 women in unscreened control groups in these trials have died. The OHRP determined that insufficient information was provided in order for these and other women to give informed consent to participate in the trial.

Towards a new order

Culpability in this matter is still an open question that might require judicial intervention. However, at this stage, it is clear that the episode demonstrates the lack of effective protocols to ensure that informed consent is truly on the basis of relevant information and the lack of clear methods to ascertain the taking of such consent. This has been partially offset by CDSCO which issued draft guidelines earlier this year on audio-visual recording of informed consent process in clinical trial. This mandates audio-visual recording and safe storage of the taking of informed consent from trial subjects. This is a welcome move. However it is imperative to keep in mind the privacy of patients who might not wish to be recorded. Thus, it is recommended that such recording should be mandatory subject only to waiver by the trial patient or the ethics committee, keeping in mind the equally significant principle of patient privacy.

Not only is the substance of the changes mentioned significant, but equally the form it takes. Best practices worldwide demonstrate that having a succinct, stand-alone set of rules governing clinical trials promotes transparency and increases certainty. Currently, the legal architecture governing clinical trials is complex with several facets governed by the Drugs and Cosmetics Rules, 1945, a slew of notifications thereunder, and some facets regulated by the proposed Drugs and Cosmetics (Amendment) Bill, 2013, pending in the Rajya Sabha.

It is essential that the recommended reforms together with any other changes proposed by CDSCO are brought under a consolidated umbrella of rules governing clinical trials. This will give the clinical trials industry the necessary certainty to undertake trials in India with confidence. The benefits for India in terms of development of new drugs, employment generation in the clinical trials industry and ensuring a safe environment for its citizens desirous of participating in clinical trials would be tremendous. Most crucially, it would demonstrate the seriousness that the government attaches to effective public health systems and scientific progress, two goals of a well-functioning clinical trials regime that must also become the pillars on which modern India is built.

Source: *The Hindu, 8th October 2014*

Indian Pharma Industry not as Attractive for Acquisitions, Says Ajay Piramal

He was one of the original 'takeover tycoons' in India's post-liberalisation era with an appetite for taking over pharmaceutical businesses. Ajay Piramal, Chairman of the Piramal Group, has since diversified his business interests, having sold his then flagship, Piramal Healthcare to Abbott for a whopping $3.7 billion in 2010. Mr. Piramal spoke to The Hindu on the industry, and his plans going forward. Edited excerpts:

The group has a presence across sectors in the Indian economy. What is the current scenario? Beyond green shoots are there more concrete signs of a recovery?

For the recovery to be seen in terms of numbers, it will take time. I can, however, see that the foundations are being laid for a recovery. The new government is trying to hasten the speed of decision-making which itself is very important. Second, there were many obstacles which were not allowing industry to grow. There was a sort of anti-industry view that was industry versus people. That is changing. Now, it is industry and people.That recognition is clearly there. Also, markets have clearly run ahead of everything else. But when they run ahead, promoters feel there is more access to funds which was not there in the last 2-3 years. Today, plans for investments are being made. Orders will take time to grow but I think it is in the right direction. In sum, decisions are being made quicker, there is a pro-industry view, there is talk of laws being amended in environment, land and labour, and markets are doing well. All this means there will be growth.

While things are looking better for the economy, how are they for the pharmaceutical industry in India? What are the issues confronting the Indian generic pharmaceutical industry? Do you regret getting out of generic pharmaceutical manufacturing?

In pharma, it is not happening yet. It falls in so many different buckets Ministries of industries, health, chemical & fertilizers. For people to get a total view of pharmaceuticals, they have to take an integrated approach.

From the generic point of view, clearly we must get in an environment which looks upon the industry in a positive manner. Earlier, the generic industry was looked upon as strength for India. I do not see that happening anymore. It is always negative whether it is pricing or promotional practices. You have to turn the approach around to make it more positive. I do not have any regrets. We are pretty happy that we did what we did because subsequently we are seeing a lot of issues in the industry. I think we have gone into other industries where we see a lot of growth opportunities. There was a plan and thinking behind it, and things have moved in that direction.

