Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 26 Apr.- May.- Jun. 2015

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 26th issue of Pharma Web Newsletter for Apr – June 2015. Our "Pharma Knowledge and Training Institute" (Finishing School) is conducting "Industrial Training programme" for fresh Pharma graduates during September/October this year for a period of one month . The subject is "QC & QA management". This is the 3rd training programme. We will be taking 25 to 30 graduates of pharmacy for this training programme. The colleges of Pharmacy in Tamilnadu may utilise this opportunity and depute fresh graduates. We will be giving actual industrial training and placements for the trainees also.

In this issue we are publishing the following articles

a. Production Planning and Control **by Mr. D. Sathesh Kumar, Senior Manager, Production, M/s. Fourrts (India), Laboratories Pvt. Ltd.,**
b. Quality by Design (QBD) ICH Q8 – Pharmaceutical Development **by Dr. Ramkumar. P, Head, Research & Development, M/s. Fourrts (India), Laboratories Pvt. Ltd.,**

We are also publishing various notifications issued by Government of India, Ministry of Health & Family Welfare under the provisions of Drugs & cosmetics Act & Rules.

We are happy to publish the important and relevant Parliament Questions & Answers pertaining to Drugs & Cosmetics items, during the year 2014 – 2015 for the benefit the readers

Important news items appeared in national News papers on various technical issues are also published in this issue.

Hope this Newsletter will benefit our Pharma professionals.. Any suggestions to improve our news letter are welcome.

With Best Regards

R. Narayanaswamy

Chief Editor

ARTICLES

PRODUCTION PLANNING AND CONTROL

By

D. Sathesh Kumar,

Senior Manager, Production, M/s. Fourrts (India) Laboratories Pvt. Ltd,
(Lecture Delivered on 7th October 2014, during the Training Programme on Production conducted by TNPSWT)

PRODUCTION

- Product are manufactured by the transformation of Raw material in to Finished product

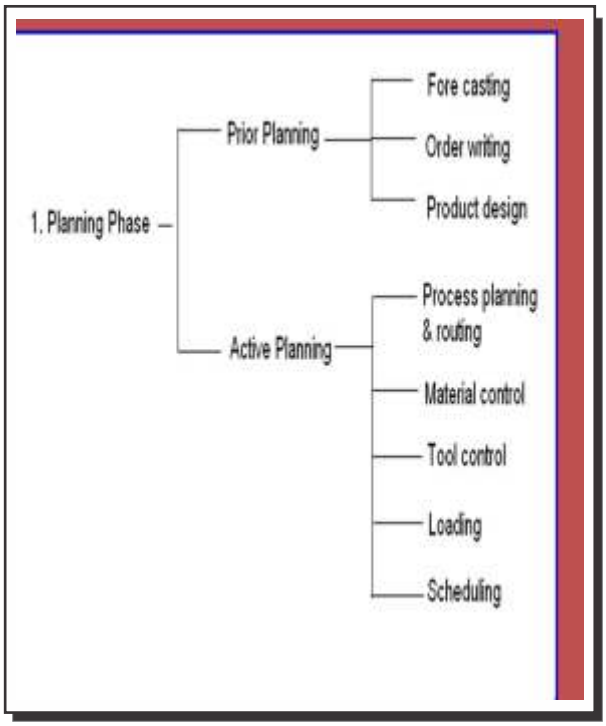
PLANNING

- Planning looks ahead, anticipates possible difficulties and decides in advance as to how the production, best be carried out.

CONTROL

- Control phase makes sure that the programmed production is constantly maintained.

- PPC system has many functions some before the arrival of raw materials, tools and others while the raw material under goes processing.



- 2.Action Phase ——→ Dispatching
- 3. Control Phase
  - Progress reporting → Data process
  - Corrective action
    - Expediting
    - Re planning

A. Forecasting:

- Estimation of type, quantity and quality of future work.

B. Order writing:

- Giving authority to one or more person to undertake a particular job.

C. Product Design:

- Collection of information regarding specification, bill of material, drawing etc..

D. Process Planning of routing:

- Finding the most economical process of doing a work and deciding how and where the work will be done.

E. Material control:

- It involves determining the required and control of materials.

F. Tool control :

- It involves determining the required and control of tool used.

G. Loading:

- Assignment of work to manpower machinery etc..

H. Scheduling:

- It is the time phase of loading and determines when and in what sequence the work will be carried out.
- It fixes the starting and the finishing time for the job.

I- Dispatching:

- It is the transition from planning to action phase.
- In this phase the worker is ordered to start the actual work.

Progress reporting

i) Data regarding the job progress is collected.

ii) It is interpreted by comparison with the preset level of performance.

Corrective action

Expediting means taking action if the progress reporting –indicates a deviation of the plan from the originally set target.

Re-planning:

- Re planning of the whole affair becomes essential – in case expediting fails to bring deviation plan to its actual path.

CONTINUOUS AND INTERMITTENT PRODUCTION

A. Continuous production involves a continuous or almost continuous physical flow of material. It makes use of special purpose M/c and produces standard items in large quantities.

E.g. Chemical processing
Cigarette mfg
Cement mfg

B. Intermittent or Interrupted flow of material.

- Makes use of general purpose M/c and produces products different in nature and in small quantities.

It in divided in to Batch production & Job production.

a) Mass and flow line production.

- Mfg in large scale – employing specialized M/c and processes. – A/C , TV set , Motor cycles come under flow productions.

b) Continuous (or) Process production.

e.g.) Petrol, chemicals etc..

All product undergo same process. RM enters one point of leaves as finish product.

Batch production

- Common type of production are mfd in batches as per specific order procured.
- Drugs, clothes, Paints (etc)
- Division of labors is possible.
- Proper maintenance of equipment and machinery is essential.
- Process and product planning is done for each batch.
- Expediting and corrective action are very essential.
- A good production control system must be developed.

Job production

Production of special purpose equipment

- A special heat treatment furnace.
- A large turbo generator.
- A special electronic m/c equipment.

Forecasting

- Forecasting mean estimation of type , quantity of quality and future work (eg) sales.
- The sales forecast which enables to determine production quantities , Labor, Equipment and raw material requirement.
- A sales forecast should be
  - accurate.
  - simple
  - economical

- Forecasting is necessary because

i) Determine volume of production and production rate.

ii) Basic of production budget, labour budget, material budget.

Sales Forecasting

4 basic element of economic data.

i) Trends

ii) Cycles

iii) Seasonal variations

iv) Irregular variations

1) Trends - are long term , long range movement of a series of economic data.

2) Cycles – are shorter duration and featured by alternative periods of expansion and contraction.

3) Seasonal variations – occur within a certain period of year and recur about it same time.

4) Irregular variations are the result of unforeseen (or) non-recurring events that have an economic influence.

Process planning

- Process planning is determining the most economical method of performing an operation or activity.
- It develops the broad plan of manufacturing the product.

Information required to process planning.

1. Quantity of work to be done along with product specification.
2. Quality of work to be completed.
3. Availability of equipment , tools and personnel.
4. Sequence of operation.
5. Names of equipment.
6. Standard time.
7. When the operation will be performed.

A. Selection of process

a) Current production commitments

b) Delivery date

c) Quantity to be produced

d) Quality standards

The choice of making the product on particular m/c , material etc..

B. Selection of material.

- Raw materials / Packing materials

C. Selection of special attachments - is necessary

ECONOMIC BATCH QUANTITY

- If the quantity is very large they cannot be manufactured in a single lot.
- Under such conditions how best it can be produced in a single lot which is most economical.

Point to be noted for economical batch size.

- Working capital investment in materials and labors.
- Cost of handling of storing materials etc..

TOOL CONTROL

- Determines tool requirements
- Procuring necessary tools
- Controlling / maintaining the tools

(e.g.) punches , change part – blister / strip

LOADING

- Loading means assignment of work to manpower, machinery – without specifying when the work is to be done.
- The objective of loading function is to maintain an up-to date picture of the available capacity in the plant.

Aims of loading

1. To check the feasibility of production process
2. To assist in efficiency planning of new work
3. To assist in balancing the plant to the existing load.
4. To assist in fixing delivery date

SCHEDULING

- It means when and in what sequence work will be done.
- It deals with orders and machines it determines which will be taken up on which m/c and in which dept. by which operator.

(e.g.) A production schedule similar to a railway time table.

Factors affecting scheduling

A) External factors

a) customer demand

b) customer delivery date.

c) Stock of goods already lying with the dealers.

B) Internal Factors

a) stock of finished goods with the finished goods store.

b) Time interval to process finished goods.

c) Availability of equipment and machinery their total capacity of specification.

d) Availability of materials

e) Availability of man power

f) Additional manufacturing facilities if required.

Manufacturing schedule

- A master schedules is too general to permit day-to-day planning by line supervisors.
- Weekly departmental manufacturing schedule supplement the master schedule.
- It must be made to reflect the immediate factors.

1. Tool down time (broken in workout)
2. Equipment down time for repair.
3. Shortage and defects in materials
4. Absenteeism
5. Cancellation and rush orders.

- The control of production is necessary to be sure that the production schedule are being met and the job will be delivered as per pre-decided plans.
- Production control involves an information feedback mechanism and a system of corrective action

The production control group

- Receives work progress reports
- Compares them with the schedule plan
- Removes causes of delays in production
- Modifies the schedule or plant capacity
- Expedites the work.

DISPATCHING

Executing the planning function.

Procedure

- Store issue order
- Toot order
- Job order
- Time ticket
- Inspection order
- Move order

Centralized and decentralized dispatches

Level of dispatch:

- Plant manage level
- Shop floor head level.
- Shop floor supervisor level – it is the best

Progress control

- Once the actual production has started it becomes essential to keep on eye at the progress of the work so that if required timely corrective action can be taken.
- Progress control means – trying to achieve the standard.
- Progress control should be such that it furnishes timely, adequate and accurate information about the progress made, delays and under-or-over loading .

a) Setting up a system to watch and record the progress of the operating facility.
b) Making a report.
c) Taking corrective action, if necessary.

Methods to take corrective action

1. Schedule flexibility
2. Capacity modification
3. Changing the number of working hour
4. Schedule modification.

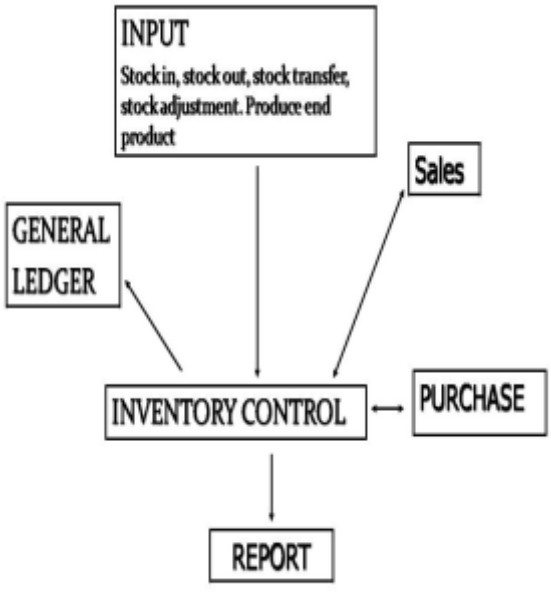
Follow up – Expediting

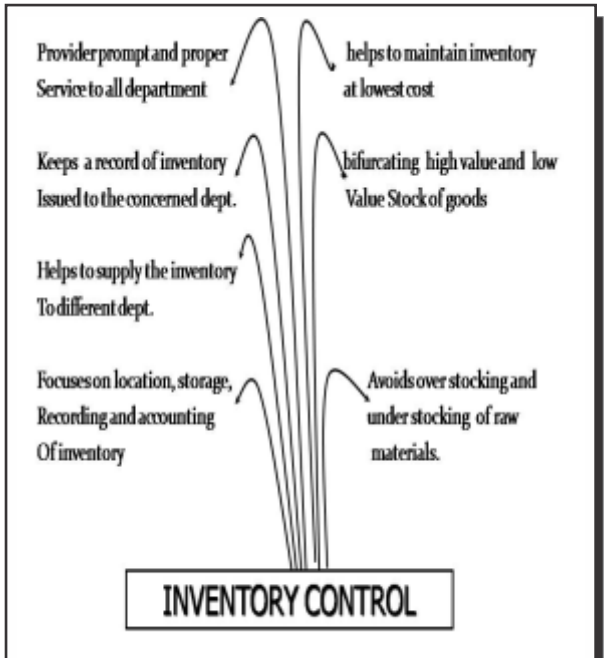
This regulates the progress of materials and components through production process.

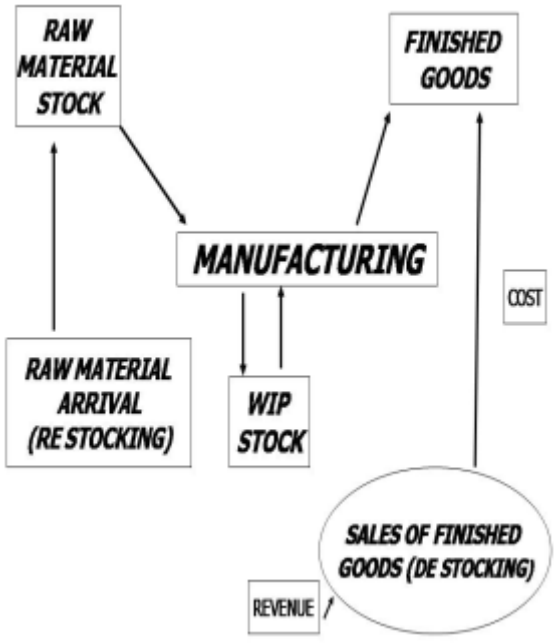
INVENTORY CONTROL

How to control inventory ?

- Is to learn how to effectively manage the inventory so you have what your customer need and want without having much excess.
- Business success comes when you known what and how much to order, when to order.
- Keeping an accurate count of your products, knowing how to handle excess and shortages.







- Some of the areas to exercise inventory control are-

1. Raw material availability

There must be enough RM inventory on hand to ensure that jobs are launched in production process in a timely manner.

But not so much that the company inventory in an inordinate amount of inventory.

Can opt for JIT delivery

2. Finished goods availability

To have high stock of FG inventory the pricing of the product may be more.

We can use just in time mfg system

3. Work in progress

It in possible to reduce the amount of inventory that in being worked on production process. Which further reduces the inventory investment.

4. Recorder point

- A key part of inventory control is that deciding Upon the best inventory level at which to re-order additional inventory.
- If reorder level is set low – it keeps inventory is kept low but increase the risk of stock out.
- If re-order level is set high- the inventory will be very high.

Alternative method is,

material requirement planning system –to order only enough inventory for expected production levels.

5. Bottle neck enhancement

Placing an inventory buffer if needed. To overcome bottle neck in production process.

QUALITY BY DESIGN (QBD)
ICH Q8 – PHARMACEUTICAL DEVELOPMENT

By

Dr. Ramkumar. P

Head, Research & Development, M/s. Fourrts (India) Laboratories Pvt. Ltd,
(Lecture Delivered on 7th October 2014, during the Training Program on Production, conducted by TNPSWT)

Aim Of Pharmaceutical Development ..

To design a quality product and its manufacturing process ..

↓

..to consistently deliver the intended performance of the product.

Quality defined..

- **Quality** - Desired characteristics of product to ensure Safety & Efficacy
- **Good pharmaceutical quality** represents an acceptably low risk of failing to achieve the desired clinical attributes.

Quality

- Testing alone cannot ensure product quality
- Quality should be built in the product

QbD is ..

- Development with consistent adherence to predefined quality
- Framework for transfer of Product knowledge & Process understanding from development to manufacture
- Manufacture to attain predefined quality of product

QbD is ..

QbD means that product and process performance characteristics are :-

- scientifically designed to meet specific objectives,
- not merely empirically derived from performance of test batches

Objective of the guidance

- Provides comprehensive understanding of product development for reviewers/inspectors
- Enhances scientific understanding of processes leading to regulatory flexibility
- Part of Common Technical Document (CTD) format. (Section 3.2.P.2 of module 3)

Scope of Pharmaceutical development work

- Design of experiments should be consistent with the intended scientific purpose
- Focus is on level of knowledge gained, not on volume of data generation
- Provides the basis for science based submissions and regulatory evaluations

Purpose of Pharmaceutical Development:

-To design a quality product

-To optimize the manufacturing process to ensure product consistency

-Helps to establish

- -Quality by design
- -Specifications
- -Manufacturing controls
- -Design space

QbD

- What is QbD?
- Integration of prior knowledge and pharmaceutical development
- Creating regulatory flexibility via design space

CMC Submission Review

* Chemistry, manufacturing, and controls (CMC) information must be submitted to support the approval of an abbreviated new drug application (ANDA).

QbD - Design Space

During Pharmaceutical Development (Q8)

- Identify Critical Quality Attributes (CQAs)
- Range for CQAs
- Changes in CQA limits – within and out of design space
- Change management – Q10

Design Space:

- The 'multidimensional combination and interaction' of input variables (material attributes) and process parameters that have been demonstrated to provide quality assurance
- Flexibility of working within design space without regulatory hassles

Design Space:

- Post approval changes outside the design space
- Support data to be generated by the applicant subject to approval by regulatory

QbD - Pharmaceutical Development (ICH Q8)

- Opportunity to present the knowledge through scientific approaches
- **Pharmaceutical Development through** "Product Validation"

QbD

Q8 - Product quality and performance achieved and assured by design of effective and efficient manufacturing processes.

