ISSUE No. 43

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. - Aug. - Sep. 2019

Delvin Formulations

Destiny for Innovation

Moving Globally

- R & D and Manufacturing of API
- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
- Medical Devices
- Surgicals

Our Group of Companies

NURAY CHEMICALS PVT. LTD.	Sai Mirra Innopharm Pvt. Ltd.	Delvin Formulations	Numen (Singapore) Healthcare Pvt. Ltd.	Delvin Klarvoyant Biogenics Pvt. Ltd.	Delvin Surgicals
R & D and Manufacturing of API	R & D and Manufacturing of Formulations	Domestic Marketing	International Marketing	Medical Devices	Surgicals

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 43rd issue of Pharma Web Newsletter for July – Sept 2019.

We regret to inform the delay in publishing this issue, due to preoccupation in organising training programme to fresh Pharmacy graduates.

This 43rd issue contains the program highlights as well as the following lectures given by various resource persons.

- Medical Device Rules - Regulatory Framework in India – **Dr. Ravi Kant Sharma**, Deputy Drugs Controller (India), CDSCO, New Delhi

- Standards of Medical Devices – A BIS Perspective – **Mr. Prakash Bachani,** Scientist E & Head (MHD) Bureau of Indian Standards (BIS)

Further we have published the latest Gazette Notification pertaining to the amendment of Drugs & Cosmetics Act & Rules issued by DCGI office

The PKTI also conducted 8th Industrial Orientation Training Programme for fresh Pharmacy graduates during the month of September 2018. The highlights of this programme will be published in this issue.

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., M/s. Acid India Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

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

MEDICAL DEVICE RULES - REGULATORY FRAMEWORK IN INDIA

by

Dr. Ravi Kant Sharma,
Deputy Drugs Controller (India), CDSCO, New Delhi

(Lecture Delivered during the Training Programme on "Management & Ensuring Safety of Medical Devices" held on 2nd & 3rd May 2019, conducted by IPC, NCC-MvPI)

Introduction

- Total market Size ~ USD 5.2 Billion
- Projected Growth Rate - 20% ⇧
- Imports - 75% of the total market size
- Notified Medical Devices and In Vitro Diagnostic are regulated.
- Approx. 450 manufacturing sites are for medical devices and 50 manufacturing sites are for IVDs.
- 100% FDI
- No price control

Healthcare Scenario in India

- The Indian healthcare sector is characterized by increasing

  A. disease burden,

  B. inadequate infrastructure

  C. limited propensity to pay

Healthcare Scenario in India...

- Non-communicable diseases (Cardiovascular disease, diabetes and cancer)

  ⇧ 75%in 2025 ⇧ 45%in 2010

- India => "the diabetes capital of the world"

38 million in 2010 ⟹ (diabetes patients) 55 million in 2018

Healthcare Scenario in India...

- Around 62 million patients suffer from coronary heart disease (the leading cause of death in India), compared to 47 million in 2010
- Similarly, around 25 million patients suffer from Chronic Obstructive Pulmonary Disease (the second leading cause of death in India), compared to 21 million in 2010

Medical Device Industry

Vision: Out reach of Medical Technology to Rural and Semi-rural population.

Strength:

- Potentially huge market with growing urban middle class population
- Growing private hospitals aiming to attract Health Tourism
- Success of pharma and other paramedical areas.

Opportunities:

- Overseas companies investing in India to set up R&D units
- Increasing Joint ventures & Overseas aid assisted projects

Major difference between Drug & Device

Drug	Device
Based on Chemistry & Pharmacology (Discovery Dominates)	Based on Engineering (Design Dominates)
Safety and Efficacy (Chemical Action)	Safety and Performance/Accuracy (Physical Action)
Clinical Trials(4 Phases) (Randomized) (Gold Standard) All drugs requires CT	Clinical Investigation (Feasibility/Pivotal) (No Gold Standard) Low Risk, Medium Risk and High Risk
GMP	QMS
Local and Systemic Toxicity	Biocompatibility
Long Product Life Cycle	Short Product life Cycle

GMP Vs QMS

- GMP is a practice
- QMS is time to look beyond the practices and understand philosophy or the concepts behind the practices.
- The QMS serves as a structure / platform for implementation of GMPs.
- QMS facilitates continual Improvement in quality of the product and process, reduction in variability etc.