You have become more like a private equity player after selling to Abbott, and identified certain sectors to grow. What are the plans ?

As we look at it, there are three really big parts to it.

One is the whole pharmaceutical space where we have a presence in critical care and make inhalation anaesthetic drugs. It is really a global market, and we are growing 20 per cent, manufacturing both in India and the U.S. although we may increase manufacturing in India a little. Sales may go up marginally by 1 per cent in India. Second is contract research and manufacturing services (CRAMS), which have been growing at 15-18 per cent where we manufacture for large and small global

companies. Third is our over-the-counter (OTC) business in India at around Rs.250 crore and growing at around 25 per cent. Finally is our R&D wing in Germany, where we have tracers for early diagnosis of Alzheimer's disease. Second is our information and data company which in healthcare converts data into insight out of the U.S. As more and more data is available, people want to know how to use it. It is for the long term. We have invested around $650 million, and will grow it through acquisitions and organic growth.

The third is in financial services business, and we made a large investment in Sriram Group. It is not a private equity investment. We are increasing our loan book in NBFCs, and these two are going to grow in India. Funds will be required across sectors, and Shriram is into second-hand vehicle finance, SME, general insurance, life insurance, and as economy grows, financial services will also grow.

India REITs , is growing well. We are providing real estate funding , and find there is good growth. There is the new trend of REITs, where commercial properties and people can get a steady yield. I think our financial markets are quite advanced, and there will be a different set of investors of low returns but without risk.

All three businesses will get their importance but sometime in the future, we may have to separate it out and hive them off. In terms of cash and investment, obviously financial services will be the largest in terms of assets. In terms of turnover, healthcare will be large.

There has been increasing regulation of the industry by the National Pharmaceutical Pricing Authority on the price of drugs sold in India. Is it becoming more difficult for the pharma industry?

We are not in the domestic pharmaceutical industry although we are in the OTC space. From what I see, all these developments are not in the right direction. There is a one-sided view, and not enough dialogue between industry and the pricing authorities.

Earlier on, it was industry versus people and it is still continuing. You cannot kill Indian manufacturing in drugs. India was a strong manufacturing base for pharmaceuticals, and they must encourage that rather than kill it. If you make pricing unviable, then industry is not going to stay. Take the example of penicillin and all the anti-infective of which there is no manufacturing in India anymore because it has become so unviable and you are dependent on China. If you talk about 'Make in India', we must have a reasonable regime which allows free markets to operate.

So, where have the authorities gone wrong? What can be done to remedy the situation?

This was going on for a while that pricing has to be regulated, and that the scope of price control has to be enlarged but I think they have gone overboard. Also, in India, there is enough generic competition so you do not have to bring down the price of everything.

People have a choice, and if they do not want to pay as much for a branded drug, they can buy the generic version. But let people exercise the choice. Why should government come and bring down prices? This I do not understand. If it is a monopoly situation and life threatening, it may be justified but you cannot have it for the whole industry. You have to encourage growth in the industry otherwise people will not be attracted to remain in manufacturing.

Is the situation ripe for a consolidation? What about fears expressed in several quarters that the Indian pharmaceutical industry will be dominated by the multi-nationals?

I do not see too much consolidation taking place in the industry because unlike other industries, pharma is not capital-intensive and I am talking more about formulations. Secondly, if you bring down a lot of the pricing, it is not very attractive as a market leader anymore. Also, with a lot of negative news reports coming out in the open, I do not see foreign companies as interested in doing acquisitions in the domestic industry as they were earlier. In bulk drugs though, there could be some consolidation because many companies had over-stretched and have gone through corporate debt restructuring (CDR) process and they were becoming NPAs with banks. I do not see global companies increasing their presence too much. Some marginal acquisitions could take place but India is not as attractive as it was earlier.