Q9 – Risk based approach for process improvements and real time QC

Q10 – Life cycle management for process and system control

Incremental steps

Pharmaceutical Development (Q8)

Past: Data transfer / Variable output

Present: Knowledge transfer / Science based / Consistent output

Quality Risk Management (Q9)

Past: Used, however poorly defined

Present: Opportunity to use structured process thinking

Pharmaceutical Quality Systems (Q10)

Past: GMP checklist

Future: Quality Systems across product life cycle

QbD - Pharmaceutical Development (ICH Q8)

- Defining Quality Target Product Profile (QTPP)
- Identifying potential CQAs
- Determine CQAs
- Select appropriate manufacturing process
- Define a Control Strategy

Q8(R2): Structure – Parent Guideline

Parent guideline: Structured according to CTD-Q

Pharmaceutical development: Introduction

- Components of the drug product
  - Drug substance – Excipients
- Drug product
  - Formulation development
  - Overages
  - Physicochemical and biological properties

Q8(R2): Structure – Parent Guideline

Pharmaceutical development: Introduction

- Manufacturing process development
- Container closure system
- Microbiological attributes
- Compatibility

- Glossary

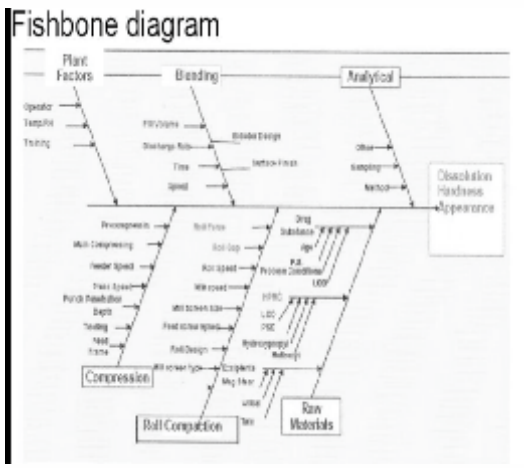
Q8(R2): Structure – Annex

- Introduction
- Elements of Pharmaceutical Development
  - Quality Target Product Profile
  - Critical Quality Attributes
  - Risk Assessment: Linking Material Attributes and Process
  - Parameters to Drug Product CQAs
  - Design Space
  - Control Strategy
  - Product Lifecycle Management and Continual Improvement

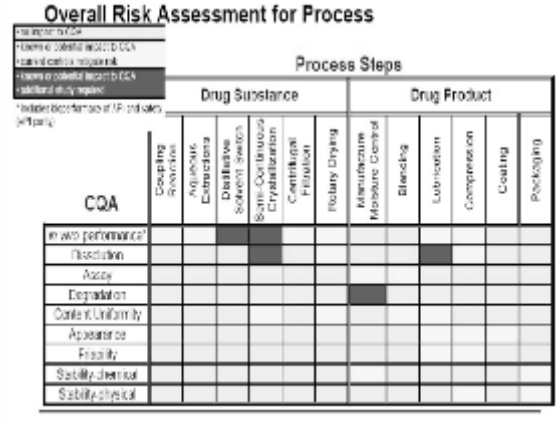
Q8(R2): Structure – Annex

- Submission CTD-Q
  - Quality Risk Management and Product and Process Development
  - Design Space
  - Control Strategy
  - Drug Substance related Information
- Glossary
- Appendix 1/2

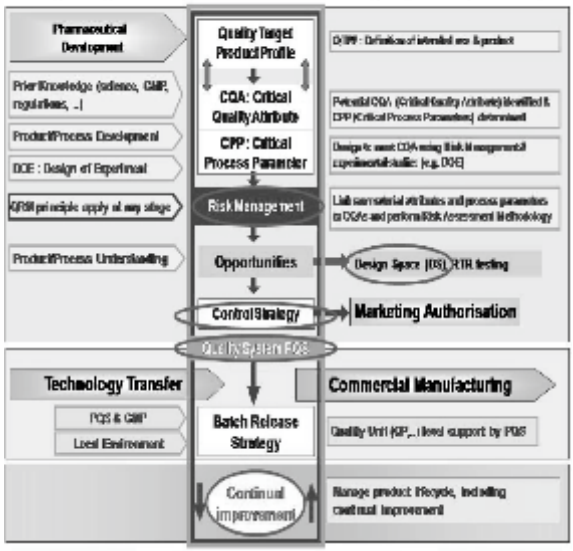
Fishbone diagram



Overall Risk Assessment for Process



Key Steps for a product under Quality by Design (QbD)



ICH Q8, Q9 & Q10 A real opportunity

Benefit of a New Paradigm

A life cycle approach: A focus investment during the development with the benefit at the manufacturing

- Process Understanding
- Process Capability and Robustness
  - Increase confidence between industry and regulators
- Continuous improvement changes
- Facilitate innovation and new technology (RMM, PAT,...)
- Increased flexibility to implement

QbD - Pharmaceutical Development (ICH Q8)

- QbD – Implementation, Continuous improvement, & Risk management for
  - Lower need of regulatory oversight
  - Leading to cGMP compliance

Benefits of Quality by design concept:

- Risk based regulatory decisions
- Manufacture process improvements within design space described in dossier, without regulatory approvals
- Reduction in post-approval submissions
- Real time quality control
- Reduction of end product release testing

QbD - Quality System Approach

- Risk- and science based concepts
- Continuous improvement concepts
- Designing quality into the process and product

QbD - Quality System Approach

- Designing "fit for purpose" concept into product
- Elimination of non-scientific controls with no added value for the product

QbD – Benefits ..

Benefits to Industry

- Clearer, better understood regulations
- Flexibility to determine suitable methods to achieve quality and to implement innovations
- Science based inspections

Tools for generating data:

-Experimental Designs (2 x 2, multivariate etc.,)

-Process Analytical Technology (PAT)

-Knowledge from public domain/previous experience

-Critical review of Research data

-Fish-Bone analysis

-Failure mode analysis

-Cause-effect relationships

Drug Substance:

Physico-chemical/biological properties which may affect manufacturability to be characterized

-Solid state properties (crystal habit, PSD, Polymorphism, flow properties, density etc.,)

-Solubility data (PSD profile, pH-profile)

-Permeability data

-Stability data

-Compatibility with additives

-Set the specifications based on *"ICH Q6A Specifications: Test procedures and acceptance criteria for New drug substances and New drug products"*

Excipients (including processing aids):

-Characterization

-Basis for selection/ Discussion on its function in the formulation

-Optimization of concentrations

-Evaluation of its influence on drug stability, performance, bio availability etc.,

-Compatibility studies (with drug, and with other excipients where relevant)

-To discuss ability to perform their intended function throughout product shelf life

-Information to support safety of excipients

Drug Product (Formulation Development):

-Identification of critical quality attributes

-Should map the evolution of the final design and process starting from initial concept

-Choice of excipients

-Optimization of excipient concentrations

-IVIVC wherever relevant

-BA/BE studies wherever relevant

-Overages justification

-Stability data evaluation

-Specification setting based on *"ICH Q6A Specifications: Test procedures and acceptance criteria for New drug substances and New drug products"*

-Describe the basis for specification acceptance criteria

Manufacturing Process Development:

-Basis for selection of the process

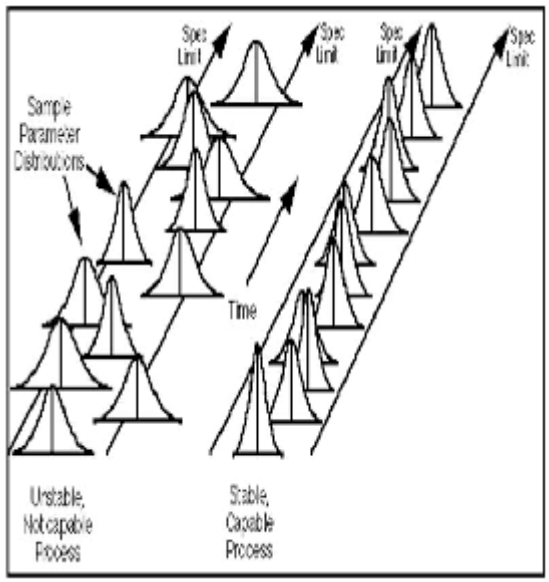
-Identification of critical process steps and their attributes

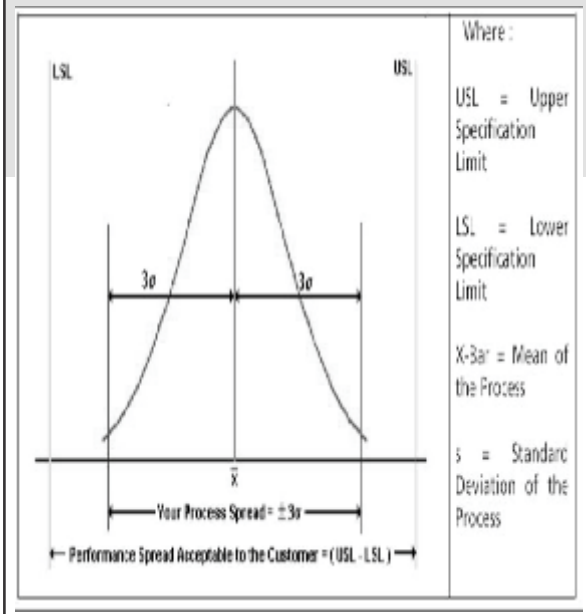
-Evaluation of each process step on product quality attributes

-Process capability index

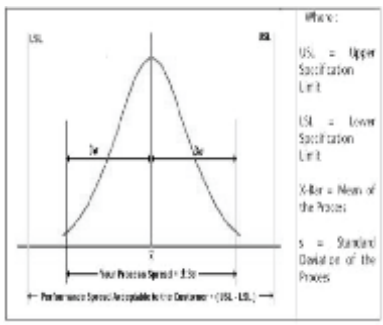
-Process robustness

-Ability of process to tolerate material/process parameter variability without impacting quality of drug product





INDEX	ESTIMATED EQUATION	USAGE
Cp	(USL - LSL) / 6s	Process Capability for two - sided specification limit, irrespective of process center.
Cpu	(USL - X-Bar) / 3s	Process Capability relative to upper specification limit.
Cpl	(X-Bar - LSL) / 3s	Process Capability relative to lower specification limit.
Cpk	Min. of (Cpu , Cpl) or Distance between mean of the process and the closest spec. limit / 0.5 of the process variability.	Process Capability for two - sided specification limit accounting for process centering.



Process capability Index:

An index to assess the repeatability and consistency of the process

Cp=(USL-LSL)/6 sigma (1 sigma = 1 std deviation)

Cp<1 means the process variation exceeds specification limits

Cp=1 means process variation meets specification

Cp>1 means process variation is less than specification

Provided mean is at the center!

Process capability Index:

Cpk (lowest of either of two below) measures process variation with respect to mean shift also

Cpk(l)=(X-LSL)/3 sigma

Cpk(u)=(USL-X)/3 sigma and X is process mean

Container closure system:

- Choice and rationale for primary packing selection
- Consideration based on intended usage of drug product
- Discuss WVTR studies
- Compatibility of components with formulation
- Performance/integrity studies
- Stability data generation

Microbiological Attributes:

- Product microbiological attributes to be discussed
- Rationale for performing/not performing microbial limit testing to be discussed
- Selection of preservative system
- Effectiveness of preservative system
  - Chemical testing
  - Efficacy testing

Microbiological Attributes: (Ctd..)

- Stability monitoring of preservative
- For sterile products, integrity of container closure system
- Justification of preservative concentration from safety/efficacy perspective

QbD – Benefits ..

Benefits to Regulators

- Efficient use of resources at review and inspections
- Mutual recognition of inspection reports of low risk products, processes and companies

QbD – Benefits ..

Benefits to Patients

- Quality medicines – "fit for purpose"
- Improved safety for patient – based on risk assessments and scientific judgment.

NDA vs. ANDA Review Process

Brand Name Drug NDA Requirements	Generic Drug ANDA Requirements
1. Chemistry	1. Chemistry
2. Manufacturing	2. Manufacturing
3. Controls	3. Controls
4. Labeling	4. Labeling
5. Testing	5. Testing
6. Animal Studies	
7. Clinical Studies	6. Bioequivalence
8. Bioavailability	

505(b)(i)←505(b)(ii)→ 505(j)

Various Divisions involved in a generic drug approval process

- Labeling
- Chemistry/Microbiology
- Bioequivalence
- Legal

Chemistry

- Components and composition
- Manufacturing and controls
- Batch formulation and records
- Description of facilities
- Specs and tests
- Packaging
- Stability

Manufacturing Compliance Programs

- Purpose - To assure quality of marketed drug products
- Mechanisms - Product Testing
  - Surveillance
  - Manufacturing/Testing plant inspections
  - Assess firm's compliance with good manufacturing processes

Format and Submission

How should QbR ANDAs be submitted?

OGD's QbR was designed with the expectation that ANDA applications would be organized..

..according to the Common Technical Document (CTD) format, a submission format adopted by multiple regulatory bodies including FDA.

Generic firms are strongly recommended to submit their ANDAs in the CTD format (either eCTD or paper) to facilitate implementation of the QbR.

Format and Submission

What is a QOS?

The Quality Overall Summary (QOS) is the part of the CTD format that provides a summary of the CMC aspects of the application. It is an important tool to make the QbR review process more efficient.

The ANDA Checklist for completeness and acceptability of an application for filing can be found on the OGD web page: http://www.fda.gov/cder/ogd/anda_checklist.pdf.

FROM BENCH TO BEDSIDE - PERCEPTIONAL CHANGE IN A PHARMACIST'S ROLE

By

Mr.R.Arun,

Nandha College of Pharmacy, Erode

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

INTRODUCTION:

Pharmacist "Back bone of medical field". Yes it is true, Doctors give life and health to the patient by applying their theoretical and practical knowledge with the help of medicine. But the pharmacist is the authorized and responsible person in manufacturing and dispensing the medicine to the patients in good quality, without drug it is highly difficult to fulfill the patient's medical requirements by the doctor, in this way the pharmacist act as a back bone to support the entire medical field. This essay will explain the various professional changes in pharmacist from bench to bedside.

PHARMACIST IN RESEARCH LAB:

From bench to bedside- It mean exactly what it implies the moment of laboratory finding (the bench) to clinical practice (the bedside). Pharmacist involved each and every steps in the development of new drugs as like parent who develop their offspring as a good social being. In designing and development of new drug the pharmacist job starts with an unrecognized molecule and finally end as a good drug with required potency with minimum side effect. We can compare research pharmacist as a sculptor- "who changes rocks into beautiful statue" In the process of drug research the molecule must undergo various departments of specific research pharmacist.

For example: Consider a semi synthetic drug, the extract is obtained from natural source with the help of department of pharmacognosy, separation is carried out with the help of analysis department. Structural elucidation and Structural activity relationship are done with the help of Chemistry department to improve the potency and to minimize the side effect of the drug. Pharmacologist involve in preclinical studies and also in clinical trial, Pharmaceutics department show their talent in formulation of this particular molecule into suitable dosage form and proper packing criteria, and finally handed over to the Clinical Pharmacist, who is responsible for providing advice about the drug to the patient and also involved in clinical trial and post marketing surveillance.

INDUSTRIAL PHARMACIST:

After successful clinical trial with various groups of healthy and infected volunteer. The drug is ready for launching into market. The work of research Pharmacist partially came to an regarding this particular drug but their work may restart in case if they found and unwanted effect of drug in post marketing surveillance they will withdraw their product and will do further research to overcome this drawback.

In the next stage the entire responsibility reaches the hands of industrial pharmacist.

Departments in manufacturing unit – Production and quality control division. Thus in the production department , production manager must be a pharmacist, who is responsible for manufacturing bulk volume of various medicines in the optimized condition and the pharmacist in quality control department is responsible person to maintain the quality of medicine in the given standard and also responsible for checking the purity of raw materials. They will analyze the quality of drugs in each and every steps of manufacturing process.

PHARMACIST IN MARKETING:

As soon as the manufacturing process came to an end, the work of pharmacist in the event of marketing or promoting the drug to the proper physician will takes place. These Pharmacists are generally known as medical representatives. But now-a-days various other graduates are involving in this aspect of marketing, but any how the pharmacist is the proper person with adequate technical knowledge and skill to explain the doctor about the new product and suggest them to prescribe this medicine to patients.

PHARMACIST IN PATIRNT RELATION SET-UP:

Hospital pharmacist, clinical pharmacist and community pharmacist are the other important role of pharmacy profession. Last but not least, they are the persons with great quality of communication skill, patience, care, kindness, smiling face towards the patients. These groups of pharmacist will have direct contact with the patients. In-spite of various divisions in research sector their entire aim is to develop a new drug but in case of clinical oriented pharmacist,their mentality is highly differ from research pharmacist .The only aim of clinical oriented pharmacist is “patient care”

Hospital pharmacist are responsible for choosing, preparing and compounding (if not available),storing, therapeutic drug monitoring and dispensing the drug with proper instruction to the patient regarding the drug.

Clinical pharmacist also play an important role in maintaining the rational and appropriate use of medicine and also involved in monitoring the therapy course and the patient's compliance with therapy minimizing the expenditures for

pharmacological treatments and will act as a member of pharmacy therapeutic committee to frame the hospital formulary and other activities.

A community pharmacist is responsible for controlling, dispensing and distributing medicine. They work to legal and ethical guidelines to ensure the correct and safe supply of medical products to the general public. They are involved in maintaining and improving people's health by providing advice and information as well as supplying prescription medicines. A community pharmacist may perform clinical activities as well as a hospital practitioner.

CONCLUSION:

"Doctor gives life to the patient with the help of medicine

But the Pharmacist gives life to the medicine"

From bench to bedside Pharmacist shows lot of changes in their role as research pharmacist, industrial pharmacist and hospital pharmacist etc… In each role they have different ethics, mode of work, skill, working place, working style etc.. But In-spite of these difference they collectively have the common goal of "social welfare"

"Proud to be a pharmacist"

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th April, 2015

G.S.R. 289(E).—Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare vide number G.S.R. 176(E), dated the 11th March, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), 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 18th March, 2014;

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

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

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2015.

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

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

(i) in rule 74, after clause (o), the following clause shall be inserted, namely:—

"(p) No advertisement of the drugs specified in Schedule H, Schedule H1 and Schedule X shall be made except with the previous sanction of the Central Government.";

(ii) in rule 74A, after clause (h), the following clause shall be inserted, namely:—

"(i) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.";

(iii) in rule 74B, after clause (6), the following clause shall be inserted, namely:—

"(7) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.";

(iv) in rule 78, after clause (p), the following clause shall be inserted, namely:—

"(q) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.";

(v) in rule 78A, after clause (7), the following clause shall be inserted, namely:—

"(8) No advertisement of the drugs specified in Schedule H, Schedule H1 or Schedule X shall be made except with the previous sanction of the Central Government.".

[F. No. X-11014/3 /2012-DFQC]

K. L. SHARMA, Jt. Secy.

Note:- The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated the 3rd December, 1945 and last amended vide notification number G.S.R. 203 (E) dated the 18th March, 2015.

MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 25th March, 2015

G.S.R. 224(E).—In exercise of the powers conferred by section 9, read with section 76, of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely:—

1. (1) These rules may be called the Narcotic Drugs and Psychotropic Substances (Second Amendment) Rules, 2015.

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

2. In the Narcotic Drugs and Psychotropic Substances Rules, 1985 (hereinafter referred to as the said rules), for rule 53, the following rule shall be substituted, namely:—

"**53. General prohibition.**—Import into and export out of India of the narcotic drugs and psychotropic substances is prohibited except with an import certificate or export authorization issued under the provision of this Chapter.

Provided that import into India or export out of India of the narcotic drugs and psychotropic substances specified in Schedule I of these rules shall be for the purpose mentioned in Chapter VIIA.".

3. Rule 53A of the said rules shall be omitted.

4. In rule 56 of the said rules, —

(i) in sub-rule (1), the words "specified in the Schedule of the Act" shall be omitted;

(ii) for sub-rule (3) and sub-rule (4), the following sub-rules shall be substituted, namely:—

"(3) Every application for an import certificate shall be in such form and manner and provide such details as may be specified by the Narcotic Commissioner.

(4) A fee of rupees one thousand shall be paid to the Central Government alongwith the application under sub-rule (1) for issue of each import certificate under this rule.".

5. In rule 56 of the said rules,—

(i) sub-rule (3) shall be renumbered as sub-rule (1A) and before sub-rule (1A) so renumbered, the following sub-rule shall be inserted, namely: –

"(3) The Narcotics Commissioner shall issue or deny the import certificate referred to in sub-rule (1) of rule 55 within a period of twenty one working days from the date of receipt of an application completed in all respects and in case the import certificate is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.";

13881/GI/15-2

(ii) in sub-rule (1A), ----

(a) the words "referred to in sub-rule (1) of rule 55" shall be omitted;

(b) for the words "Collector of Customs", wherever they occur, the words "Commissioner of Customs" shall be substituted.