GMP Vs QMS

- GMP provides guidance on most of the essential elements of a QMS but lack detail on Quality Risk Management.
- GMP address CAPA but not proactive continual improvement.
- GMP does not address management responsibilities and outsourced activities in detail.

Drugs and Cosmetics Act 1940 :

Presently, The quality, safety and efficacy of notified medical devices manufactured, imported and sold in the country are regulated under the Drugs and Cosmetics Act, 1940. Under this Central Act, medical devices are regulated as drugs as defined in Section 3 (b) (iv) that:

"Such devices intended for internal or external use inthe diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board"

The Govt of India has notified...

S. No.	Name of the device	Notification Number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O.1468(E)	06-10-2005
6	Drug Eluting Stents	S.O.1468(E)	06-10-2005
7	Catheters	S.O.1468(E)	06-10-2005
8	Intra Ocular Lenses	S.O.1468(E)	06-10-2005
9	I.V. Cannulae	S.O.1468(E)	06-10-2005
10	Bone Cements	S.O.1468(E)	06-10-2005
11	Heart Valves	S.O.1468(E)	06-10-2005
12	Scalp Vein Set	S.O.1468(E)	06-10-2005
13	Orthopedic Implants	S.O.1468(E)	06-10-2005
14	Internal Prosthetic Replacements	S.O.1468(E)	06-10-2005
15	Ablation Devices	S.O.237(E)	25.01.2016

The Products which were already regulated as 'drugs' but now fall under the scope of Medical Devices Rules, 2017

16. Blood Grouping Sera
17. Ligatures, Sutures and Staplers
18. Intra Uterine Devices (Cu-T)
19. Condoms
20. Tubal Rings
21. Surgical Dressings
22. Umbilical tapes
23. Blood/Blood Component Bags

Govt. of India has already notified the following medical devices vide S.O. 5980 dated 03.12.2018, which are to be regulated with effect from 01.01.2020.

24. Nebulizer
25. Blood Pressure Monitoring Device
26. Digital Thermometer
27. Glucometer

Ministry of Health and Family Welfare vide S.O. 775 (E) dated 08.02.2019 has notified eight categories of medical devices namely,

28. All implantable medical devices
29. MRI equipment
30. CT Scan equipment
31. Dialysis machine
32. PET equipment
33. X-ray machine
34. Defibrillator
35. Bone marrow cell separator.

- Also, Ministry of Health and Family Welfare vide S.O. 1500 (E) dated 02.04.2019 has notified Organ preservative solution as drugs with immediate effect.

- Total notified categories
  23 +4+8+1=36

Medical Device Rules,2017

- Medical Device Rules, 2017 have been published vide GSR 78 (E), dated 31.01.2017.

- New rules already effective from 01.01.2018.

Scope of the regulation

Medical Device Rules,2017 shall be applicable to:

(I) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

Scope of the regulation...

(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940); and

(iii) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

Salient Points

Medical Device Rules,2017 Content

Chapter- I
Title, Application, Commencement, Definition

Chapter - II
Classification of MD, Grouping of MD, Essentials Principles

Chapter - III
Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,

Chapter - IV
Manufacture of MD-Application, Inspection, grant of lic, conditions of lic, Suspension, Cancellation, Appeal, Test License

Chapter - V
Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use

Chapter - VI
Labelling requirement

Medical Device Rules,2017 Content...

Chapter - VII
Clinical Investigation- Permission, Medical management, Compensation, Inspection

Chapter - VIII
Permission to import or manufacture medical device which does not have predicate medical device

Chapter -IX
Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body

Chapter -X
Regulation of Laboratories for carrying test or evaluation

Chapter - XI
Sale of Medical Devices

Chapter - XII
Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Medical Device Rules, 2017-Schedules

Schedule Number	Title
First	Classification of MD and IVD
Second	Fee
Third	Registration and functions of Notified Bodies
Fourth	Documents required for grant of mfg and Import licence
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

Medical Device Rules, 2017 – Salient Points

New Definitions

- Medical Device
- Substantial Equivalence
- Predicate device
- Investigational Medical Device
- New in-vitro diagnostic
- Clinical Investigation
- Notified Body
- Clinical Performance Evaluation

Risk based classification……..……

- Medical devices shall be notified by the Central Government and classified by the CLA based on the classification rules specified in the First Schedule of the drafted rules.
- Following are the risk Classes and the classification criteria based on the severity of risk associated with the medical device.