There is somehow negative news as far as how pharmaceutical regulation is taking place in India. One is clearly on the pricing that we are seeing. Secondly, there is this talk about Intellectual property (IP) and clinical trials. So, people do not think India will be a base for their R&D. Thirdly, there is the talk about coming down strongly on promotional practices. All these are getting bad press, and so, it is no longer as attractive so I do not see major transactions taking place.

With regard to multi-nationals dominating here, it cannot happen because look at the situation even today. The largest company has a 7 per cent market share, and there are so many players. It is a highly fragmented industry, and multi-national pharmaceutical companies have been in India for over 100 years and have not been able to make so much of a dent.

We have seen that even the level of R&D in the pharmaceutical sector has been moving out of India. Can the government take remedial steps to bring that back?

I do not think so. It will continue to move out of India. It is because the way approvals for clinical trials are being given or the way they are conducted, which reflects a lack of understanding about how clinical trials are run. Till recently, it was almost completely banned and clinical trials had stopped completely.

Now, they have relaxed some things but you cannot have that as clinical trials may take years, and there is a shortage of quality investigators. People approving clinical trials today do not have the expertise or the experience so they just put in conditions. I do not see much happening unless there is a major change in the outlook.

Source: *The Hindu, 13th October 2014*

Price Cap Goes, Drug Cos Eye Double Digit Growth

India's pharmaceutical industry hopes to post double-digit growth this fiscal following the drug price regulator's decision to scrap its July order to cap prices of 108 formulation packs of anti-diabetic and cardiovascular drugs.

Analysts say the 18.8% growth in September compared to the year-ago period, the highest in recent months, has raised hopes of a better performance than last year. Sales revenue grew 9% in 2013-14. "The growth rate will be 12-14% for the current financial year," said Alok Dalal, analyst with Motilal Oswal securities.

According to analysts, sector reported a healthy growth in September on account of a low base and high contribution of volume growth in both NELM and non-NELM drugs. Though there was significant growth in therapies across segments, revenue from acute therapy drugs grew two to four times while chronic therapy drugs saw growth of up to two times compared with the year-ago period.

Analysts attribute the sales revenue growth of acute therapy drugs at 19.8% in September, highest since April 2013, to seasonal spike, benefits of lower base in 2013 and benefits of price rise in April 2014.

Within the acute therapy drugs category, respiratory drugs segment witnessed a strong turnaround with 28.6% growth in September after sliding over the past five-six months, said Surajit Pal, analyst with Prabhudas Lilladher, in his latest report last week. In September, the domestic pharma market grew to Rs 80,500 crore while the monthly sales stood at Rs 7,740 crore.

In September, the domestic Pharma market grew to Rs 80,500 crore ($13.4 billion) while the monthly sales stood at Rs 7,740 crore. According to Pal, the industry saw broad based growth in September when 46% of the companies in top 50 and 45% therapeutic areas surpassed the industry growth rate. “Incrementally non-NLEM drugs contributed 91% of growth in formulation sales in September 2014. We believe that benefits from withdrawal of price ceiling in cardiac and anti-diabetic drugs have partially helped increase growth of non NLEM drugs.

With 76% contribution in September sales growth volume (NLEM and non NLEM) growth was also another key contributor: This is also reflected in unit (volume of SKUs) growth of NELM and non-NLEM drugs at 6.6% and 12.1% respectively, in September 2014.

Lupin's chief financial officer, Ramesh Swaminathan said he hoped the upbeat trend would continue. We expect the industry to grow well as the overall economy seems to be picking up and we anticipate a 20% growth rate for us in the current financial year with about Rs 3000 crore of revenue from India” .