6. In rule 57 of the said rules, the words "specified in Schedule of the Act" shall be omitted.

7. In rule 58 of the said rules,—

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

"(1) No narcotic drug or psychotropic substance shall be exported out of India without an export authorization issued by the Issuing authority in respect of the consignment, in Form No. 5 appended to these rules.";

(ii) for sub-rule (3) and sub-rule (4), the following sub-rules shall be substituted, namely: —

"(3) Every application for an export authorization shall be in such form and manner and provide such details as may be specified by the Narcotic Commissioner.

(4) A fee of rupees one thousand shall be paid to the Central Government alongwith the application under sub-rule (1) for issue of each export authorization under this rule.".

8 In rule 59 of the said rules,—

(i) sub-rule (1) shall be renumbered as sub-rule (1A) and before sub-rule (1A) as renumbered, the following sub-rule shall be inserted, namely:

"(1) The Narcotics Commissioner shall issue or deny the export authorization referred to in sub-rule (1) of rule 58 within a period of twenty one working days from the date of receipt of an application completed in all respects and in case the export authorization is not issued within the stipulated time period or denied, the Narcotics Commissioner or any other officer authorised by him in this regard shall inform the applicant the reasons thereof.";

(ii) in sub-rule (1A),

(a) the words "referred to in sub-rule (1) of rule 58" shall be omitted;

(b) for the words "Collector of Customs", the words "Commissioner of Customs" shall be substituted.

9. In rule 60 of the said rules,—

(i) the words "specified in Schedule of the Act" shall be omitted;

(ii) for the words "Collector of Customs", the words "Commissioner of Customs" shall be substituted.

10. In rule 61 of the said rules,—

(i) for the words "Collector of Customs", the words "Commissioner of Customs" shall be substituted;

(ii) the words "specified in Schedule of the Act" shall be omitted.

11. In rule 62 of the said rules, for the words "Collector of Customs", wherever they occur, the words "Commissioner of Customs" shall be substituted.

12. For rule 64 of the said rules, the following rule shall be substituted, namely:—

"64. Manufacture of psychotropic substances.—(1) No person shall manufacture any of the psychotropic substances except in accordance with the conditions of a license granted under the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the 1945 rules) framed under the Drugs and Cosmetics Act, 1940 (23 of 1940), by an authority in-charge of Drugs Control in a State appointed by the State Government in this behalf:

Provided that a license to manufacture a psychotropic substance specified in Schedule I shall be issued only for the purposes mentioned in Chapter VIIA:

Provided further that the authority in charge of the drug control in a State shall consult the Narcotics Commissioner before issuing a license to manufacture a psychotropic substance specified in Schedule I.

(2) The authority in charge of drugs control in a State (hereinafter referred to as the Licensing Authority) shall consult the Narcotics Commissioner with regard to the assessed annual requirements of each of the psychotropic substances in bulk form referred to in sub-rule (1) in the country and taking into account the requirement of such psychotropic substances in the State, the quantity of such substance required for supply to other manufacturers outside the State and the quantity of such substance required for reasonable inventory to be held by a manufacturer, shall

specify, by order, the limit of the quantity of such substance which may be manufactured by the manufacturer in the State.

(3) The quantity of the said psychotropic substance which may be manufactured by a licensee in a year shall be intimated by the Licensing Authority to the licensee at the time of issuing the licence.".

13. For rule 65 of the said rules, the following rule shall be substituted, namely:

"65. **Registration and submission of returns**.—(1) A person who has been issued licence to manufacture one or more psychotropic substances shall register with the Narcotics Commissioner for each of the substances in the form and manner as may be specified by the Narcotics Commissioner.

Provided that the requirement of registration under this sub-rule shall be complied within a period of one hundred and eighty days from the date of coming into force of these rules.

(2) A person who has registered with the Narcotics Commissioner under sub-rule (1) shall file quarterly return with the Narcotics Commissioner in such form and manner as may be specified by the Narcotics Commissioner.

(3) The return for a quarter shall be filed before the last day of the month following that quarter.

(4) If the return for a quarter is not filed before the due date by a person registered under sub-rule (1), the Narcotics Commissioner may issue notice to explain the reasons there for and after considering the reasons submitted, if any, may pass orders for revoking the registration.

(5) The registration under sub-rule (1) shall be deemed to be revoked, if the quarterly return for three successive quarters is not filed.

(6) An appeal against an order passed under sub-rule (5) may be made to the Secretary, Government of India, Ministry of Finance, Department of Revenue or any other officer, not below the rank of Additional Secretary to the Government of India, authorized by him in this behalf, within thirty days from the date of communication of such order.

(7) Every memorandum of appeal shall be accompanied by a copy of the order appealed against.

(8) The Appellate Authority shall, after making such further inquiry as may be considered necessary, pass such orders as it thinks fit, confirming, modifying or annulling the order appealed against.

Explanation.– For the purposes of this rule, the expression "quarter" shall be January to March, April to June, July to September and October to December of every year.".

14. In rule 65A of the said rules, the following proviso shall be inserted, namely:—

"Provided that sale, purchase, consumption or use of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VIIA.".

15. In rule 66 of the said rules, for sub rule (1), the following sub-rule shall be substituted, namely:—

"(1) No person shall possess any psychotropic substance for any of the purposes covered under 1985 rules, unless he is lawfully authorized to possess such substance for any of the said purposes under these rules.

Provided that possession of a psychotropic substance specified in Schedule I shall be only for the purposes mentioned in Chapter VIIA.".

16. In rule 67 of the said rules, —

(i) for sub-rule (3), the following sub-rule shall be substituted, namely:-

"(3) No consignment of psychotropic substance shall be transported, imported inter-State or exported inter-State unless such consignment is accompanied by a consignment note in Form 6 appended to these rules and in the manner as provided hereinafter:

Provided that a psychotropic substance specified in Schedule I shall be transported, imported inter-State or exported inter-State only for the purposes mentioned in Chapter VIIA;

Provided further that a psychotropic substance specified in Schedule I shall be transported for export out of India only after an export authorization is issued by the Narcotics Commissioner under rule 99.";

(ii) sub-rule (3) shall be omitted.

17. Schedule II and Schedule III of the said rules shall be omitted.

[F. No. N-11011/2/2012-NC-III]

SATYA NARAYANA DASH, Under Secy.

Note.- The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 837(E), dated the 14th November, 1985 and subsequently amended *vide* notifications numbers S.O. 786(E), dated the 26th October, 1992, S.O. 599(E), dated the 10th August, 1993, G.S.R. 748(E), dated the 14th December, 1993, G.S.R. 541, dated the 24th October, 1994, G.S.R. 82, dated the 14th February, 1995, G.S.R. 556(E), dated the 14th July, 1995, G.S.R. 25(E), dated the 12th January, 1996, G.S.R. 509(E), dated the 4th November, 1996, G.S.R. 550(E), dated the 25th June, 1997, G.S.R. 214(E), dated the 19th March, 2002, G.S.R. 753(E), dated 14th November, 2002, G.S.R. 115(E), dated the 21st February, 2003, G.S.R. 129(E), dated the 26th February, 2003, G.S.R. 317(E), dated the 17th March, 2003, G.S.R. 95(E), dated the 4th February, 2004, G.S.R. 104(E), dated the 25th February, 2005, G.S.R. 756(E), dated the 22nd December, 2005, G.S.R. 649 (E), dated the 25th October, 2006, G.S.R. 2 (E), dated the 1st January, 2008, S.O. 1661(E), dated the 13th July, 2010, S.O. 739 (E), dated the 11th April, 2011, G.S.R. 470(E), dated 21st June, 2011, G.S.R. 905(E), dated 28th December, 2011, G.S.R. 426(E), dated 1st July, 2014, and G.S.R. 74(E), dated 5th February, 2015.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 22nd December, 2014

G.S.R. 908 (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. 312(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 19th May, 2014;

And whereas, no objections and suggestions were received from the public on the said rules;

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 (7th 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, in rule 3A, for sub-rule (8), the following sub-rule shall be substituted, namely:

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

(b) The kits or class of drugs referred to in clause (a) are-

(1) Blood grouping reagents.

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

(3) Blood products-

(a) Human Albumin;

(b) Human Normal Immunoglobulin (intramuscular and intravenous);

(c) Human Coagulation Factor VIII;

(d) Human Coagulation Factor IX;

(e) Plasma Protein Fractionation;

(f) Fibrin Sealant Kit;

(g) Anti Inhibitor Coagulation complex.

(4) Recombinant products such as-

(a) Recombinant Insulin and Insulin analogues;

(b) Recombinant Erythropoietin (rHPO);

(c) Recombinant Granulocyte Colony Stimulating Factor (G-CSF).

(5) Biochemical kits-

(a) Glucose Test Strips;

(b) Fully automated analyser based glucose reagents.".

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

S. 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 vide notification number G.S.R. (E), dated the 12th December, 2014.

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MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 16th January, 2015

G.S.R. 38(E).— In exercise of the powers conferred by section 52A of the Narcotic Drugs and Psychotropic Substances Act, 1985, (61 of 1985), hereinafter referred to as the said Act, and in supersession of notification number G.S.R. 339(E) dated 10th May, 2007, except as respects things done or omitted to be done before such supersession, the Central Government, having regard to the hazardous nature, vulnerability to theft, substitution, and constraints of proper storage space, in respect of any narcotic drugs, psychotropic substances, controlled substances or conveyances, hereby specifies the narcotic drugs, psychotropic substances, controlled substances and conveyances which shall, as soon as may be after their seizure, be disposed of, the officers who shall dispose them of and the manner of their disposal.

2. **Items to be disposed of.**—All narcotic drugs, psychotropic substances, controlled substances and conveyances shall be disposed of under section 52A of the said Act.

3. **Officers who shall initiate action for disposal.**—Any officer in-charge of a police station or any officer empowered under section 53 of the said Act shall initiate action for disposal of narcotic drugs, psychotropic substances, controlled substances or conveyances under section 52A of that Act.

4. **Manner of disposal.**—(1) Where any narcotic drug, psychotropic substance, controlled substance or conveyance has been seized and forwarded to the officer-in-charge of the nearest police station or to the officer empowered under section 53 of the said Act or if it is seized by such an officer himself, he shall prepare an inventory of such narcotic drugs, psychotropic substances, controlled substances or conveyances as per Annexure 1 to this notification and apply to any Magistrate under sub-section (2) of section 52A of the said Act as per Annexure 2 to this notification within thirty days from the date of receipt of chemical analysis report of seized narcotic drugs, psychotropic substances or controlled substances.

(2) After the Magistrate allows the application under sub-section (3) of section 52A of the said Act, the officer mentioned in sub-paragraph (1) shall preserve the certified inventory, photographs and samples drawn in the presence of the Magistrate as primary evidence for the case and submit details of the seized items to the Chairman of the Drug Disposal Committee for a decision by the Committee on the disposal, and the aforesaid officer shall send a copy of the details along with the items seized to the officer-in-charge of the godown.

5. **Drug Disposal Committee.**—The Head of the Department of each Central and State drug law enforcement agency shall constitute one or more Drug Disposal Committees comprising three Members each which shall be headed by an officer not below the rank of Superintendent of Police, Joint Commissioner of Customs and Central Excise, Joint Director or Directorate of Revenue Intelligence or officers of equivalent rank and every such Committee shall be directly responsible to the Head of the Department.

6. **Functions.**—The functions of the Drug Disposal Committee shall be to-

(a) meet as frequently as possible and necessary;

(b) conduct a detailed review of seized items pending disposal;

(c) order disposal of seized items; and

(d) advise the respective investigation officers or supervisory officers on the steps to be initiated for expeditious disposal.

7. **Procedure to be followed by the Drug Disposal Committee with regard to disposal of seized items.**—(1) The officer-in-charge of godown shall prepare a list of all the seized items that have been certified under section 52A of the said Act and submit it to the Chairman of the concerned Drug Disposal Committee.

(2) After examining the list referred to in sub-paragraph (1) and satisfying that the requirements of section 52A of the said Act have been fully complied with, the members of the concerned Drug Disposal Committee shall endorse necessary certificates to this effect an thereafter that Committee shall physically examine and verify the weight and other details of each of the seized items with reference to the seizure report, report of chemical analysis and any other documents, and record its findings in each case.

8. **Power of Drug Disposal Committee for disposal of seized items.**—The Drug Disposal Committee can order disposal of seized items up to the quantity or value indicated in the Table below, namely:—

TABLE

(1)	(2)	(3)
Sl. No.	Name of item	Quantity per consignment
1.	Heroin	5 Kg
2.	Hashish (Charas)	100 Kg
3.	Hashish oil	20 Kg
4.	Ganja	1000 Kg
5.	Cocaine	2 Kg
6.	Mandrax	3000 Kg
7.	Poppy straw	Up to 10 MT.
8.	Other narcotic drugs, psychotropic substances, controlled substances or conveyances	Up to the value of Rs. 20 lakhs

Provided that if the consignments are larger in quantity or of higher value than those indicated in the Table, the Drug Disposal Committee shall send its recommendations to the Head of the Department who shall order their disposal by a high level Drug Disposal Committee specially constituted for this purpose.

9. **Mode of disposal of drugs.**—(1) Opium, morphine, codeine and thebaine shall be disposed of by transferring to the Government Opium and Alkaloid Works under the Chief Controller of Factories.

(2) In case of narcotic drugs and psychotropic substances other than those mentioned in sub-paragraph (1), the Chief Controller of Factories shall be intimated by the fastest means of communication available, the details of the seized items that are ready for disposal.

(3) The Chief Controller of Factories shall indicate within fifteen days of the date of receipt of the communication referred to in sub-paragraph (2), the quantities of narcotic drugs and psychotropic substances, if any, that are required by him to supply as samples under rule 67B of the Narcotic Drugs and Psychotropic Substances Rules, 1985.

(4) Such quantities of narcotic drugs and psychotropic substances, if any, as required by the Chief Controller of Factories under sub-paragraph (3) shall be transferred to him and the remaining quantities of narcotic drugs and psychotropic substances shall be disposed of in accordance with the provisions of sub-paragraphs (5), (6) and (7).

(5) Narcotic drugs, psychotropic substances and controlled substances having legitimate medical or industrial use, and conveyances shall be disposed of in the following manner:-

(a) narcotic drugs, psychotropic substances and controlled substances which are in the form of formulations and labeled in accordance with the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder may be sold, by way of tender or auction or in any other manner as may be determined by the Drug Disposal Committee, after confirming the composition and formulation from the licensed manufacturer mentioned in the label, to a person fulfilling the requirements of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules and orders made thereunder, provided that a minimum of 60% of the shelf life of the seized formulation remains at the time of such sale;

(b) narcotic drugs, psychotropic substance and controlled substances seized in the form of formulations and without proper labeling shall be destroyed;

(c) narcotic drugs, psychotropic substances and controlled substances seized in bulk form may be sold by way of tender or auction or in any other manner as may be determined by the Drug Disposal Committee, to a person fulfilling the requirements of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), and the rules and orders made thereunder, after confirming the standards and fitness of the seized substances for medical purposes from the appropriate authority under the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder;

(d) controlled substances having legitimate industrial use may be sold, by way of tender or auction or in any other manner as may be determined by the Drug Disposal Committee, to a person fulfilling the requirements of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and the rules and orders made thereunder;

(e) seized conveyances shall be sold off by way of tender or auction as determined by the Drug Disposal Committee.

(6) Narcotic drugs, psychotropic substances and controlled substances which have no legitimate medical or industrial use or such quantity of seized items which is not found fit for such use or could not be sold shall be destroyed.

(7) Destruction referred to in sub-paragraph (b) shall be by incineration in incinerators fitted with appropriate air pollution control devices, which comply with emission standards and such incineration may only be done in places approved by the State Pollution Control Board or where adequate facilities and security arrangements exist and in the latter case, in order to ensure that such incineration may not be a health hazard or polluting, consent of the State Pollution Control Board or Pollution Control Committee, as the case may be, shall be obtained, and the destruction shall be carried out in the presence of the Members of the Drug Disposal Committee.

10. **Intimation to Head of Department on destruction.**—The Drug Disposal Committee shall intimate the Head of the Department regarding the programme of destruction at least fifteen days in advance so that, in case he deems fit, he may either himself conduct surprise checks or depute an officer for conducting such surprise checks and after every destruction operation, the Drug Disposal Committee shall submit to the Head of the Department a report giving details of destruction.

11. **Certificate of destruction.**- A certificate of destruction (in triplicate) containing all the relevant data like godown entry number, gross and net weight of the items seized, etc., shall be prepared and signed by the Chairman and Members of the Drug Disposal Committee as per format in Annexure 3 and the original copy shall be pasted in the godown register after making necessary entries to this effect, the duplicate to be retained in the seizure case file and the triplicate copy shall be kept by the Drug Disposal Committee.

12. **Details of sale to be entered in godown register.**- As and when the seized narcotic drug, psychotropic substance, controlled substance or conveyance is sold by way of tender or auction or in any other manner determined by the Drug Disposal Committee, appropriate entry indicating details of such sale shall be made in the godown register.

13. **Communication to Narcotics Control Bureau.**—Details of disposal of narcotic drugs, psychotropic substances, controlled substances and conveyances shall be reported to the Narcotics Control Bureau in the Monthly Master Reports.

Annexure I

INVENTORY OF SEIZED NARCOTIC DRUGS, PSYCHOTROPIC SUBTANCES, CONTROLLED SUBSTANCES AND CONVEYANCES

[under Section 52A (2) of the Narcotic Drugs and Psychotropic Substances Act, 1985]

Case No.:----------

Seizing agency: ----------

Seizing officer:----------

Date of seizure:----------

Place of seizure:----------

Name and designation of the officer preparing this inventory:----------

TABLE

Sl. No.	Narcotic Drug/ Psychotropic Substance/ Controlled Substance/ Conveyance	Quality	Quantity	Mode of packing	Mark and numbers	Other identifying Particulars of seized items or packing	Country of origin	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

Signature, name and designation of the officer

Certification by the Magistrate under sub-section (3) of Section 52A of the Narcotic Drugs and Psychotropic Substances Act, 1985

Whereas the above officer applied to me under sub-section (2) section 52A of the Narcotic Drugs and Psychotropic Substances Act, 1985 to certify the above inventory, and sub-section (3) of that section requires any Magistrate to whom an application is made to allow the application as soon as may be, I, having been satisfied that the above inventory is as per the seizure documents and the consignments of seized goods related to the case presented before me, certify the correctness of the above inventory.

Signature, name and designation of the Magistrate

Annexure 2

APPLICATION FOR DISPOSAL OF SEIZED NARCOTIC DRUGS, PSYCHOTROPIC SUBTANCES, CONTROLLED SUBSTANCES AND CONVEYANCES UNDER SECTION 52A (2) OF THE NDPS ACT, 1985

[Application to be made by the officer in-charge of a police station or an officer empowered under section 53 of the Narcotic Drugs and Psychotropic Substances Act, 1985 *who has custody of the seized narcotic drugs, psychotropic substances, controlled substances and conveyances]*

To,

Learned Magistrate,

Sir,

Sub: Application for certification of correctness of inventory, photographs and samples of seized narcotic drugs, psychotropic substances, controlled substances and conveyances

1. All narcotic drugs, psychotropic substances, controlled substances and conveyances have been identified by the Central Government under section 52A of the Narcotic Drugs and Psychotropic Substances Act, 1985 as vulnerable to theft and substitution vide Notification No.....dated.....