We are introducing more in-licensing products in the areas of dermatology oncology etc to push sales growth apart from promoting sales through our network of people. “Hoping that the government will not again look at price cuts that could destabilize the industry. Swaminathan said the regulator's decision to scrap its order should help industry perform better over the coming months.
Analysts expect price rise in non-NELM drugs, which account for a third of domestic Pharma sector to drive growth in sales revenue across industry. “With withdrawal of price ceiling in cardiac and anti-diabetic drugs,we also expect strong price growth in non-NLEM drugs in the third quarter of 2014-15,” said Pal of prabhudas Lilladher Cipla, which has about 5% share in domestic market, saw a growth of 38.4% in sales at Industry analysts Rs 497 crore in September.

Source: *The Economic Times, 30th October 2014*

PARLIAMENT QUESTION ANSWERS

LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS

Question No. 749
Answered on 15.07.2014

SHORTAGE OF ESSENTIAL DRUGS

749 Shri PARAYAMPARANBIL KUTTAPPAN BIJU

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the essential/scheduled drugs are being sold at exhorbitant rates due to shortage/insufficient supply of such drugs in the country;

(b) if so, the details thereof and the reaction of the Government thereto;

(c) whether there is any mechanism in place to monitor the stock/availability of essential/scheduled drugs from time to time;

(d) if so, the details thereof along with the estimated stock/production of these drugs in the country; and

(e) the steps taken/proposed to be taken by the Government for ensuring supply /production of essential/scheduled drugs in adequate quantity to the consumers?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND)

(a) to (e): All the medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in Schedule I of Drugs (Prices control) Order, 2013 (DPCO, 2013) and are under price control. There are 680 NLEM medicines and out of these, National Pharmaceutical Pricing Authority (NPPA) has fixed / notified the ceiling prices in respect of 440 medicines upto 30th June, 2014 under provisions of the said order.

NPPA regularly monitors shortages & availability of drugs on the basis of monthly reports received from State Drugs Control Administration and also complaints,if any, received from NGOs, individuals etc. On receipt of such reports, NPPA immediately takes up the matter with the concerned manufacturer and advice them to rush the stock in the affected area. NPPA has not received any specific report that due to shortage / insufficient supply, life-saving drugs are being sold at exorbitant rates.

DPCO, 2013 vide its para 21(1) provides for monitoring the availability of essential medicines included in its First Schedule. The manufacturer of scheduled formulations and the Active Pharmaceutical Ingredients contained in the scheduled formulations are required to furnish the details relating to production and sale in the specified Proforma i.e. Form-III of the said order on Quarterly basis. The drug-wise estimated stock / production is not available. But, under para 21 of DPCO,2013 no manufacturer of scheduled drug can discontinue production without prior approval.

Question No. 1656
Answered on 22.07.2014

DRUGS UNDER PRICE CONTROL

1656 Shri ANURAG SINGH THAKUR

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether drugs for cancer including antibiotics are very costly in the country;

(b) if so, the reasons therefor and there action of the Government thereto along with the number of drugs covered under the price control at present;

(c) whether the Government proposes to further extend the coverage of price control;

(d) if so, the details thereof and the timeby which it is likely to be made;

(E) whether the method of pricing of drugs is not rational and if so, the reasons therefor; and

(f) whether the Government proposes to fix the price of medicines on the basis of manufacturing cost of medicines instead of average price of medicines available in the market and if so, the time by which it is likely to be done and if not, the reasons there for?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND

(a) to (d): All the medicines specified in the National List of Essential Medicines, 2011 (NLEM, 2011) have been included in Schedule 1 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) which contains 348 drugs covering 680 formulations which also include some drugs for cancer and antibiotics. National Pharmaceutical Pricing Authority(NPPA) has notified prices of 440 scheduled formulations upto 30.6.2014. Significant reduction in prices have been effected on the medicines notified under DPCO, 2013 as compared to the highest price prevalent prior to that which differs from formulation to formulation.

National Pharmaceutical Pricing Authority (NPPA), an independent body of experts under this Department, has been delegated the power under DPCO, 2013 to fix the ceiling price or retail price of any drug. NPPA has also fixed the prices of anti-diabetic and cardio vascular medicines in respect of 108 non-scheduled formulations on 10.7.2014.