2. As required under sub-section (2) of section 52 A of the Narcotic Drugs and Psychotropic Substances Act, 1985, I submit the enclosed inventory of seized narcotic drugs, psychotropic substances, controlled substances, and/or conveyances and request you to-

(a) certify the correctness of the inventory;

(b) permit taking, in your presence, photographs of the seized items in the inventory and certify such photographs as true; and

(c) allow drawing of representative samples in your presence and certify the correctness of the list of samples so drawn.

3. I request you to allow this application under sub-section (3) of Section 52 A of the Narcotic Drugs and Psychotropic Substances Act,1985 so that the seized narcotic drugs, psychotropic substances, controlled substances, and/or conveyances can thereafter be disposed of as per sub-section (1) of section 52A of the said Act retaining the certificate, photographs and samples as primary evidence as per sub-section (4) of section 52A (4).

Yours faithfully,

Signature, name and designation of the officer

Date :

CERTIFICATE BY THE MAGISTRATE UNDER SUB-SECTION (3) OF SECTION 52A OF THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES ACT, 1985

I allow the above application under sub-section (3) of section 52A of the Narcotic Drugs and Psychotropic Substances Act, 1985 and hereby, certify the correctness of the enclosed inventory, the enclosed photographs taken and the list of samples drawn in my presence.

Signature, name and designation of the Magistrate

Date :

Annexure 3

CERTIFICATE OF DESTRUCTION

[See Paragraph 11 of Notification No. dated the.....]

This is to certify that the following narcotic drugs, psychotropic substances and controlled substances, were destroyed in our presence.

1. Case No.

2. Narcotic Drug / Psychotropic Substance / Controlled Substance:

3. Seizing agency:

4. Seizing officer:

5. Date of seizure:

6. Place of Seizure:

7. Godown entry number:

8. Gross weight of the drug seized:

9. Net weight of the narcotic drugs, psychotropic substances, controlled substances destroyed (after taking samples, etc.):

10. Where and how destroyed.

Signature(s), name(s) and designation(s) of Chairman/Members of the Drug Disposal Committee.

[F. No. V/2/2004-NCB]

SATYA NARAYANA DASH, Under 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 FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 5th February, 2015

G.S.R. 74 (E).- In exercise of the powers conferred by section 9, read with section 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely:—

1. (1) These rules may be called the Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2015.

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

2. In the Narcotic Drugs and Psychotropic Substances Rules, 1985, in Schedule I, under sub-heading II "Psychotropic Substances", for item 4 and entries relating thereto, the following shall be substituted, namely:—

"4.	Mephedrone	4-methylmethcathinone (4-MMC) 4-methylephedrone	(RS)-2-methylamino-1-(4-methylphenyl) propan-1-one
5.	Salts and preparations of above".		

[F. No. N/11011/2/2014-NC-II (2)]

SATYA NARAYANA DASH, Under Secy.

Note.- The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.837(E), dated the 14th November, 1985 and subsequently amended vide notifications numbers S.O. 786 (E), dated the 26th October, 1992, S.O. 599 (E), dated the 10th August, 1993, G.S.R. 748 (E), dated the 14th December, 1993, G.S.R. 543, dated the 24th October, 1994, G.S.R. 83, dated the 14th February, 1995, G.S.R. 556 (E), dated the 14th July, 1995, G.S.R. 25 (E), dated the 12th January, 1996, G.S.R. 509 (E), dated the 4th November, 1996, G.S.R. 350 (E), dated the 25th June, 1997, G.S.R. 214 (E), dated the 19th March, 2002, G.S.R. 763 (E), dated 14th November, 2002, G.S.R. 115 (E), dated the 21st February, 2003, G.S.R. 129 (E), dated the 26th February, 2003, G.S.R. 217 (E), dated the 17th March, 2003, G.S.R. 95 (E), dated the 4th February, 2004, G.S.R. 104 (E), dated the 25th February, 2005, G.S.R. 736 (E), dated the 22nd December, 2005, G.S.R. 639 (E), dated the 13th October, 2006, G.S.R. 2 (E), dated the 1st January, 2008, S.O. 1661 (E), dated the 13th July, 2010, S.O. 739 (E), dated the 11th April, 2011, G.S.R. 470(E), dated 21st June, 2011, G.S.R. 905(E), dated 28th December, 2011 and G.S.R. 426(E), dated 1st July, 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 17th February, 2015

G.S.R. 107 (E).—Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published *vide* notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare *vide* number G.S.R. 310(E), dated the 5th May, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), 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 12th 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 by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:

1. (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2015.

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

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, against serial number 35, under the heading "Extent and Conditions of Exemptions," the words, figures and letter "In Form 20C" shall be omitted.

[F. No. X.11016/9/2013-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 *vide* notification number G.S.R. 908(E), dated the 22nd December, 2014.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th March, 2015

G.S.R. 203(E).—Whereas certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published *vide* notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare *vide* number G.S.R. 350(E), dated the 23rd May, 2014, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 28th 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 by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2015.
   (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945;—

   (a) in Schedule Q, in Part I,—

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

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

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

   "31. Liquid foundation make-up IS 14318

   32. Cold Wax-Hair remover IS 15152

   33. Face pack IS 15153

   34. Kajal IS 15154

   35. Oxidation Hair Dyes (Emulsion type) IS 15205

   36. Cream Bleach IS 15608".

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

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended *vide* notification number G.S.R. 107(E) dated the 17th February, 2015.

MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 5th February, 2015

S. O. 375 (E).— In exercise of the powers conferred by clauses (viia) and (xxiiia) of section 2 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes following amendment to the notification of the Government of India, Ministry of Finance, Department of Revenue, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), *vide* number S.O. 1055 (E), dated the 19th October, 2001, namely: —

In the said notification, in the Table, after serial number 238E and the entries relating thereto, the following serial number and the entries shall be inserted, namely:—

Sl No.	Name of Narcotic Drug and Psychotropic Substance (International non-proprietary name)	Other non-proprietary name	Chemical Name	Small Quantity (in gm.)	Commercial Quantity (in gm./kg.)
1	2	3	4	5	6
"238F.	Mephedrone	4-methylmethcathinone (4-MMC) 4-methylephatrone	(RS)-2-methylamino-1-(6-methylphenyl) propan-1-one	2	50 gm."

[F. No. N-11011/2/2014-NC-II (3)]

SATYA NARAYANA DASH, Under Secy

Note.- The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 1055 (E), dated the 19th October, 2001 and subsequently amended by notification number S.O. 2941 (E), dated the 18th November, 2009 and S.O. 1430 (E) dated 21st June, 2011.

MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 5th February, 2015

S. O. 376 (E).— Whereas, the Central Government is satisfied, on the basis of information and evidence which has become available to it with respect to the nature and effect of, or the scope of abuse of, any substance (natural or synthetic) or natural material or any salt or preparation of such substance or material, that it is necessary or expedient to add the following substance or natural material or salt or preparation of such substance or material in the list of psychotropic substances specified in the Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) (hereinafter referred to as the said Act);

Now, therefore, in exercise of the powers conferred by section 3 of the said Act, the Central Government hereby makes the following addition in the list of psychotropic substances specified in the Schedule of the said Act, namely:-

Now, therefore, in exercise of the powers conferred by section 3 of the said Act, the Central Government hereby makes the following addition in the list of psychotropic substances specified in the Schedule of the said Act, namely:-

In the Schedule of the said Act, after serial number 110A and the entries relating thereto, the following serial number and the entries shall be inserted, namely:—

S. No.	International Non-proprietary names	Other non-proprietary names	Chemical name
"110B.	MEPHEDRONE	4-methylmethcathinone (4-MMC) 4-methylephedrone	(RS)-2-methylamino-1-(4-methylphenyl) propan-1-one".

[F. No. N-11011/2/2014-NC-II (1)]

SATYA NARAYANA DASH, Under Secy.

Note: The Schedule to the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) was amended *vide* S.O. 785(E) dated 26th October, 1992 and subsequently amended by S.O. 49(E) dated 8th January, 1993, S.O. 39(E) dated 12th January, 1996, S.O. 475(E) dated 11th June, 2003, G.S.R. 621(E) dated 1st August, 2003, G.S.R. 1(E) dated 2nd January, 2004 and S. O. 311 (E) dated 10th February, 2011.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health And Family Welfare)

NOTIFICATION

New Delhi, the 30th March, 2015

S.O. 873(E).—In pursuance of the provisions of sub-rule (4) of rule 24A, sub-rule (4) of rule 34, sub-rule (4) of rule 34A and sub-rule (3) of rule 129A of the Drugs and Cosmetics Rules, 1945, the Central Government hereby specifies the following additional banks for the purposes of payment of fee to be paid along with the applications for various licences or permissions to be submitted to the office of Drugs Controller General (India), namely:—

(i) Bank of Baroda, Law Garden Branch, Bank of Baroda Towers, Ellis Bridge, Ahmedabad-380006;

(ii) Bank of Baroda, Plot No. 8/3/2014/17, Annapurna Nilayam, B.K. Guda, S.R. Nagar, Hyderabad Nagar 500038;

(iii) Bank of Baroda, Raj Nagar Branch, Raj Nagar, Ghaziabad-201002, Uttar Pradesh.

(iv) Bank of Baroda, Tardeo Branch, Everest Building, D.J. Dadaji Road, Tardeo, Mumbai-400034;

(v) Bank of Baroda, India Exchange Branch, 4, India Exchange Place, Kolkata-700001;

(vi) Bank of Baroda, Chennai Main Branch, 70, Rajaji Salai, Chennai-600001;

(vii) Bank of Baroda, SCO-212, Sector-40-D, Chandigarh-160036;

(viii) Bank of Baroda, Gandhinagar Branch, Gole Market, Gandhinagar, Jammu, Jammu Tawi;

(ix) Bank of Baroda, Vasco-Da-Gama Branch, P.O-144, Swatantra Path, Vasco-Da-Gama, Goa-403802; and

(x) Bank of Baroda, Malleswaram Branch, 74, Seventh Cross, Malleswaram, Bangalore-56003.

[F. No. D.21013/152/2014-DC/DFQC]

K. L. SHARMA, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)
NOTIFICATION
New Delhi, the 3rd February, 2015

G.S.R. 68(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 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 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 (Second Amendment) Rules, 2015.

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

(a) in rule 71, after sub-rule (6), the following sub-rule shall be inserted, namely:-

"(6A) The applicant shall, while applying for licence to manufacture drugs, furnish to the Licensing Authority evidence and data justifying that the drugs are stable for proposed shelf life under the condition of storage recommended and the data shall be generated as per Appendix IX of Schedule Y.".

(b) rule 71-B shall be numbered as sub-rule (1) thereof and after sub-rule (1) as so numbered, the following sub-rule shall be inserted, namely:-

"(2) The applicant shall, while applying for licence to manufacture drugs, furnish to the Licensing Authority evidence and data justifying that the drugs are stable for proposed shelf life under the condition of storage recommended and the data shall be generated as per Appendix IX of Schedule Y.".

(c) in rule 76, after sub-rule (7), the following sub-rule shall be inserted, namely:-

"(7A) The applicant shall, while applying for licence to manufacture drugs, furnish to the Licensing Authority evidence and data justifying that the drugs are stable for proposed shelf life under the condition of storage recommended and the data shall be generated as per Appendix IX of Schedule Y.".

(d) rule 76A shall be numbered as sub-rule (1) thereof and after sub-rule (1) as so numbered, the following sub-rule shall be inserted, namely:-

"(2) The applicant shall, while applying for licence to manufacture drugs, furnish to the Licensing Authority evidence and data justifying that the drugs are stable for proposed shelf life under the condition of storage recommended and the data shall be generated as per Appendix IX of Schedule Y.".

(e) in Schedule D, against item number 1, under the column "Class of drugs", for the entry "Substances not intended for medicinal use", the following entry shall be substituted, namely:-

"Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile".

[F.No. X.11014/2/2014-DFQC]

K. L. SHARMA, Jt. Secy.

Foot note: The principal rules were published in the Gazette of India *vide* notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended *vide* notification number GSR 908(E) dated 22nd December, 2014.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd February, 2015

G.S.R. 69(E).—Whereas the Central Government is of opinion that circumstances have arisen which render it necessary to amend the Drugs and Cosmetics Rules, 1945 without consulting the Drugs Technical Advisory Board;

And whereas the Central Government proposes to consult the Board within six months of making the amended rules;

Now therefore, 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 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by sections 12 and 33 of the said Act 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 these draft rules are made available to the public;

Any person interested in making any objections or suggestions 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 Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 527 'C', Nirman Bhawan, New Delhi-110011.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2015.

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

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the principal rules), in rule 122 DA, in sub-rule (3), for the *Explanation*, the following *Explanation* shall be substituted, namely:—
   'Explanation.—For the purposes of these rules,—
   (a) "Clinical Trial" means a systematic study of any new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug;
   (b) "Global Clinical Trial" means any clinical trial which is conducted as part of multi-national clinical development of a drug;
   (c) "Investigational New Drug" means a new chemical entity or a product having therapeutic indication but which has never been tested earlier on human being;
   (d) "New Chemical Entity" means an active substance in developmental stage which may be specified as a drug under the Act, after undergoing any clinical trial.".
3. Rule 122 DAA of the principal rules shall be omitted.

4. In *SCHEDULE A* of the principal rules, in Form 44, under the heading "A. Permission to market a new drug:', after item (10), the following items shall be inserted at the end, namely:—
   "(11) New Chemical Entity and Global Clinical Trial
      (a) Assessment of risk versus benefit to the patients
      (b) Innovation vis-à-vis existing therapeutic option
      (c) Unmet medical need in the country."

5. In *SCHEDULE Y* of the principal rules, in APPENDIX I, after sub-item 11.1, the following shall be inserted, namely:—

"12. New Chemical Entity and Global Clinical Trial

12.1 Assessment of risk versus benefit to the patients

12.2 Innovation vis-à-vis existing therapeutic option

12.3 Unmet medical need in the country.".

[F. No. X.11014/4/2014-DFQC]

K. L. SHARMA, Jt. Secy.

Foot note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated 21st December, 1945 and last amended by notification published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 908(E), dated the 22nd December, 2014.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, dated the 3rd June, 2015

G.S.R. 449(E).—Whereas, the Central Government is of opinion that it is necessary to authenticate the genuineness of drugs and for this purpose, it has been proposed to amend the Drugs and Cosmetics Rules, 1945;

And Whereas, the Central Government has consulted the Drugs Technical Advisory Board for carrying out the amendments in the said rules;

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 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required under sections 12 and 33 of the said Act, 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 these draft rules are made available to the public;

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

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (Fifth Amendment) Rules, 2015.

(2) They shall come into force after the expiry of 180 days from the date of the publication of the final rules in the Gazette of India.

2. In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), after clause (xii) the following clause shall be inserted, namely:-

"(xiii) (A). The manufacturers of drug formulations shall print the details specified below to n facilitate tracking and tracing of their product-

(a) at primary level packaging of two dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the primary pack;

(b) at secondary level packaging of one or two dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the secondary pack;

(c) at tertiary level packaging of one dimensional barcode encoding unique and universal global product identification code in the 14 digits Global Trade Item Number format along with batch number, expiry date and a unique serial number of the tertiary pack.

(B) The manufacturer of drug formulation shall maintain the data in the parent – child relationship for all three level of packaging and their movement in its supply chain.

(C) The data referred to in sub-clause (B) shall be uploaded on the central portal of the Central Government by the manufacturer or its designated agency before release of the drugs for sale or distribution.

(D) The responsibility of the correctness, completeness and timely uploading of data on the Central portal shall be that of the manufacturer:

Provided that the provision of this sub-rule shall not be applicable to such drug formulation which is manufactured for export purpose and where the Government of the importing country has mandated a specific requirement and the exporter intends to avail the option of printing the bar codes in the format specified by the importing country with the permission of licensing authority appointed under rule 21:

Provided further that the tertiary level of the packaging shall have an additional printing of barcode as per sub-clause (A) in addition to any other requirement by the importing country.

Explanation.- For the purposes of this clause, -

(i) (a) primary packaging level means the package which is in physical contact with the drug;

(b) secondary packaging level means the carton containing multiple primary packs including a mono carton; and

(c) tertiary packaging level means a shipper containing multiple secondary packs as per guidelines issued for data requirement, by the Central Government;

(ii) parent-child relationship between tertiary, secondary and primary packaging levels means-

(a) relationship between tertiary and secondary packs is the tertiary pack as the parent and secondary pack is the child; and

(b) relationship between secondary and primary packs is the secondary pack as the parent and primary as the child.".

[F. No. 02/Misc./2010-DC/DFQC]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number GSR 390(E), dated the 18th May, 2015.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th June, 2015

S.O. 1597(E).---In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby appoints Smt. Kiran Pandey, Deputy Assistant Director, Central Drugs Laboratory, Central Research Institute, Kasauli at the Central Drugs Laboratory, Central Research Institute, Kasauli, District Solan, Himachal Pradesh to be the Government Analyst, for the whole of India in respect of the following classes of drugs, namely:---

1. Sera
2. Solution of Serum Proteins intended for injection
3. Vaccines (Parenteral and Oral)
4. Toxins
5. Antigens
6. Anti Toxins
7. Sterilized surgical Ligature and Sterilized surgical sutures
8. Bacteriophages

[F. No. X.11035/153/2014-DFQC]

K. L. SHARMA, Jt. Secy.

INFORMATION

M.Pharm & Pharm D Scholarships 2014-15 awarded by TNPSWT

Profile of 2nd Rank Projects

PHARMACEUTICS

Name: Ch.Sai Krishna Reddy

Project Title: "Formulation Development of Colchicine Transdermal Drug Delivery System for limiting Gastro Intestinal Tract (G.I.T) Toxicities"

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr.K.Gowthamarajan

PHARMACEUTICAL CHEMISTRY

Name: Mr.L.Ragu Bharathi

Project Title: Design, Synthesis, Characterization and Biological Evaluation of some novel Imidazole Derivatives as Anti-tubercular Agents

College: Madras Medical College, Chennai

Guide's Name: Dr.A.Jerad Suresh

PHARMACEUTICAL ANALYSIS

Name: Ms.P.Ponguzhali

Project Title: UV Spectrophotometric and RP-HPLC method Development and Validation of Paracetamol, Ambroxol hydrochloride, Levocetirizinedihydrochloride, Pseudoephedrine hydrochloride in Bulk and in Formulation

College: Adhiparasakthi College of Pharmacy, Melmaruvathur

Guide's Name: Dr. (Mrs.) D. Nagavalli

PHARMACOLOGY

Name: Ms. M.Dhivya

Project Title: Evaluation of Immunomodulatory Activity of Cow Urine in Diabetic Rats.