(e) & (f): NPPA fixes the prices of scheduled medicines as per the provisions /methodology provided in DPCO, 2013 based on market based data.

Question No. 1702
Answered on 22.07.2014

PRICE RISE BY PHARMA INDUSTRY

1702 Shri B. S. YEDDYURAPPA

SHIVAJI ADHALRAO PATIL

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the pharma industry has been increasing prices of medicines upto2% annually in contravention of the government policy;

(b) if so, the details thereof and the reaction of the Government thereto;

© whether the Government has delegated powers regarding revision of the Prices of drugs to National Pharmaceutical Pricing Authority (NPPA); and

(d) if so, the details thereof and the stepstaken by the Government to control theprices of drugs?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND)

(A) & (b): As per provisions of para 16(2)of Drugs (Prices Control) Order, 2013 (DPCO, 2013) the manufacturer may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale Price Index (WPI) with respect to previous calendar year and no prior approval of the Government in this regard shall be required. As regards, non-scheduled formulations, no manufacturer is authorized to increase the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. NPPA regularly monitors the prices of both scheduled and non-scheduled formulations as per provisions laid down in the DPCO, 2013

(c) & (d): Yes, Sir. NPPA, an independent body of experts under this Department has been delegated the power under DPCO, 2013 to fix the ceiling price or retail price of any drug. As per delegated powers, NPPAhas notified the ceiling prices in respect of 440 medicines upto 30thJune, 2014 out of total 680 NLEM medicines under scheduled category of DPCO, 2013. Further, NPPA has also fixed the prices of anti-diabetic and cardiovascular in respect of 108 non-scheduled formulations.

Question No. 1792
Answered on 22.07.2014

DRUG POLICY TO REGULATE PRICES OF DRUGS

1792 Smt. GEETHA KOTHAPALLI

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) Whether the Government proposes to formulate a new Drug Policy to regulate the prices of drugs in the country and to make it available at affordable prices to the common man ?

(b) If so, whether the Government proposes to have consultation with States in this regard; and

(c) If so, the details thereof and the time by which such new drug policy is likely to be formulated

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI NIHAL CHAND)

(a) The National Pharmaceutical Pricing Policy (NPPP) was notified on 7th December, 2012 with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines-“essential medicines” at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-being for all. It aims to bring the prices of essential medicines, as listed under National List of Essential Medicines-2011, under price control.

At present, there is no proposal under consideration for formulating a new Drug Policy.

(b) and (c): In light of (a) does not arise.

Question No. 1795
Answered on 22.07.2014

OVERCHARGING BY PHARMACOMPANIES

1795 Shri RAMSINH PATALYABHAI RATHWA

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:-

(a) whether the Government is aware that many Pharmaceutical Companies have sold medicines to the consumers at higher prices than the prices fixed by the Government/National Pharmaceutical Pricing Authority (NPPA);

(b) if so, the names of such companies and the time since when such companies have been overcharging along with the action taken thereon so far, company-wise;

(c) whether the Government proposes to recover the excess money charged by them along with penalty;

(d) if so, the details thereof and the present status of the process of recovery and the penalty from the guilty companies along with the manner in which consumers would be compensated for the loss suffered; and

(E) the companies which have been issued notices till date and the guide lines issued by the NPPA in recent past to address the issue?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND)

(a) & (b): There are a number of cases where pharmaceutical companies have been found to be selling some of their medicines to the consumers at a price higher than the price notified by National Pharmaceutical Pricing Authority (NPPA). Since inception of NPPA in August 1997, there are 1040 cases as on 30.06.2014 where demand notices have been issued by NPPA to the pharmaceutical companies amounting to Rs.3603.04 Crore for selling the medicines at a price higher than the price fixed by NPPA. The hard copy of the list of 1040 overcharging cases is very voluminous running into several pages and hence not provided with the reply. The same has been made available on the website of NPPA i.e. Www.nppaindia.nic.in. (c & d) In confirmed cases of overcharging, the excess amount charged by selling medicines at higher price than the price fixed by NPPA, including interest thereon, is recovered from the pharmaceutical companies. Till 30.06.2014, an amount of Rs.341.11 Crore has been realized.