College: Madras Medical College, Chennai

Guide's Name: Dr. K.M.Sudha

PHARMACOGNOSY

Name: Ms.G.Praveena

Project Title: Formulation and Evaluation of Herbal gel from Leaves of HolarrhenaantidysentericaWall., for wound healing activity

College: Madras Medical College, Chennai

Guide's Name: Dr.N.Jayshree

PHARMACY PRACTICE

Name: Mr.Tijo Sam Thomas

Project Title: :"Study on Management and Health Related Quality of Life of Patients with Ischemic Stroke"

College: SRIPMS, Coimbatore

Guide's Name: Dr.S.Sriram

PHARM D- PHARMACY PRACTICE

Name: Ms. Brejeet K. V., Ms. ElenCharly, Ms.Grace Mary John

Project Title: Impact of Pharmaceutical Care and Health Literacy on Quality of Life in Post-operative Coronary Artery Bypass Graft Patients

College: P.S.G College of Pharmacy, Coimbatore

Guide's Name: Mrs. Prudence A Rodrigues

PHARM D- CLINICAL PHARMACY

Name: Ms. ChittineniPriyanka, Mr. Yeswanth .G, Ms. Sneha .K, Mr. Abha Singh

Project Title: A Comparative Study on Efficacy of Metformin verses Insulin in the treatment of Gestational Diabetes Mellitus

College: Sri Ramachandra University, Porur, Chennai

Guide's Name: Ms.N.Vanitha Rani

NEWS

Medicine Wars

There is no credible evidence yet of the effectiveness of either homeopathic or ayurvedic medicines and treatments, a range of medical experts have told The Hindu. Yet, both schools of medicine form an integral part of India's public health system, and their importance looks all set to grow.

Across the public health spectrum in India, from common colds to HIV, alternative medicines and treatments have official sanction. Created in 1995 as the Department of Indian Systems of Medicine and Homoeopathy under the Ministry of Health, the re-named Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy or AYUSH became a full-fledged ministry in May 2014, when the NarendraModi-led BJP government took oath. As of March 2015, India has just over nine lakh allopathic doctors and nearly eight lakh AYUSH practitioners, over 90 per cent of whom are either homeopaths or ayurveds. The Ministry has a Rs. 1,200 crore budget for this year.

Worrying evidence

However, the scientific evidence on homeopathy and ayurveda is worrying. Two major systematic reviews — one published by medical journal Lancet in 2005, and the other published in early 2015 by Australia's National Health and Medical Research Council — found no evidence of homeopathy being any more effective at treating disease than a placebo. The UK House of Lords Committee on Science and Technology, in a comprehensive review of alternative medicine in 2000, found that "in the case of homeopathy, although it is covered by a separate Act of Parliament, we were not able to find any totally convincing evidence of its efficacy", and "there is at present no credible evidence base to support the value of any of the therapies that we list in our Group 3", a category that included ayurveda.

India has never conducted any systematic review of any of the systems of medicine under AYUSH. For homeopathy, several double blind placebo-controlled trials or Randomised Control Trials (RCTs) — clinical trials in which a drug's effectiveness is tested against a placebo — have been conducted in India, but the standards were not acceptable to the Lancet or the Australian review. Dr. R. K. Manchanda, Director General of the Central Council for Research in Homeopathy (CCRH), the AYUSH Ministry's nodal homeopathic research arm, has conducted many such trials himself, which he candidly told The Hindu were found wanting by the Australian review and their results dismissed.

In the case of ayurveda, there is extensive research, but few RCTs. "I can count the number of RCTs on the fingers of one hand," Dr. BhushanPatwardhan, Professor and Director of the Interdisciplinary School of Health Sciences, Pune University, told The Hindu. As a result, there has been no proper review of the trials. The first such review is now underway at the University.

How they work

There is one significant difference between homeopathy and ayurveda. While the science of how ayurveda works is not questioned, the very basis of homeopathy — highly diluting a substance in alcohol or distilled water, stirring a fixed number of times in precise directions, striking a pestle against a mortar certain times, for instance — has been dismissed as scientifically impossible. The way ayurveda works, on the other hand, is well established within the theories of science. "How it works is not very different from modern medicine," said Dr. T. Sundararaman, Professor and Dean of the School of Health Systems Studies at the Tata Institute of Social Sciences, Mumbai. "Most modern

medicine is derived from active ingredients of roots or plants that are used in ayurveda," said Dr. Dinesh Katoch, Joint Adviser in the AYUSH Ministry. But because of this, say experts, there is no reason why ayurveda should not be subject to the same tests as modern medicine.

Among the ayurvedic and homeopathic academic fraternities, there is much debate over the lack of RCT-derived evidence of effectiveness. Among ayurveds, who have had less of a bad rap internationally than homeopaths, there is introspection. "The ancient texts were written a long time ago, and the environment has changed a lot since. It is fair to wonder whether those treatments would work in the modern era," said Dr. Patwardhan. "Ayurveda primarily focuses on prevention and creating a healthy person. Unfortunately, as our society has become increasingly medicalised, there are perverse incentives against investing in preventive healthcare".

"Maybe AYUSH will be more acceptable as preventive health than as drugs," he suggested. Among homeopaths, meanwhile, there are questions about whether to do more RCTs at all. "We are doing research, both observational studies and RCTs. But the question is whether a scrutiny of homeopathy through RCTs is really required?" said practitioners.

Both schools stress that their medicine treats the individual and not the disease, and are affected by context and temperament. But few public health experts agree that this can be the way going forward. "They cannot hide behind mysticism. All medicine is for individuals. Since trials involve a group of individuals, they account for individual idiosyncrasies," said Dr. SamiranNundy, noted gastroenterologist at Delhi's Sir Ganga Ram Hospital and editor-in-chief of the journal, Current Medicine Research and Practice. Dr. Sundararaman agreed: "Everything cannot rest on the claims of practitioners."

Allopathy's failure

None of this exculpates modern medicine either. "A lot of unnecessary and irrational treatments go on in modern medicine too. Just look at digestives, most vitamin supplements and cough expectorants, for example," said Dr. Sundararaman.

The Hindu spoke to dozens of people seeking treatment who talked of the opacity of allopathic treatments, the high prices charged, the lack of accountability, and the apathy.

Bhim Singh (50) is seated in the waiting room of a government-run homeopathy centre in Noida. He is there for a dermatological condition. He rues the thousands he has spent on allopathic treatments, and the terrible side-effects of the medicines. "Even when I went back to complain about the side effects, the doctor would not take more than 10 seconds. Here at least they ask you about you, your job, lifestyle," he said. Ultimately, said Dr. Sundararaman, it isn't always clear what cures a disease — pharmacology, the withdrawal of other harmful medicines, lifestyle changes, physical confidence, or even just rest.

Whether the government should continue with its AYUSH programme in its present form, with little to no evidence to back any of it, is an open question, however. As of today, ayurvedic and homeopathic treatments for HIV/ AIDS and cancer, homeopathic prophylactics against swine flu, and a range of other drugs and treatments for serious diseases have official sanction.

Until now, no health body, Indian or international, has expressly suggested that India curtail or amend its AYUSH programme. "The [Australian] NHMRC Statement on Homeopathy advises that

homeopathy should not be used to treat health conditions that are chronic, serious, or could become serious. People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence of safety and effectiveness," a spokesman for the Council told The Hindu, but added that questions on what India should do were for the Indian government to answer.

The World Health Organization did not respond to requests for comments from The Hindu, but the organisation's 2006-11 Country Cooperation Strategy with India included a supplement on traditional medicine, which recommended both more research and greater mainstreaming of AYUSH. Their 2007-12 document does not mention AYUSH separately. In India, the Indian Medical Association has objected to AYUSH doctors performing allopathic treatments, but not to AYUSH itself.

What's ahead

The AYUSH Ministry is aware of the questions swirling around, but is unlikely to make any major changes. "For the thousands of years that ayurveda has been practised, nobody asked for evidence. Now, because the medicines are being exported, these questions are being asked," Shripad Yesso Naik, Union Minister for AYUSH, told The Hindu. "We are still going to do the research, and not just for medicines that will be exported," he added.

The draft National Health Policy 2015 suggests greater integration of AYUSH with modern medicine, a type of "cross-pathy" that the Indian Medical Association has strongly opposed.

"India has always had a pluralistic health system. Every system has its own philosophy and even its own testing criteria. It will not be appropriate to apply the same parameters to different sciences," said Dr. Katoch. The Ministry will, however, continue to carry out research.

AYUSH: The six systems

Ayurveda

Ayurveda ("science if life") is a system of Indian traditional medicine with roots in the ancient Hindu texts, particularly the Atharva Veda, and later the CharakaSamhita and the SushrutaSamhita. Ayurveda believes that all living beings comprise five elements, whose permutations and combinations determine three types of humours — Vata, Pitta and Kapha. A key principle of ayurveda is balance; an imbalance of the doshas is believed to result in disease. Treatments follow one of two possible approaches: Vipreeta, in which medicines and diet are meant to "antagonise" the disease, and Vipreetarthkari, in which medicines, diet and activity are targeted to exert effects similar to the disease process. Most medicines and treatments are derived from herbs.

Yoga

Yoga ("to join" or "to unite") is a physical and spiritual discipline that has its roots in the Indian sub-continent and has been recorded in the Upanishads and later in the Yoga Sutras of Patanjali. The practice of yoga is meant to lead to a stage of higher consciousness and is also described as "soul therapy". Japa Yoga, Karma Yoga, Gyana Yoga, Bhakti Yoga are spiritual, while Raja Yoga, more popularly known as Ashtanga Yoga, involves eight steps, including the pranayama or breathing exercises. Some forms of yoga and their modern practice focus mostly on asanas. Practitioners say yoga can cure diseases, and the government runs the Central Council for Research in Yoga and Naturopathy. Early indications from an on-going five-year study at Harvard indicate that yoga helps with chronic stress.

Homeopathy

Homeopathy is of European origin and dates back to the end of the 18th century, to the work of German physician Samuel Hahnemann. Homeopathy is premised on the belief that highly diluting a substance in alcohol or distilled water increases its potency, a principle that is almost universally disputed in scientific communities. Remedies involve dilutions on a logarithmic scale, and grinding of insoluble compounds with a mortar and pestle according to prescribed motions. Diagnosis involves detailed consultations, including questions about the individual's personal life. Medicines are either small pills, made of an inert compound with drops of the dilute solution added, or powders.

Unani

Introduced by Arabs and Persians to India in the 12th century and with a rich literature, Unani medicine remains popular in parts of South and Central Asia. Freedom fighter and physician Hakim Ajmal Khan was among its champions in India. Unani shares many common principles with ayurveda, including the belief in the four humours. The human body is believed to be made up of elements whose permutations and combinations determine temperament. Medicines have herbal, animal and mineral origins.

Siddha

An ancient form of traditional medicine, Siddha originated in Tamil Nadu through the work of “siddhars” or scientist-saints. Siddha sharedmany principles with ayurveda, including the belief in humours, elements and imbalance.Diagnosis involves a key checklist of eight signs and symptoms. Drugs are herb-based and treatments are both internal and external. Siddha's chemistry around its drugs is complex. Research, teaching and practiseis largely restricted to Tamil Nadu.

Naturopathy

Naturopathy is an umbrella term for a range of alternative treatments derived from natural products. Naturopaths believe that, except for accidents, the cause of all disease is the accumulation of “morbid matter” in the body, and treatment means the removal of this matter. Therapies include special diets, mud packs, acupuncture, acupressure and magnet therapy. Prayer is an important part of treatment. Naturopathy schools exist across the world.

'Ayurveda believes every substance is medicine’

Interview with Dr. Dinesh Chandra Katoch, Adviser (Yoga) in the AYUSH Ministry.

There is no credible scientific evidence yet of the effectiveness of ayurveda in placebo-controlled trials. Is this a cause of concern within the Ministry?

Applying the same parameters to different sciences will not be appropriate. India has always had a pluralistic health system, and every system has its own philosophy, parameters and even testing criteria. In ayurveda, for example, it is believed that every substance in the world is medicine — then what is a placebo? In ayurveda, the individual's temperament is very important; we believe that you can't classify only by disease.

So trials cannot establish the effectiveness of these schools of medicine?

Earlier, there were a lot of complaints about heavy metals in ayurveda, but the thing people don't know is that these metals go through many processes. Now, some people are even saying that nanotechnology might prove homeopathy. The problem is that protocols for AYUSH trials are not available in the Western world. The whole world is doing research in modern medicine, but here we are doing everything de nouveau. It takes time to develop expertise. We now have an AYUSH research portal with nearly 20,000 articles. The same is the problem with drugs. It takes 15 years to create a drug. Look at turmeric, for example; it has now been proven that turmeric has anti-cancer

properties. The active ingredient in it was isolated and it became an allopathic drug. For ayurveda, the whole substance is used for treatment; it becomes difficult to find what is effective.

Are RC trials really required?

Dr R K Manchanda, Director- General, Centre Council for Research in Homeopathy

Is the lack of evidence of the effectiveness of homeopathy worrying the homeopathy establishment?

In India, it is true that we haven't had many RCTs (Randomised Control Trials) and what we have been doing is more observational studies. But there is a fundamental difference in homeopathy's approach; homeopathy treats the person in the disease, not the disease in the person. This makes RCTs a bit difficult, because the practitioner's and patient's attributes matter much more. A negative outcome of RCTs is not tantamount to disproving homeopathy. I have myself conducted RCTs which have shown the effectiveness of homeopathy —in the treatment of warts for example — but these RCTs were dismissed by the Australian review. Among the homeopathic community there is now a feeling whether scrutiny through RCTs is really required.

Given the questions over its effectiveness, should homeopathy have official sanction for the treatment of serious diseases?

In our hospitals, there is testing and treatments for HIV/ AIDS, but the patients are taking standard Anti Retroviral Treatments, and homeopathy is united into the treatment. Homeopathy is being used and is effective against multi drug-resistant tuberculosis. It has a valuable role in alcohol de-addiction

Source: The Hindu, 26th April 2015

Small & Medium Pharma Firms Wary of Global Regulatory Regime

Small and medium-sized pharmaceutical companies are wary ahead of a meeting called by the government to decide whether India should become part of a multinational regulatory regime.

Stricter standards, many fear, could drive up costs and make them uncompetitive, but being a part of the new system could make it smoother for Indian firms to access lucrative export markets.

The commerce ministry will talk to industry bodies on Monday about whether there is value in joining the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme, known as PICS.

The agency, now consisting of 45 drug importing countries, wants exporters such as India to comply with strict regulations to gain access to their markets.

The government had asked the Pharmaceuticals Export Promotion Council (Pharmexcil) to study the impact on the drug and a global agency appointed by the Pharmexcil for the study has recently submitted its draft report to the government.

Officials from the department of pharmaceuticals, the drug regulator and executives representing Indian medicine manufacturers have been invited to attend the meeting on Monday, said PV Appaji, director general of Pharmexcil.

PIC/S, headquartered in Geneva, Switzerland, prescribes two international instruments for member countries and their pharmaceutical authorities for "active and constructive cooperation" in the field of good manufacturing practices.

A PIC/S committee has also resolved to expand its mandate from the existing manufacturing standards to new fields such as good clinical practices and good pharmacovigilance practices.

Adhering to the new rules mean that Indian companies that export their drugs will be having one single regulatory body – PIC/S - for the procurement of drugs from any exporting country.

However, small and medium size drug companies, especially those that only cater to the domestic market, would not support the idea of joining the global league as their units should be upgraded to global standards, which may result in expenditure of Rs 5 crore to Rs 20 crore per unit, according to a senior official of a mid-sized Hyderabad based pharma company.

"Some of the member countries are asking us whether India is PIC/S compliant for procuring medicines for their government orders. Small countries which do not have regulatory expertise are insisting on it," Appaji said.

If India wanted to become a member of the PIC/S, it should be first treated as an observer country and post verification and approval from the regulatory body and the existing members it will attain permanent membership.Then, all the pharma manufacturing units will have to be upgraded to PICS standards even those that do not export.

"We are just exploring and assessing the possibility of joining the global league as a member country . But the government doesn't want to impose its decision on the industry unilaterally .That's why we have called on the industry bodies to discuss on various issues in this regard," a senior official in the commerce department said seeking anonymity.

India has about 4,000 pharma units and about 10,000 pharma companies, including marketing and trading firms, according to the industry estimates. At least 60% exports are to these PICS countries and that may be affected in the medium to long term if country doesn't become a member.

India exported $15-billion (Rs 95,000 crore) worth drugs in 2013-14 and that is expected to have grown by about 5% during the last fiscal (2014-15).

Indian Drug Manufacturers' Association president SV Veerramani told ET that his organisation will attend the meeting on Monday and understand the government's position. "Then we will react accordingly ," he said.

The commerce department will also be discussing issues pertaining to implementing mandatory barcoding for primary packaging for all the drugs that are exported from July 1.

Source: The Economic Times, 27th April 2015

Tax Relief for Gifts to Docs : CAG Exposes Tricks of Pharma Cos

The Indian pharma industry has been resorting to a slew of dodgy tax avoidance practices which include claiming exemptions for illegal freebies given to doctors, research work which was not taking place, and other tricks, reveals a new report of India's audit watchdog, the CAG. The report also takes to task the Income Tax Department for allowing these practices causing tax losses worth crores of rupees.

Taking an innovative approach to digging out the dirt on the flourishing pharma sector, Comptroller & Auditor General (CAG) asked the income tax department to show tax assessments of the whole pharma sector in India. The tax office had no database of pharma manufacturers and was able to produce only 2868 assessment records. These were put under the scanner by CAG and they found 246 cases involving tax deficiency of over Rs.1348 cr.

The most startling of the dirty tricks played was that of claiming tax exemption for giving gifts to doctors to lure them into prescribing certain drugs or treatments. The Medical Council of India expressly prohibits this and the statutory Central Board of Direct Taxation has also clarified in 2012 that such expenses are not allowable for tax exemptions. Yet, the CAG found that in 21 cases spread over five states this was allowed by assessing officers resulting in a tax loss of Rs.45.43 cr.

Giving examples, the CAG report, says that a company in Gujarat spent Rs.7.48 cr on "doctors' travelling expenses along with spouse, gift articles distributed, etc." and was given exemption resulting in tax loss of Rs.2.54 cr. In another case, a pharma company from Mumbai spent Rs.2.91 cr on what they candidly called "Heart Touching Celebration, Sponsorship of Doctors and corporate /brand recall items" and got a Rs.11.91 cr exemption. A Bangalore company spent Rs.18.43 cr over three years towards "Doctor's domestic and foreign travelling expenses including hotel bookings, gifts" and they got an exemption of Rs.6.26 cr.

Besides these clear cut cases, there were 11 cases where such illegal expenditures were concealed within larger "sales promotion" heads of spending. Also cases of expenditure on "physicians' samples" being claimed as tax exempt were found which have been held to be illegal by the income tax department itself earlier.

The biggest deficiency caught by the CAG related to claims of exemption for research and development (R&D) that were not valid. All kinds of tricks were being utilized to this end by pharma companies. Over Rs.570 cr worth of taxes were lost because companies were claiming exemption for R&D whereas in reality they had either not been granted permission by DSIR or such permission had expired.

Source: The Times of India, 11th May 2015

Ranbaxy Labs Accused of Violating FDA Rules to Thwart Rivals

Ranbaxy Laboratories Ltd was accused in a lawsuit of conspiring with a web of lawyers and consultants to manipulate the US Food and Drug Administration (FDA) and block competition in the generic drug business.

Ranbaxy for years filed false or incomplete paperwork with the FDA to win 180 days of marketing exclusivity for generic drugs that the Gurgaon, India-based company wasn't ready to make, according to a complaint filed Tuesday in a Boston federal court.

The proposed class action was brought by Michigan retailer Meijer Inc. and its distribution arm. They are seeking to represent buyers of Roche Holding AG's Valcyte, which treats a virus afflicting transplant patients and people with AIDS, and Novartis AG's blood-pressure drug Diovan. The lawsuit also names Sun Pharmaceuticals Industries Ltd, which completed its acquisition of Ranbaxy this year. A call to Sun's press office in India after regular business hours wasn't answered.

Ranbaxy's actions broke US antitrust law and

amounted to a racketeering scheme that blocked competitors from getting generic medicines to market faster, the retailer alleged.

Generics makers race for "first-to-file" status to win 180 days of exclusivity, during which a drug's price plummets and generics makers reap the bulk of their profit, according to the complaint.

'Intentionally deceive'

Ranbaxy "stands out as one willing to intentionally deceive the FDA in order to win that race," the buyers said in the complaint. "The speed and volume of Ranbaxy's numerous filings came at the expense of truthfulness and accuracy."

Ranbaxy could also use its first-to-file status "as a valuable bargaining chip with its brand and generic competitors," the plaintiffs said.

The drugmaker allegedly carried out the scheme with a group of lawyers and a "purportedly independent regulatory consultant" to dodge FDA scrutiny and give the appearance of prompt action and truthful reporting, according to the complaint.

Source: The Economic Times, 14th May 2015

Pharmacy Offers Range of Lucrative Option

Despite being one of the most career oriented courses available pharmacy is largely underestimated and under-marketed. Many people equate a course in pharmacy with opening a medical shop. They have little idea how wide its scope is and due to this there are few takers for the course.

Here's why B Pharmacy is one of the best courses a student can pursue and the opportunities it opens up to graduates.

The pharmaceutical industry is mostly non-fluctuating and records a steady growth of around 20% a year in India, in particular, the course has that great options. Other countries have dubbed India the 'pharmacy to the world' as it exports medicines to at least 220 countries.

Students can get into the pharmaceutical industry, in manufacturing, and quality assurance of drugs, or become regulatory officials. Graduates can also become formulations scientists or analytical research scientists. Even the IT sector requires pharmacists for software dealing with life sciences. Another avenue is patenting of medicine.

As in a doctor's profession, however the first few years after graduation can be challenging. A professional requires good training and takes time to establish himself but, after the initial years, there is tremendous scope.

When I enrolled for a B Pharmacy course in Madras Medical College in the 80's, government colleges in Tamilnadu offered only 50 seats. Madras Medical College and Madurai Medical College were the only two institutions that offered the course and had 25 seats each.

While most private colleges offer a two year diploma in pharmacy and a four year B Pharmacy course, none of the government colleges in Tamilnadu even offer the six year Pharm D doctorate course introduced four years ago. This is unfortunate because an in-depth course can give students cutting edge expertise.

Source: The Times of India, 14th May 2015

FDA Nod for Drugs Crucial for Lupin, DRL

Price erosion in base business and delay in new product approvals in the US, the world's largest pharma market, impacted the March quarter performance of India's leading drug makers — Lupin and Dr Reddy's Laboratories (DRL).

Lupin posted its worst quarterly performance with a drop in growth in key markets like US and Japan, resulting in flat revenues over the year-ago period and a 300-bps drop in operating margin. Contributing one-fourth of the overall sales, the domestic business grew 15% for the quarter.

The latest quarterly performance is worrying given that Lupin has a track record of posting a fairly consistent performance. While DRL's performance was not as disappointing, it was a mixed bag. The company's top line was boosted by double-digit growth in its key markets of US and India. Its European and contract manufacturing services also posted a strong recovery.

Its domestic business has been on a strong recovery path and is poised to be strengthened by the company's acquisition of select brands from Belgian drug maker UCB. The bottom line was, however, impacted by high R&D spend and adverse impact of currency volatility in emerging markets.

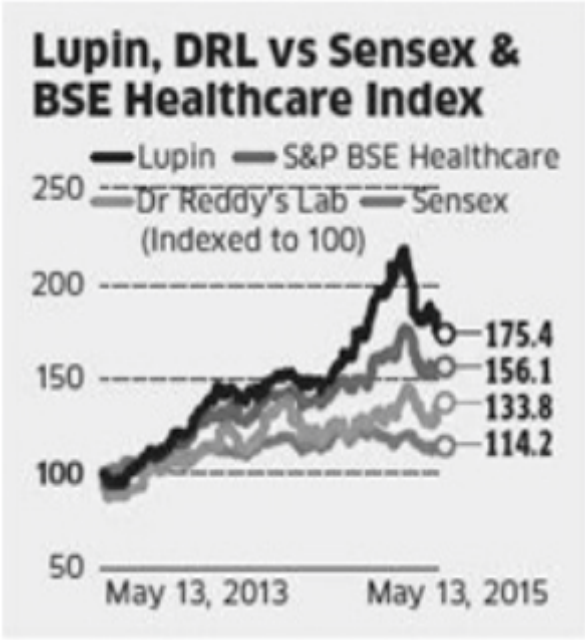
DRL spent 13% of its revenues on R&D, a positive factor from a long-term point of view. The delay in drug approvals in the US has built uncertainty in the growth prospects of both these companies there.

While Lupin has a pipeline of 110 drugs pending approval from the US FDA, DRL has 68. Some of these products have exclusive marketing opportunities. Hence, much of the future performance of these companies depends on when and which drugs receive approval from the US FDA.

The latest quarterly performance, however, doesn't change the long-term valuations of these stocks, given that the growth prospects remain promising. For now, Lupin's inclusion in the MSCI India Index will see increased buying in the stock as index funds include the stock in their portfolio.

DRL, which has underperformed the BSE Healthcare Index, is likely to trade at current levels in the absence of fresh positive triggers.

Any update on FDA's stance on its bulk drugs facility at Srikakulam could become the next trigger.



Source: The Economic Times, 14th May 2015

4 Out of 10 Stents Used in India is Desi

Mention stents, and an image of an imported medical device with a hefty price tag comes to mind. But the latest data from the Cardiological Society of India shows that a sizeable number of stents-tiny, mesh-like tubes that are used to open up narrowed diseased arteries - used across hospitals in 2014 carried the 'Make in India' label.

Almost four out of every 10 stents used in Indian hospitals carry a local tag, said the National Interventional Council (NIC) registry maintained by the CSI. "The Indian stents offer a price advantage," said a doctor. Only 396 out of the 624 cath labs (where stenting is carried out) across India report to the registry, but it provides the best insight into heart-care and disease patterns across the country.

"A total of 3,10,190 stents were reported to be used for 2,48,152 coronary interventions, an average of just over 1.2 per procedure," said Dr Praveen Chandra, a cardiologist from MedantaMedicity in Gurgaon who worked out the NIC data. His data shows that 40.5% of these 3.1 lakh stents were made by Indian companies, while three multinational companies enjoy 59.5% of the market share.

Indian stents effective enough: Cardiologists

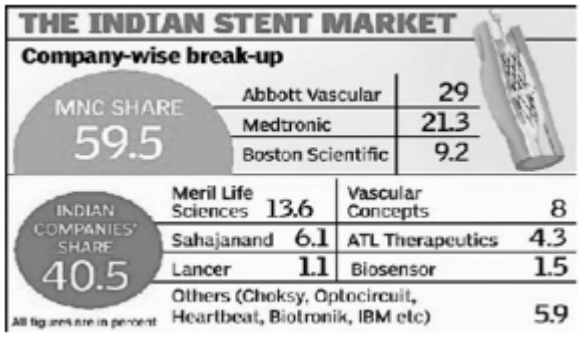
In recent times, stents have come to symbolize corruption in the Indian healthcare system; charges of overpricing are rampant. The Maharashtra Food & Drug Administration last week said that imported stents were sold to Indian patients at 700% more than the import cost: a stent with a landing price of Rs 25,000 costs Rs 1.55 lakh to the hospitalized patient.

The debate between imported versus Indian stent thus gains importance. Cardiologists say that Indian stents seem effective enough; they added that there is little to show in terms of scientific data. Dr A B Mehta, director of cardiology from Jaslok Hospital, Peddar Road, said, "The Indian stents are not only cheaper but some of them have great specifications. The stents made by Meril, for instance, have less thickness than the imported ones and are hence quite popular."

But there are many doctors who don't use Indian stents because of the lack of academic work. "I have never used a stent that hasn't been thoroughly researched," said DrPrafullaKerkar, who heads the cardiology department of KEM Hospital in Parel. Even for the poor patients operated under the Maharashtra-government-run Rajeev Gandhi ArogyaYojana, he prefers to use an imported stent specially procured by the state government at the cost of Rs. 23,000.

"A poor patient can never get what is considered the Iphone 6, but let us at least give him or her anIphone 4 that has great amount of data and research behind it," he said. Stents, like smartphones, come with various upgrades and are named as 'generation 1', 'generation 2' and so on. The Maharashtra government procures drug-eluting stents costing between Rs 23,000 and Rs 28,000 for patients operated under its health schemes.

Senior cardiologist Dr Ashok Seth from Fortis Escorts Heart Institute in New Delhi said that he had conducted two studies on the efficacy of Indian stents. "Indian stents are no doubt good, but they are at best copies of the original stents," he said.



All medical devices and medicines need to pass through a clinical trial before being offered to patients. "However, the Indian stents only need to show safety in 100 patients to get regulatory

approval. The imported stent, on the other hand, goes through clinical and safety trials as well as one-, two- and five-year follow-up studies," said Dr Seth. It is time Indian companies invested in research, he added.

All doctors whom TOI spoke to supported the idea of governmental regulation in pricing of stents, but they said the government should standardize safety and efficacy aspects as well.

Source: The Times of India, 25th May 2015

Health Ministry Moots Online Sale of Drugs; Regulator Works on Guidelines

As online shopping catches up, you could buy medicines too with a click of the mouse for which the health ministry is evaluating a proposal. The drug quality regulator is framing guidelines and mechanism to monitor such sale.

The proposal is expected to be taken up for discussion in the drugs consultative committee meeting next month, a senior regulatory official said.

At present, the Drugs & Cosmetics Act does not allow sale of Schedule 'H' medicines without a doctor's prescription. In fact, even over-the-counter (OTC) pharmaceutical products can be sold only by licensed retailers.

However, lately various cases were reported to the central drug regulator in which online retail platforms were found selling medicines.

Monitoring sales of prescription drugs on e-commerce websites tough: Analysts

In the absence of guidelines, regulatory agencies are finding it difficult to track and monitor such sale.

"With changing trends, it is important that we bring in provisions for online sale of medicines and develop a mechanism to monitor it," the official said. The Drugs Controller General of India (DCGI) has also asked state drug regulators to suggest mechanisms to monitor such sale.

The central regulator is also consulting various international drug regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency as well as examining their models to understand how quality and standards of medicines sold through e-commerce portals are monitored in these countries, the official said.

Apart from quality, efficacy and standards, monitoring the sale of medicines is also crucial because many drugs can be misused if not traded through prescription, experts say. Besides, there are certain medicines which are allowed with restrictions and if taken without proper prescription and supervision, it can lead to serious consequences.

The detailed proposal being worked out by the government is likely to address these issues, while also specifying which medicines can be sold online.

The annual Indian pharmaceutical market is pegged at around Rs 79,000 crore, growing at around 20%. If the government decides to allow online sale of drugs, it is likely to give a major boost to sales of the sector while also making medicines accessible to remote areas

Source: Times of India, 30th May 2015

Patent Official Pulled up for 'Non-Application of Mind' in Pfizer Case

Rapping a patent official for "non application of mind", the Intellectual Property Appellate Board (IPAB) has asked the patent office in Delhi to consider afresh US based Pharma Pfizer's patent application for a drug used for the treatment of psychotic disorders.

In 2010, Pfizer filed an application before the assistant controller of patents and designs, Delhi for grant of patent for inventing an antipsychotic compound "ZiprasidoneMesylateTrihydrate" (generic name of the drug is Zeldox). This was however, rejected. Counsel for Pfizer said the verdict of the assistant controller was laible to be set aside for 'non-application of mind'. The controller had compared the invention to a non-existing compound and rejected the patent. "In view of the basic consideration of the wrong prior art compound, the entire order is vitiated due to non-application of mind and misconception" said the counsel.

Also, despite furnishing comparative experimental data proving significant improvements in the therapeutic properties of the drug, the official had failed to consider it. The firm was also not provided with further opportunities to substantiate its claims, said the counsel.

A bench of chairman Justice K N Basha and technical member (patents) D P S Parmarsaid : "We are of the view that the assistant controller proceeded to consider the claim on the basis of comparison with a non-existing prior art compound. This reflects total non application of mind. We have no hesitation to hold that the entire order is vitiated".

Source: The Times of India, 30th May 2015

Clean Chit to Halol Plant, Strategic Buys Key for Sun's Future

The skills of Sun Pharma BSE -1.30 % to turn around a distressed asset will be thoroughly tested with Ranbaxy Labs, its largest ever acquisition. The end of March marked the first quarter when the M&A savvy drug major reported its results inclusive of Ranbaxy's, giving out consolidated numbers that disappointed investors. Though the Street was betting on a muted show of Sun in its new avatar as the country's largest pharma company, the actual performance fell well below expectations.

There cannot be a year-on-year comparison of Sun Pharma's performance due to the Ranbaxy merger in 2014-15.

But the sequential quarterly performance shows the March quarter being worse than the December quarter. The Sun management, in the post-results earnings call, admitted that Ranbaxy's integration is likely to take more time than originally envisaged.

During the quarter under review, its most promising US business was impacted by disruptions in supplying products due to the on-going remediation measures at some of its facilities and price erosion in certain products. Higher expenses (or, one-time charges) related to Ranbaxy integration also impacted the bottom line. The subdued quarterly performance led to the company failing to meet its guidance for the last fiscal.

Considering the time taken and complexities involved in Ranbaxy Lab's.. integration and in receiving USFDA's clean chit to its manufacturing facility at Halol, management of the company refrained from providing growth guidance for the current fiscal year.

The management is aiming at cultural integration: ensuring compliance of good manufacturing practices, targeting more product filings, improving productivity and achieving revenue integration and efficient procurement. Given that the new Sun is bigger than Dr Reddy's Labs and Lupin put together, the integration is likely to be a daunting task. Does it mean that Sun will not acquire targets for some time now? Not really. While the bandwidth of the senior management is currently occupied with Ranbaxy Sun's acquisitive spirit acquisitive

spirit has not been doused.

With a cash pile of Rs 15,500 crore and a debt of Rs 7,000 crore, it is ready to look at opportunities to expand its global footprint.

However, the focus would be to buy targets which are strategic to the business and demand less involvement of the senior management. Where does this place the company's investors, who were fast getting used to revenue growth of more than 30 per cent, operating margin of over 45 per cent and the stock's outperformance on the Street.

Sun's latest performance has put a spanner to their ambitions for now. The operating margin for the year-ended March 2015 stood at 29.5 per cent. Sun's stock is likely to trade weak till any positive development related to the Halol plant or any buyout brightens its growth prospects. Investors have to brace themselves for a period of wait-and-watch as Sun manages to turn around yet another difficult buyout.

The jury is out on whether Sun can achieve in the next three years what Daiichi Sankyo couldn't in seven years.

Source: The Economic Times, 2nd June 2015

IDMA Taking Steps to Strengthen and Tap Biz Opportunities for SMEs

S.V. Veerramani, the new president of the Indian Drugs Manufacturers Association (IDMA) speaks about the various issues in the pharmaceutical industry in the country and the problems being faced by the manufacturers, especially those in the SME sector. He says that the all India body of the drugs manufacturers in India is curiously viewing the issues in the Indian pharmaceutical sector and taking up them with the government and the department of pharmaceuticals (DoP) for getting resolved. Putting hundred percent confidence in the NarendraModi government, he hopes that IDMA's endeavours to strengthen the Indian pharmaceutical industry will bring positive results. In an interview with PeethaambaranKunnathoor, he speaks of the government policies, regulatory issues, common problems in the industry and the strategic steps IDMA is taking to strengthen the pharma SME sector. Excerpts:

Sir, you are now the President of the IDMA which comprises mostly the Micro, Small and Medium Enterprises (MSMEs) in the pharma sector. So, you are rightly responsible to heed to the issues in the pharma MSME sector and get them resolved for the growth of the industry. What do you think the government should do to settle the problems faced by the MSME manufacturers in the country?

The Indian Drug Manufacturers' Association represents Small, Medium and Large enterprises. Of-course, there are a large number of SME members in IDMA.

IDMA has been working for the welfare of SMEs over the years. We would like our SMEs to tap the business opportunities available in government purchases, contract manufacturing, regional marketing and exports. They need training and technology upgradation of their plants. We have been appealing to the government to announce technology upgradation schemes for pharma SMEs so that many of them can not only tap the opportunities in contract manufacturing, but also emerge as exporters.

How does the NarendraModi government at the centre support pharma industry and what are the major developmental schemes going to be implemented by it? Do you think the pharma industry will prosper under Modi regime? Any positive indication of that?

The slogan of our Hon'ble Prime Minister, NarendraModi "Make in India" rhymes well for the Indian pharmaceutical industry, which is aspiring to make pharmaceuticals in India for more than 200 countries in the world. If the government slogan of improving ease of doing business in India is materialised, it will help the pharmaceutical industry immensely.

According to you what are the major common problems being raised by the small scale pharma industrial units in the country? What role does your organisation play for their solution?

The major common problems raised by the pharma SMEs are in the areas of new regulations and amendments. IDMA is very conscious about the impact of these on the SME sector and constantly representing to the government, in the SMEs point of view. For example, in the case of requirement of 'barcoding' for exports, we have requested the government not to enlarge the same to primary packaging and mono-cartons, which can cause financial burden to the SMEs.

The SMEs want more and more interest subsidy schemes for loans sanctioned by nationalized banks and cash subsidy on investment. Besides, they want price preference for the local companies by state governments. As an umbrella organisation what steps does IDMA take to satisfy their demands with central and state governments?

Government purchase is an area where SMEs can get a good share. IDMA has been constantly writing to all the tendering authorities in India not to stipulate turnover clause or WHO-GMP clause for participation in government tenders. They can test every supply for quality compliance before taking into their stocks. But, a turnover clause, in the order of 25 to 50 crores can deny opportunities for many aspiring SMEs.

Similarly, Schedule M compliance is adequate for supplies in India and insistence of WHO-GMP which is meant for exports, should not be stipulated for supplies in India.

With respect to IDMA's request for Technology Upgradation Fund for SMEs, we have sought for interest subsidy and wanted not to insist on collateral security for loans.