The amount recovered from the pharmaceuticals companies for overcharging is deposited in the Consolidated Fund of India. The detection of overcharging cases acts as a deterrent to the pharmaceutical companies to charge higher prices from the consumer and it ensures availability of medicines to the consumers at reasonable price.

(e): Two internal guidelines have been brought out on processing the price violation / overcharging cases. Guideline No.1/2012 dated 04.10.2012 is with regard to the “price violation cases” which are to be referred to concerned State Drug Controller for prosecution under para 8 of DPCO, 1995. Guideline No.2/2012 dated 09.10.2012 is regarding dealing with “Overcharging and Without Price Approval cases”. Subsequently an amendment to internal guideline no.2/2012 was also issued by NPPA on 08.10.2013. The main object of issuing

the guidelines was to bring clarity, consistency and transparency in dealing with overcharging / price violation cases expeditiously.

RAJYA SABHA

Question No. 3266

Answered on 08.08.2014

IMPACT OF NEW DRUGS (PRICES CONTROL) ORDER

3266 Shri Palvai Govardhan Reddy

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:
(a) whether it is a fact that a new Drugs (Prices Control) Order was notified recently;
(b) whether any assessment has been made to find out the impact of the above Order on pharma companies;

(C) whether it is a fact that due to depleted profits many pharma companies are forced to close their establishments; and

(d) if so, how Government looks at it and the alternative steps proposed to protect pharma companies, particularly smaller companies?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI NIHAL CHAND)

(a) Pursuant to the announcement of National Pharmaceutical Pricing Policy (NPPP), 2012, the Government has notified Drug (Price Control) Order, 2013 (DPCO, 2013) on 15.05.2013 in supersession of DPCO, 1995. All the medicines specified in the National List of Essential Medicines (NLEM), 2011 have been included in the first schedule of DPCO, 2013 and brought under price control.

(b) Out of total 680 National List of Essential Medicines (NLEM) under scheduled category of DPCO, 2013, National Pharmaceuticals Pricing Authority (NPPA) has already notified the ceiling prices in respect of 444 medicines up to 10.07.2014 under provisions of the said order. Significant reduction in prices has been effected on the medicines notified under DPCO, 2013 as compared to the highest price prevalent prior to that, as per details mentioned in table below:
% Reduction with respect to highest Price to Retailer No. of Drugs
0<=5% 35
5<=10% 41
10<=15% 50
15<=20% 40
20<=25% 60
25<=30% 43
30<=35% 27
35<=40% 34
Above 40% 114
Total 444

In addition to above, NPPA has fixed prices of 108 non-scheduled formulations under DPCO, 2012.

© and (d) : The objective of National Pharmaceuticals Pricing Policy (NPPP)-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required Medicines - “essential medicines” at reasonable Prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well-being for all.

Question No. 3267

Answered on 08.08.2014

ACTIVE PHARMACEUTICAL INGREDIENT

3267 SHRI A.W. RABI BERNARD

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

(a) whether Government intends to revive country's Active Pharmaceutical Ingredient (API) by formulating a separate policy which will promote the industry internationally apart from catering the domestic market;

(b) if so, the details thereof;

(c) Whether the new policy will address the concerns of bulk drug manufacturing by way of incentives and creating infrastructure through bulk drug parks etc.; And

(d) If so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI NIHAL CHAND)

(a) Yes, Sir

(b) to (d) A Committee of Secretaries under the Chairmanship of Secretary, Department of Health Research with Member Secretary, National Manufacturing Competitiveness Council (NMCC), Secretary, Department of Pharmaceuticals, Secretary, Department of Health, Secretary, Department of Commerce, Secretary, Deportment of Industrial Policy & Promotion as members has been constituted to study and identify the Active Pharmaceutical Ingredients (APIs) of critical importance and to workout a package of interventions/concessions required to build domestic production capabilities, and examine the cost implication. The report of the said Committee is awaited.