During one of my interactions with industry captains in Tamil Nadu, they said a single-window system for clearances of all governmental registrations and approvals would help the entrepreneurs very much. How can these get implemented by each state government?

From industry's point of view, it will be a good concept to have a single window system of clearance, since they need not have to run to different departments for getting approvals. If the state and central government can have single window cell for major industries like pharmaceutical industry, it will do a lot of good in improving ease of doing business.

According to industry doyens in Tamil Nadu, the SME units cannot compete with those operating in the Excise Free Zones in Baddi and Uttarakhand. Associations of pharma SMEs in several states are now asking for EFZ areas for their crisis survival. What growth prospect do you see in founding EFZ or SEZ areas for pharma sector? Has your organisation made any request with the state governments to set up such zones?

If so, details please……..

The excise benefits given to the industries in Baddi and Uttarakhand are coming to a close and we understand that government is not keen to provide excise benefits to any new zone. But, the special economic zones can provide interest subsidies, power subsidies, Common Effluent Treatment Plant, Common Testing Facilities, etc. It will also be easy for them to have a single window clearance.

We understand that Telangana and AP Governments are coming out with special packages for pharma industrial zones. Tamil Nadu and Maharashtra may also follow suit. IDMA will be sensitizing their members on the facilities as and when they are offered.

IDMA is now in a progressing stage. How many State Boards does your organisation have in the country at present? What is your plan to increase the number?

Besides our Secretariat in Mumbai, IDMA has seven State Boards; in Gujarat, West Bengal, Tamil Nadu & Puducherry, Himachal Pradesh &Uttarakhand, Haryana, Madhya Pradesh (Indore)

and Telangana. We are planning to have 3 more State Boards; in Karnataka, Goa and Andhra Pradesh, to bring the total number of branches to 10. Similarly, we are planning to increase our membership from the current 810 to above 1000.

What sort of programs do you plan to partner with other pharma industry organisations to take the industry forward, and how far you are satisfied in achieving the confidence of others?

IDMA encompasses all sections of pharmaceutical industry like Small, Medium and Large enterprises both in formulations and bulk drug sectors. IDMA, with the standing of 54 years in India, is like an umbrella organisation to all the pharma industry associations and representing the interests of all sectors. Hence, IDMA enjoys the confidence of all other associations.

It is learnt that there are associations of big pharma players who are not cooperating with IDMA, but working separately or independently. How do you see the situation when you want to strengthen the industry sector? Do you get support or cooperation from any other pharmaorganisation?

It is not true that IDMA is not getting cooperation from associations of big pharma players. In fact, many of them are members of IDMA, although some of them may be members of other associations. They have confidence in IDMA and whenever there are common issues, they seek the support of IDMA and we are willing to support them, when they are in the interest of the national pharmaceutical industry.

For employment generation for pharmacy graduates, a demand is raised now by the graduates and post graduates in pharmacy. They are demanding that the industry should absorb only people with pharmacy background for all the vacancies in the industry, except clerical level. Do you think that their demand is genuine and legitimate? If so, what IDMA would suggest for it? Do you have any project for employment generation for pharmacy graduates?

Certainly, the pharmacy graduates need to be given their legitimate positions in Industry. IDMA is the only organisation which recognises university toppers (in the field of pharmacy) all over India in their Annual Day Celebrations. Several of them who have received the Awards from IDMA are now holding premier positions in the Indian pharmaceutical industry. Recently, we have also formed a special committee for "Industry-Institute Interactions" in order to explore the possibilities for working with academic institutions.

The ISM manufacturing companies in Tamil Nadu are also members of IDMA state unit. They are facing serious problems with regard to regulatory matters. Their complaint is that the state ISM Commissionerate is not industry-friendly and not supporting them in any manner. For the last several years, the ISM units are not getting licences for proprietary drugs and their complaints are not heard of by the concerned authorities. The entire industry is in trouble now. Can IDMA do anything to save the industry from crisis?

IDMA Tamil Nadu State Board is working with the local associations in order to resolve the problems of ISM manufacturing companies in the state. IDMA Tamil Nadu is also having a separate committee on ISM to look after the various issues involving ISM. If they require the support of the all India body (IDMA), we will extend the same.

Apart from being the president of IDMA, you are the Founder and Managing Director of Fourrts India Laboratories, Chennai. There are more than 400 SME units operating in Tamil Nadu, and a few major players like you. Do you have any idea or concept to escalate the Tamil Nadu Pharma Industry to the level of those in Gujarat and Maharashtra?

Tamil Nadu pharmaceutical industry has many quality manufacturers who are well appreciated all over India. Many of them are also exporting to several countries. Tamil Nadu pharma industry has the potential to rise to the level of other premier states in India.

On the 03rd & 04th of July 2015, we are organizing a Trade Show, ' Pharmac South 2015', which will showcase the capabilities of Tamil Nadu and South India manufacturers. IDMA Tamil Nadu has also made an appeal to the Tamil Nadu government to establish pharma parks to raise the level of Tamil Nadu pharmaceutical industry.

There was a plan among the industry in Tamil Nadu to set up a pharma cluster somewhere near Chennai with the help of state government. But now it seems that the idea has been dropped for ever. Will IDMA be able to revive the idea in order to materialize their dream?

IDMA Tamil Nadu has made a fresh appeal to the Tamil Nadu government and the Department of Pharmaceuticals, government of India to consider a 'Bulk Drug Park' near Gummidipoondi and a 'Formulation Park' near Chengalpet. Our request is being considered favourably by the government.

It is known that the Department of Pharmaceuticals, government of India, is moving towards promoting Indian bulk drugs industry, as a special program this year. Will this attempt help reduce the prices of medicines in the domestic market, and how does IDMA view the move of DoP?

The move of the Department of Pharmaceuticals and the government of India to promote Indian bulk drug industry will be very valuable in reducing dependence on China for supply of bulk drugs. On a long term basis, this will reduce the monopolistic situation created by supplies from China to greater self-reliance of India. If this happens, it can reduce the prices of medicines in the domestic market.

In the union territory of Puducherry, there is no strong association for manufacturers, and they are all operating without proper guidance from any association, according to information from several sources……. As you are aware, there were complaints against some manufacturing units in the recent past for violation of drugs act and DPCO. CBI enquiry was also conducted in certain cases. How do you observe the situation there now? Do you think the industry people will correct the mistakes, if any?

The industry scenario in Puducherry is improving very well, thanks to the initiatives taken by IDMA Tamil Nadu & Puducherry State Board. Over the last one year, IDMA TNPSB has been conducting several seminars on GMP, Quality Assurance and Self Audits for the pharmaceutical manufacturers in Puducherry. Recently, IDMA has been able to organise a meeting involving Department of Pharmaceuticals and government of Puducherry to remove all bottlenecks and help the pharmaceutical industry of the UT.

Source: Pharmabiz, 4th June, 2015.

Medical Devices Like Stents, Implants Set to Come Under Price Control

Faced with complaints of overpricing of medical devices like cardiac stents and implants, the government seems to be finally getting its act together.

According to a government official, in a string of measures to regulate the industry under the Draft National Medical Device Policy, it has recommended creating an autonomous body — the National Medical Devices Authority (NDMA) — pricing control for medical devices by including them under the Essential Commodities Act and, most importantly, floating a separate pricing division in the drug pricing regulator, NPPA.

Significantly, the draft says the government may announce a separate policy for regulating prices of identified medical devices and implement it through a separate medical devices control order. Currently, prices of medicines are notified through the Drug Prices Control Order, by the department of pharmaceuticals.

The NMDA may be headed by an officer of the rank of additional secretary/joint secretary and include a member secretary (rank of joint secretary), two medical practitioners, two medical device

technologists or scientists and the secretary general of Quality Council of India (ex-officio).

In a patient-friendly measure, the draft mentions adopting policies on efficacy and safety testing, and quality control through a 'Made in India' marking (BIS) specific to medical devices in line with global standards.

In fact, the objective of the National Medical Device Policy 2015 is "strengthening the Make in India drive by reducing dependence on imports and setting up a strong base for medical devices, especially those with critical implications in terms of affordability and availability of patients".

Medical devices, which are classified as equipment, implants and disposables, are mainly import driven, with nearly 70-80% high-end devices and equipment brought into the country, while the domestic industry manufactures disposables and medical supplies. "Lack of national regulation helped the MNCs in doing business in this sector," it says.

Source: The Times of India, 9th June 2015

FDA Panel Backs New Drug to Fight Heart Attacks

An expert group recommended on Tuesday that the Food and Drug Administration approve a powerful new drug to protect against heart attacks. If approved, it would be the first in a major new class of medicines in a generation that significantly lower levels of cholesterol, the leading cause of heart disease.

Dr. Joshua W. Knowles, a Stanford cardiologist, called the medicines “a triumph of the modern genetic revolution.”

The idea for such drugs arose from genetic studies about a decade ago and has tantalized cardiologists ever since. Early results of clinical trials raised hopes that the therapies would be critical new additions to the treatment arsenal for those at risk of heart disease, the biggest killer of Americans.

People who have taken them have seen their LDL cholesterol, the so-called bad cholesterol, plunge to remarkably low levels. But definitive evidence of the drugs’ effectiveness in reducing heart attacks and deaths will come only after large clinical trials are completed in 2017. The panel, in a 13 to 3 vote, recommended the approval of Sanofi andRegeneron Pharmaceuticals’ drug, alirocumab. On Wednesday, the committee will turn to Amgen’s drug, evolocumab. The F.D.A. usually follows the recommendations of its advisory panels, but not always. The agency says that if it approves the drugs based on their effects on cholesterol, the approval will not be rescinded even if trials now underway fail to show the drugs reduce the risk of heart attacks and deaths.

Once a drug is approved doctors can prescribe it to patients other than those for whom it was intended, although insurers generally will not pay.

The drugs are injected every two weeks or once a month, depending on the formulation. The companies are asking that they be approved for use in three groups: patients with high levels of LDL cholesterol who cannot lower it enough with statins, the mainstay drug for cholesterol lowering first introduced in the late 1980s; people at very high risk because they have already had a heart attack or have diabetes and cannot get their levels low enough with statins; and people with high levels of LDL who cannot tolerate statin.Doctors often aim for LDL levels of 70 for people at high risk.

The problem for the expert group was to decide if there was enough evidence to approve the Sanofi drug without waiting for results from the large clinical trials. Those who voted no said drugs should not be approved until clinical trials established their efficacy, and voiced the worry that people participating in the trials would drop out once the drugs were approved so they could be sure to get the medicine, not a placebo.

“We need clinical outcomes,” said Dr. Peter Wilson of Emory University.

Some on the panel felt comfortable recommending approval only for a narrow group of people with a genetic condition, heterozygousfamilial hypercholesterolemia, who cannot control their cholesterol with statins alone.

Source: The Times of India, 11th June 2015

Pharmacist's Prescription for Docs: Write in Capital Letters to Save Lives

A one-man campaign that started in the sleepy town of Nalgonda in 2012 is on its way to rewrite (literally) medical history — making it mandatory for doctors to write prescriptions in capital letters so as to make these legible.Prescriptions, the way they are written now, have taken lives.

While a formal gazette notification by the Union health ministry is round the corner, the Medical Council of India (MCI) is circulating a prescription format (to be used by doctors) to all state medical councils across the country. The letter, which TOI has a copy of, says doctors must write the name of medicines, dosage, strength, duration and total quantity in "capital letters only".

From his run-down pharmacy in Nalgonda, 47-year-old ChilkuriParamathma used the Right to Information Act, filed PILs and wrote innumerable letters to the Union health ministry, the MCI, the Drugs Controller-General of India (DCGI) and the Director-General of Health Services (DGHS) to enforce his 'prescription' for prescriptions.

"In my 25 years of practice as a pharmacist, names of medicines always fascinated me. There are several similarly spelt drugs that can stump a pharmacist as one single letter or even a hypen can sometimes be the only difference between two completely opposing drugs. Imagine the havoc it can cause," said Paramathma.

On February 22, 2012, Paramathma got to know of a Hyderabad-based pregnant woman who was advised Microgest 200 mg (used for fetus growth). "So illegible was the writing in the prescription that the pharmacist mistook Microgest for Misoprotol — which is used for abortion. The woman lost her baby," he recounted.

In July 2013, a patient died in Hyderabad after he was administered a wrong injection by a pharmacy. The drug control administration later shut down the pharmacy.

Paramathma cites a plethora of drugs that spell and sound almost the same, but have quite different effects on the body. "Consider L-CIT and L-COT, KARDIA and KARDIN, JUCAN and JUGAM, IKA and IKKA, IDEBEN and IDIBEND, NEPOMOX and NEPOTOX, NIFDEC and NIFEDINE, OCUVIT and OCUWET, E-PRIN and EPRIL... The list is endless," he says.

Following several missives to various departments and a hearing at the Andhra Pradesh HC, a division bench in 2014 directed MCI to look into the aspect of illegible handwriting of doctors. Following this, the Union health ministry directed MCI to look into the case.

Source: The Times of India, 18th June 2015

Need A Dose of Regulation

Selling medicines online is mushrooming in India as a consequence of booming e-commerce.

The advent and proliferation of on-line sale of medicines on e-commerce platforms no doubt buttress the government's case of 'access to all' but the recent case of prescription drugs being sold online has alerted authorities to extent and dangers of this unregulated practice.

As such, selling medicines online is prevalent in developed markets and its mushrooming in India is a consequence of the booming e-commerce segment in India. But, clearly selling over-the-counter (OTC) medicines online, which is permissible, is quite different from selling prescription drugs online where the attendant dangers of abuse are high.

"A prescription issued by a doctor cannot be re-used randomly. There is a danger that scheduled drugs can be re-ordered and misused by the consumer,'' JayeshLele, President, Indian Medical Association (IMA), a body representing over 2.50 lakh medical practitioners across the country, said.

"Besides, there are several `do's and don'ts' with regard to storage and dispensing of prescription medications that need to be adhered to,'' he added.

According to Mr. Lele, self-medication is a rampant practice in India, and online sale of drugs would only encourage it. "Indiscriminate use leads to patient resistance which is very dangerous as has been the case with tuberculosis drugs.''

After a brief lull, the Rs.85,000-crore pharmaceutical industry in India is back to growth in 2014, notching up 12 per cent growth, S.V. Veeramani, President, Indian Drug Manufacturers Association (IDMA), said. "With double-digit growth back, the fledgling on-line medicine segment is also booming and there is a much needed regulation of this new practice.''

"We are strongly opposed to the online medicine sale as is prevalent today,'' J.S.Shinde, President, All India Organization of Chemists & Druggists (AIOCD), which represents 7.5 lakh retail pharmacies, said.

Scheduled drugs

There has been a call for regulation because the existing Drugs and Cosmetics Act does not have any guidelines in place for e-commerce players in the pharmaceutical industry. However, it is very clear that 'scheduled' drugs should be sold only by licensed pharmacies against a doctor's prescription.

The authorities have responded with alacrity to the situation, and last week, the Drugs Controller General of India (DCGI) pointed out the need to have in place a regulatory framework to bring online medicine sale under its ambit. Industry body FICCI has been appointed as the nodal agency by the DCGI to consolidate the guidelines, and it will seek the views of representative bodies such as AIOCD, IMA, Organisation of Pharmaceutical Producers of India (OPPI) and others.

"The role, responsibilities, and liabilities of e-commerce marketplace and the product sellers need to be clearly defined,'' G.N. Singh, DCGI, said at a consultative meeting last week.

"It becomes even more critical to have a framework in place when the intermediary is selling drugs where the safety and health of the consumer is of paramount importance.''

Supply chains

The interest of small retailers would be protected and existing supply chains would not be adversely impacted by e-pharmacies, the DCGI said adding that the aim was to integrate e-pharmacy into the existing system.

While supporting the need for an unambiguous regulatory framework, Mr. Shinde felt existing brick-and-mortar pharmaceutical retailers were prepared as retailers were embracing new technology and "even deliver drugs home in the case of aged patients. But this is all only within the law and prescriptions for scheduled drugs are non-negotiable,'' he said. "We want a level playing field.''

Source: The Hindu, 22nd June 2015

Pharmexcil South Zone Office to be Opened at 'Pharmac South', Inaugural Ceremony on 3rd July in Chennai

The fourth zonal office of the Pharmaceuticals Export Promotion Council (Pharmexcil) will be opened for the export promotion services of the south Indian pharma companies on July 3, at the inaugural ceremony of 'Pharmac South 2015', the second edition of the south Indian pharmaceutical products exhibition

The two-day event will be held at the Chennai Trade Centre on the 3rd and 4th of this month and is expected that the exhibition will bring participants from all the six south Indian states and give exposure to more than one hundred manufacturing companies to showcase their products. This year the visitors are expected from all over India and from ASEAN (Association of South East Asian Nations) countries.

The office of Pharmexcil in Chennai will be inaugurated by its chairman, Ashutosh Gupta in a

ceremony chaired by S.V Veerramani, national president of the IDMA. Dr VK Subburaju, secretary, department of pharmaceuticals, government of India, will be the guest of honour

The exhibition will be opened for the visitors at 11 am on Friday by DrSubburaju. Sudhamsu Pant, joint secretary, department of commerce, Dr J Radhakrishnan, secretary, department of health, government of Tamil Nadu, Dr S Manivannan, deputy drug controller, CDSCO South Zone, S Abdul Khader, director of drugs control, Tamil Nadu and J Jayaseelan, TN IPA will speak on the occasion

Sharing details about the role of Pharmexcil, its director general, Dr P V Appaji said Pharmexcil is joining with the Indian Drugs Manufacturers Association (IDMA) for conducting the product exhibition this year. In order to support the manufacturers from south India for export of their products, the Council will organise a 'buyer-seller meet' on the first day and an interactive session covering the details of product registration and other technicalities on the second day. DrAppaji said Pharmexcil will provide all technical support to the manufacturers from Tamil Nadu, Kerala, Puducherry and Karnataka to export their products to other countries

Later while briefing Pharmabiz, M Rajaratinam, chairman of TN IDMA, said registration of over one hundred stalls has been done already and confirmation from about two thousand visitors has also received. In the afternoon, a seminar on domestic marketing, covering discussions on three subjects- 'Building Brands to Enhance your Market Share', 'Building & Retaining a High Performing Sales Team' and 'ICMR's Initiative Towards Affordable Technologies' is arranged for the participating manufacturers

He said the visitors will include manufacturers of pharmaceuticals, neutraceuticals, dietary supplements, ayurvedic and herbal products, and functional foods

On the second day, at 10 am, the chairman of Pharmexcil will conduct a session at the seminar hall on exports. Dr PV Appaji and SV Veerramani will speak on the occasion. DrSudhamsu Pant, joint secretary, department of commerce, will deliver the keynote address.

Source: Thursday, July 02, 2015, 08:00 Hrs [IST]

India Should Stand up for its IPR Regime

Trade minister NirmalaSitharaman is perfectly right to assert India's compliance with the Trade-Related Intellectual Property Rights (Trips) agreement of the World Trade Organization and, thereby, reject much of the criticism mounted against India in the latest version of the US government's so-called Special 301 report. India must make it absolutely clear to the US government that there would be no rethink or review of Section 3(d) of India's patent law, which mandates higher therapeutic efficacy for a new form of an already patented drug to qualify for a new patent. India should actively lobby all developing and developed countries to incorporate a similar provision in their own patent laws.