Question No. 3271
Answered on 08.08.2014
RISE IN PRICE OF NON SCHEDULED DRUGS

3271 SHRI R. LAKSHMANAN
Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:
(a) whether Government has come across any instances of increase in price of non-scheduled drugs beyond 10 per cent per annum;
(b) if so, the details of the drugs and their manufacturers; and
(c) the details of the action taken by Government in this regard?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND)

(a) to (c): Para 20 of Drugs (Prices control) Order, 2013 (DPCO, 2013) provides that no manufacturer shall increase the maximum retail price of a non-scheduled drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, such manufacturer shall be liable to reduce the same to the level of ten percent of maximum retail price for next twelve months. National Pharmaceutical Pricing Authority (NPPA) presently monitors prices of non-scheduled formulations based on random test samples purchased from different parts of the country for its monitoring and enforcement activities. So far, NPPA has not come across any instance of price increase beyond ten per cent in respect of non scheduled formulations based on the random sample tests carried out by it.

Question No. 2487
Answered on 01.08.2014

FIXATION OF PRICE OF ANTI DIABETIC AND ANTI CARDIAC DRUGS

2487 Shri P. Bhattacharya

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:
(a) whether National Pharmaceutical Pricing Authority (NPPA) has decided to fix prices of 50 anti-diabetic and cardiac medicines, if so the details thereof;

(b) to what extent, it will bring down the prices of these drugs;
(c) whether they will be capped with medicines in essential list; and
(d) if so, the reaction of the pharmaceutical industry thereto?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI NIHAL CHAND)

(a) & (b): The National Pharmaceutical Pricing Authority (NPPA) has capped MRP in respect of 108 non-scheduled formulations related to diabetes and cardiovascular under para 19 of Drugs (Prices Control) Order, 2013 (DPCO, 2013). As per the prices notified for these medicines, reduction in prices has been worked out in all these cases ranging 0.16% to 79.33% from the highest price brand available in the market.

(c): These 108 formulations are not part of the National List of Essential Medicines and, as such, fall under the category of non-scheduled formulations under DPCO, 2013.

(D): Some Pharma Associations have made representations for withdrawal of the said notifications on the ground that the action runs contrary to the NPPP, 2012 and DPCO, 2013. One of the Pharma Associations has filed a Writ Petition in the Bombay High Court which is at admission stage.

Question No. 2493
Answered on 01.08.2014

SELLING OF MEDICINES BY MNCS AT HIGH PRICE

2493 SHRI NARESH AGRAWAL

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government is aware of the fact that Multi National Companies (MNCs) are selling medicines listed under National Essential Medicine List at exorbitant price;

(b) if so, the details thereof; and
(c) the remedial measures action taken by the Government in this regard, if not, the reasons thereofor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI NIHAL CHAND)

(A) to (c): All the medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the Schedule I of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) and brought under price control. The National Pharmaceutical Pricing Authority (NPPA) fixes/revises the prices of scheduled medicines as per the provisions of DPCO, 2013. No person is authorized to sell any scheduled formulation (medicine) to a consumer at a price exceeding the price notified by the NPPA. Whenever any case of overcharging is brought to the notice of NPPA or is detected by NPPA during its monitoring and enforcement activities, necessary action is taken for initiating recovery proceedings under the DPCO, 2013. NPPA has initiated action for overcharging in respect of 451 formulations under DPCO, 2013 which inter-alia, also includes formulations manufactured/marketed by Multi National Companies (MNCs). Further, NPPA has issued demand in two cases for an amount of Rs.54.03. crore and has recovered Rs.54.01 crore which includes suo-moto payment in four cases till 30.6.2014 under DPCO, 2013. However, no separate record in this regard for MNCs is being maintained by NPPA.