At the same time, New Delhi must act on, rather than fend off, legitimate criticism. Both the Controller General of Patents and the Intellectual Property Appellate Tribunal have taken the view that import does not necessarily amount to working a patent. The law must be clarified to nullify such a view, whose logic, if extended to compulsory licences, would rule out, say, an African nation with a health emergency issuing a compulsory licence to an India-based company. The right way to make patented drugs affordable is price control, if negotiations, together with purchase commitments, fail. The courts have been slow to prevent Indian companies profiting from patent infringements. Why should there be any delay, as has happened in

a recent, well-known case, in stopping the marketing of an alternate form of a patented drug when the law deems such alternate forms to be patented, too?

Further, can there be any dispute over the need to crack down on the manufacture and sale of spurious and substandard drugs? The US trade review is bothered about shoddy drugs in India because the same laxity of standards at the level of manufacturers and regulators feeds into the drugs exported to the US. India should stamp out the menace of spurious drugs for the sake of Indians' own health, besides for the credibility and reputation of Indian exports.

Source: The Economic Times, 5th May 2015

Government of India - Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals - New Delhi – 110 001

Call for Expression of Interest (EoI)

The Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers, Government of India intends to render financial assistance to Medium Pharmaceuticals Enterprises, mainly for compliance to WHO/International GMP norms for technological upgradation under its proposed scheme to be titled as **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS).**

In this connection, Expression of Interest (EoI) is invited for selection of a **Suitable Financial Institution for** disbursement and management of soft loans to Medium Sector Pharmaceutical Enterprises out of a corpus fund proposed to be created by the Department of Pharmaceuticals (DoP) to render financial assistance under its proposed Scheme to be titled as **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) to Medium Enterprises (MEs) for compliance** to WHO/International GMPs.

The EoI documents containing the details regarding the scope of work schedule, prescribed qualifications, evaluation criteria etc, can be accessed/downloaded from the website of DoP at https://pharmaceuticals.gov.inThe eligible and interested FinancialInsitutions may submit their EoI documents complete in all respects along with the prescribed application fee of **Rs 5,000/- by 4.00 p.m. on Monday. the 10th August 2015** at the following address:

Dr. M.ArizAhammed,
Joint Secretary,
Department of Pharmaceuticals,
Room No 206, D-Wing, ShastriBhawan,
New Delhi- 110 001

PARLIAMENT QUESTION - ANSWERS
LOK SABHA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No. 253
Answered on 13.03.2015

PET BOTTLES FOR PACKAGING OF MEDICINES

253. Maragatham Smt. K.,Kashyap Shri Virender

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) Whether plastic or polyethylene terephthalate (PET) bottles used for storing/ packaging liquid medicines are health hazards and if so, the details thereof;
(b) Whether a number of health experts have urged the Government to impose a ban on plastic/PET bottles as primary packaging material for pharmaceutical products;
© If so, the details thereof along with the action taken/proposed to be taken by the Government thereon;
(d) Whether the Government has also received representations against the ban on use of plastic/PET bottles; and
(e) if so, the details there of?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 253 FOR 13TH MARCH, 2015

(a) to ©: In May, 2013 and August, 2013, a Dehradun based Non-Governmental Organisation (NGO) requested that a ban be imposed on the use of Polyethylene Terephthalate (PET) bottles as primary packaging material in Pharmaceutical liquid orals, suspensions and dry syrups. The NGO claimed that use of PET bottles had severe adverse effects on human health due to presence of endocrine disruptors and leaching which takes place under varying storage and temperature conditions and the age of packaging.

The representation was considered by Drugs Technical Advisory Board (DTAB) and an Expert Committee under the Head of the Department (HOD), Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi, was constituted to examine the issues raised in the representation. In the light of the information provided by the NGO and that available in the existing literature, the Expert Committee suggested that sufficient evidence to establish a definite correlation of causality of plastic container for pharmaceutical products and adverse health effects is not established and that this was an important health concern and needed detailed investigation. It also added that the 'absence of evidence' may not be considered as 'evidence of absence' of the potential harmful effects of packaging pharmaceutical products in plastic containers.

Thereafter, a draft notification was published in the Gazette of India dated 29th September, 2014, inviting objections and suggestions from the public including all the stakeholders. The Expert Committee had also stated that scientific evidence needs to be generated over a period of time.

(d) & (e): In response to the draft notification, a large number of representations were received from various stakeholders against the proposed ban. Around 292 representations inter alia opposed the ban and stated that sufficient scientific evidence is not available about the alleged ill-effects of the use of PET bottles for packaging medicines. Some of these representations also cited studies by various agencies to claim that use of such bottles is safe and is widely used across the world. Four representations supported imposition of ban.

Question No. 258
Answered on 13.03.2015

TRACK AND TRACE MECHANISM FOR SAFE MEDICINES

258. Khan Shri Md. Badariddoza, Chaudhury Shri Jitendra

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the Government proposes to launch a `track and trace` mechanism through which patient will be able to check the safety and authenticity of the medicine;

(b) if so, the details and the objective thereof along with the cost to be incurred on the said mechanism for the domestic market;

(c) the time by which the `track and trace` mechanism is likely to be launched and the manner in which it is likely to be made operational in the country; and

(d) the other steps being taken by the Govern ment to provide quality and standard medicines to the consumers?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (d): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 258 FOR 13TH MARCH, 2015

(a) Yes.

(b) A 'Track and Trace' mechanism has been developed with the objective of authenticating that the medicines being sold and stored in the country are the genuine products of the manufacturer. Under the system, the primary, secondary and tertiary packs of medicines will have a unique bar code allotted to a particular manufacturer. The data relating to all medicinal products will be available on the internet and any person having access to internet would be able to cross check the authenticity of the medicines.

(c) Rules for implementing the Track and Trace mechanism will be framed and will be operationalized after allowing a reasonable period for transition. Compliance with the requirements of this mechanism will be mandatory for all manufacturers of drugs.

(d) The Drugs and Cosmetics Act, 1940, provides stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable. The inspectorate staff of Central Drugs Standard Control Organisation also keeps a vigil and draws samples of drugs for test and analysis to monitor the quality of drugs in the country.

Question No. 2917
Answered on 13.03.2015

SAFETY OF FIXED DOSE COMBINATIONS

2917 Rao Shri Rayapati Sambasiva, Jayadevan Shri C. N.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether as per the study report of an international medical journal, India`s Drug Act has aided proliferation of harmful combination with little medical rationale and makes it possible for fixed dose combinations to evade clinical trials and the Central Drugs Standard Control Organisation`s approval;

(b) if so, the details thereof along with the reaction of the Government thereto;

(c) whether certain fixed dose combinations including those for diabetes control being used in the country are not recommended by national or international treatment guidelines;

(d) if so, the details along with the facts in this regard; and

(e) the corrective measures being taken by the Government to test/screen all drug combina tions being sold in the country in order to ensure that these have scientific rationale for their safety?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (d):

A report published in a journal 'Lancet' mentions that the Indian Act relating to drugs makes it possible for companies to evade Central Drugs Standard Control Organization (CDSCO) approval for Fixed Dose Combinations (FDCs). It is also mentioned in the report that Metformin FDCs are not recommended by international or national treatment guidelines for management of type 2 diabetes. The licenses for manufacture of FDCs can be granted by the State Licensing Authorities after approval by Drugs Controller General (India) in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. In the past, however some FDCs have been approved by the State Licensing Authorities without obtaining approval of DCG(I).

(e): The DCG (I) had, on 15.01.2013, directed all State Drug Controllers to ask the manufacturers of such FDCs to prove the safety and efficacy of FDCs being manufactured by them within a period of 18 months failing which manufacture and marketing of such FDCs in the country was to be prohibited. 6220 applications were received in response to the direction of the DCG (I). The applications so received ave been scrutinized by an Expert Committee constituted for the purpose.

Question No. 2974
Answered on 13.03.2015

SALE OF PRESCRIPTION DRUGS

2974 Munde Dr.Pritam Gopinath, Giluwa Shri Laxman, Lekhi Smt. Meenakashi, Choudhary Shri Ram Tahal, Pal Shri Jagdambika

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether a number of non-prescribed medi cines and drug combination containing undefined value or quantity of food supple ments/steroids/tonics are being sold over the counter throughout the country, and if so, the details thereof indicating the estimated annual turnover of the prescribed and non-prescribed medicines, separately in the country;

(b) whether widespread and indiscriminate sale of medicines, steroids, food supplements and triple/quadruple drug combinations has led to rising instances of drug resistant infections in the country, and if so, the details thereof;

(c) whether the Government has formulated/proposes to formulate any guide lines/policy to rationalize the sale and use of steroids food supplements and drugs including various drug combinations in the country and if so, the details thereof;

(d) the measures being taken by the Govern ent to make doctor`s prescription mandatory for sale of drugs and enforce the aforesaid guidelines/policy; and

(e) the action plan of the Government to improve access to new prescription drugs not produced by generic drug manufacturers in the Country?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): No such report has been received by the Government.

(b) to (e):

The Government is aware of the existence of multi-drug resistance. A Task Force consti tuted by the Government recommended various steps to rationalize the use of antibiotics in the country. Based on the recommendations of the Task Force, the Drugs & Cosmetics Rules, 1945 have been amended vide Gazette Notification GSR 588 (E) dated 30-08-2013 incorporating a new Schedule H1 to restrict indiscriminate sale of certain antibiotics, Anti TB drugs and habit forming drugs. Accordingly, such drugs can be sold only on prescription of a Registered Medical Practitioner

RAJYA SABHA

MINISTRY OF HEALTH AND FAMILY WELFARE

Question No. 1817

Answered on 12.05.2015

LABORATORIES FOR TESTING MEDICAL DEVICES

1817 Shri Baishnab Parida

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the country does not have laborato ries to test medical devices, if so, the details thereof; and

(b) whether Government proposes to get such labs that would be funded by the concerned Ministry to give a boost to manufacturing sector in the country and if so, the details thereof?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): Medical devices are currently tested in the following laboratories:

(i). National Institute of Biologicals, Noida - For testing diagnostic devices viz. HIV, HBsAg and HCV;

(ii). Central Drugs Testing Laborato ries, Mumbai – For testing of Intra Uterine Devices viz Cu-T & Tubular Rings which are included in Schedule R to the Drugs and Cosmetics Rules,1945;and

(iii). Central Drugs Testing Laborato ries, Chennai - For testing of Condoms.

(b): The current emphasis of the Department of Health and Family Welfare is on strengthening the existing laboratories. However, when

required, the Department of Commerce also supports establishments of common testing laboratories for medical devices and diagnos -tic equipment under Central Assistance to States for Infrastructure Development of Export Scheme to support the growth of the industry.

Question No. 1824
Answered on 12.05.2015

DEPENDENCE ON CHINA FOR SUPPLY OF KEY VACCINES

1824 Dr. Prabhakar Kore

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether it is a fact that India's over depend ence on China for key vaccines and mainly for sourcing of raw material used in medicines has become a cause of concern for the Govern ment; and

(b) whether Government has agreed to pay more for additional supplies of Japanese Encephali tis (JE) vaccines to China, and if so, the details thereof?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): The Government procures only Live Attenu ated Japanese Encephalitis (JE) Vaccines from Chengdu Institute of Biological Products (CIBP), China through M/s HLL Life Care Limited. Other key vaccines like DPT, TT, Hep-B, Measels, BCG, t-OPV and b-OPV are procured from domestic manufacturers. However, bulk drugs and drug intermediates are also imported from China.

(b): The Government has been procuring Live Attenuated JE Vaccines from China which is not manufactured in India. Requirement of 2013-14 and 2014-15 was 669.84 lakh doses which were procured at a rate of Rs.19.94 per dose. For 2015-16 and 2016-17, the requirement is 901.52 lakh doses for which the rate has been finalized at Rs.27.73 per dose.

Question No. 1038
Answered on 05.05.2015

PRODUCTION OF FDCS WITHOUT PERMISSION

1038 Shri Kiranmay Nanda

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether it is a fact that more than 294 drugs with fixed dose combination (FDC) are in production without proper permission of Drug Controller General ofIndia;

(b) if so, the action taken or proposed by Government; and

(c) if not, the reasons therefor?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) & (b):
The case regarding 294 FDCs, licensed by the State Licensing Authorities without approval of Drugs Controller General (India) [DCG (I)], is sub-juidice in Madras High Court. In addition, in response to the directions issued to the manufacturers to prove the safety and efficacy of FDCs being manufactured by them, the Central Drugs Standard Control Organization received 6220 applications. The rationality, safety and efficacy of these FDCs have been examined by an Expert Committee constituted for this purpose.

(c): Does not arise.

Question No. 1042
Answered on 05.05.2015

REINING IN OF QUACKS AND SALE OF FAKE DRUGS

1042 Shri Motilal Vora

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether it is a fact that there are 40 thousand MBBS doctors in Delhi and an equal number of quacks too;
(b) if so, the steps taken by Government to rein in the quacks;
(c) whether Government is aware of the fact that generic medicines are still out of reach of the patients;
(d) if so, the steps taken by Government to make the common patients aware of the generic medicines and to ensure their availability for them;
(e) whether Government will lay concrete infra structure to probe the doctors and the chem ists of Delhi and of other parts of the country; and
(f) if so, by when?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): As informed by Government of NCT of Delhi, 65,000 doctors are registered with Delhi Medical Council. No data on quacks is maintained.

(b): The Indian Medical Council Act, 1956, prohibits a person other than a medical practitioner enrolled on a State Medical Register to practice medicine in the State. Punishment of imprisonment for a term which may extend to one year or with a fine which may extend to Rs.1,000/- or both is also prescribed.

(c) & (d):

For popularizing and promoting generic drugs in the country, the Government through its agency – BPPI has been publicizing through print media to generate awareness among general public about the advantages of generic medicines and availability of generic medicines from Jan Aushadhi Stores.

Further, under NHM upto 5% funding over and above the normal allocation of the States is also provided as an incentive for those States that implement policy and systems to provide free generic medicines to all in public health facilities.

(e) & (f):

Medical Council of India (MCI) in its regula tions namely the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 under Clause 1.5 has prescribed as under:

"Use of Generic names of drugs: Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs."

RAJYA SABHA
MINISTRY OF CHEMICALS AND FERTILIZERS

Question No. 1428
Answered on 08.05.2015

INDIAS DEPENDENCE ON CHINA FOR BULK DRUGS AND APIS

1428 Dr. Prabhakar Kore

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

(a) whether it is a fact that India's overdependence for bulk drug or Active Pharmaceutical Ingredients (APIs) used in medicine formulations on China can lead to severe shortages and force to pay more for additional supplies; and

(b) whether Government proposes to support domestic pharmaceutical industry to rebuild Active Pharmaceutical Ingredient (API) clusters and start manufacturing key medi cines in public sector enterprises to avoid a crisis in future, and if so, the details thereof?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) and (b):

As per the Boston Consulting Group Report of 2013 import of Active Pharmaceutical Ingredients (APIs) during the year 2013 was approximately US$ 3.5 billion of which a large share was from China. The Government had constituted a High Level Committee known as the Katoch Committee on 08.10.2013 to study and identify the APIs of critical importance and to work out a package ofinterventions / concessions required to build domestic production capabilities and to examine the cost implications. The Katoch Committee has inter-alia recommended establishment of Mega Parks for APIs with common facilities such as common Effluent Treatment Plants (ETPs), Testing facilities, Captive Power Plants / assured power supply by state systems, Common Utilities/Services such as storage, testing laboratories, IPR manage ment, designing, etc., maintained by a separate Special Purpose Vehicle (SPV); a scheme for extending financial assistance to states to acquire land and also for setting up common facilities; revival of public sector units for starting the manufacturing of selected and very essential critical drugs (e.g. penicillins, paracetamol etc.); financial investment from the Government for development of clusters which may be in the form of a professionally managed dedicated equity fund for the promotion of manufacture of APIs and extending fiscal benefits to creation of the entire community cluster infrastructure and individual unit infrastructure; extension of fiscal and financial benefits to promote the bulk drugs sector; promoting stronger industry-academia interaction, synergising R&D promotion efforts by various govt. agencies; incentivising scientists, duty exemptions for capital goods imports.

These recommendations are being examined for formulation of a Policy for Promotion of Manufacturing of Bulk Drugs.

Question No. 147
Answered on 24.04.2015

BOOST TO PRODUCTION OF BULK DRUGS APIS

147 Smt. Vandana Chavan

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether Government has noted the increasing dependence of the Indian pharmaceutical companies on bulk drugs and Active Pharma Ingredients from China, if so, the steps taken by Government to address this issue;

(b) the number of companies engaged in production of bulk drugs in the country, including name of company, bulk drugs produced and production capacity;

(c) the percentage of import dependence on bulk drugs;

(d) the steps taken by Government to encourage R & D and production of bulk drugs; and

(e) the challenges faced by the manufacturers of bulk drugs in the country and steps taken/to be taken to address the same?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a), (d) and (e):

As per the Boston Consulting Group Report of 2013 import of Active Pharmaceutical Ingredients (APIs) during the year 2013 was US$ 3.5 billion which was primarily from China. The Government had constituted a High Level Committee known as the Katoch Committee on 08.10.2013 to study and identify the APIs of critical importance and to work out a package of interventions/concessions required to build domestic production capabilities and examine the cost implication. The Katoch Committee has inter-alia recommended establishment of Mega Parks for APIs with common facilities such as common Effluent Treatment Plants (ETPs), Testing facilities, Captive Power Plants / assured power supply by state systems, Common Utilities/Services such as storage, testing laboratories, IPR man age ment, designing, guest house / accommodation, etc., maintained by a separate Special Purpose Vehicle (SPV); a scheme for extending financial assistance to states to acquire land and also for setting up common facilities; revival of public sector units for starting the manufacturing of selected and very essential critical drugs (e.g. penicillins, paracetamol etc.); financial investment from the Government for development of clusters which may be in the form of a professionally managed dedicated equity fund for the promotion of manufacture of APIs and extending fiscal benefits to creation of the entire community cluster infrastructure and individual unit infrastructure; extension of fiscal and financial benefits to promote the bulk drugs sector; promoting stronger industry-academia interaction, synergising R&D promotion efforts by various govt. agencies; incentivising scientist, duty exemptions for capital goods imports.

These recommendations are being examined for formulation of a Policy for Promotion of Manufacturing of Bulk Drugs.

(b): As per the survey of National Pharmaceuticals Pricing Authority (NPPA) conducted in 2007, there were 2389 bulk drug manufacturing units. The said survey, however, does not gives information about the bulk drugs produced and production capacity of the individual companies.

(c): As per the Boston Consultancy Group Report, the total production of APIs in 2013 was US$ 10.4 billion and India imported APIs amounting to US$ 3.5 billion in 2013. The country is, however, 80-90% dependent on imports of APIs for certain medicines mentioned in National List of Essential Medicines viz. Paracetamol, Metformin, Ranitidine, Amoxicillin, Ciprofloxacin, Cefixime, Acetyl salicylic acid, Ascorbic acid, Ofloxacin, Ibuprofen, Metronidazole and Ampicillin.