Risk Criteria	Risk Class
Low	Class A
Low-Moderate	Class B
Moderate-High	Class C
High	Class D

Scope of Notified Bodies

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- Conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license / registration

Clinical Investigation of Medical Devices

- Pilot clinical investigation- means to be carried out for the first time in human participants.
- Pivotal Clinical Investigation- based on the data emerging from pilot clinical investigation.
- No permission for conduct of academic clinical study on licensed medical device is required.
- Medical devices claiming substantial equivalence to a predicate device shall not be marketed unless CLA approved.

Clinical Investigation of Medical Devices...

- CLA has to grant permission to conduct clinical investigation within a period of 90 days from the date of application if all requirements fulfilled.
- Where an injury/death is caused related to clinical investigation, the sponsor shall provide the compensation and medical management.

Manufacture of Medical Device for Sale or Distribution

Class A and B

- Manufacturer shall apply through an identified online portal of Ministry with requisite documents as per Fourth schedule and fees specified in Second schedule.
- No audit for class A device prior to grant of license.
- The audit may be carried out within 120 days from the date of issue of license.

Manufacture of Medical Device for Sale or Distribution...

- The audit for Class B device is necessary prior to the grant of manufacturing license and the audit shall be carried out within 90 days from the date of application.
- The notified body shall furnish its report to SLA within 30 days.

Manufacture of medical Device for Sale or Distribution

Class C and D

- The application shall be made with requisite documents and fees through online portal of the Central Government to CLA.
- CLA may use the services of any expert and of a notified body and may carry out an inspection within a period of 60 days from the date of application.

Manufacture of medical Device for Sale or Distribution

- No inspection of a medical device manufacturing site for grant of loan license to be carried out if the site is already licensed to manufacture such devices.
- After completion of inspection , the inspection team shall forward the report to CLA through online portal.

Salient features of schedule V

Schedule V in line of Quality Management System (QMS) as per IS: 15579 (ISO :13485) applicable to Medical Device and In-vitro Diagnostics

- Management Responsibility
- Control of Documents
- Control of records
- Competence, awareness and training
- Design and Development
- Purchasing information
- Control of Non-conforming product
- Analysis of data
- Corrective action and preventive action
- Consumer related processes

Salient features of schedule V

Annexure- "A"

- Device Master File containing specific information about the device

Annexure- "B"

- Site master file containing specific information about the production and/ or control of device manufacturing carried out at the premises

Annexure- "C"

- Environmental requirements for notified device with type of operation and ISO Class

Manufacture of medical Device for Sale or Distribution

- The SLA shall carry out inspections for Class A and Class B at least 2 percent of the total audits carried out by notified bodies.
- A license shall remain in perpetuity subject to payment of license retention fee.
- A license holder shall be liable to pay a late fee calculated at the rate of 2 percent of the license retention fee for every month.

Shelf life of the Medical Devices

- The shelf life of the medical devices shall not exceed 60 months from the date of manufacturer to be reckoned from month to month except a satisfactory evidence is produced from the manufacturer for justifying shelf life of more than 60 months.
- A device whose total shelf life is claimed as less than 90 days then its residual shelf life should be 40 percent on the date of import. If it is between 90 days and 1 year then residual shelf life should not be less than 50 percent. If the total shelf life is more than 1 year than residual shelf life should be 60 percent.

Export

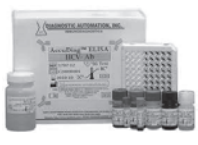
- As per the notification G.S.R.318 (E) dated 18.04.2019, the FSC for class A and B shall be issued by SLA and for Class C and D by CLA with the fees as per category and note by distinct device (Rs.1000 per category as per Second Schedule).
- The labels on packages of devices for export shall be adopted to meet the specific requirements of the importing country. If consignee does not want to label the name and address of manufacturer then code number or special code number should be mentioned as per the approval of CLA.

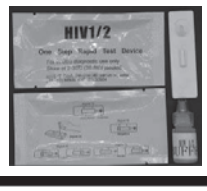
Standards of medical Devices

- The medical device shall conform to the standards laid down by BIS or may be notified by Central Government from time to time. If, such standards are not available then ISO, IEC or any other pharmacopeial standard. If all are nor available then device shall conform to the validated manufacturers standard

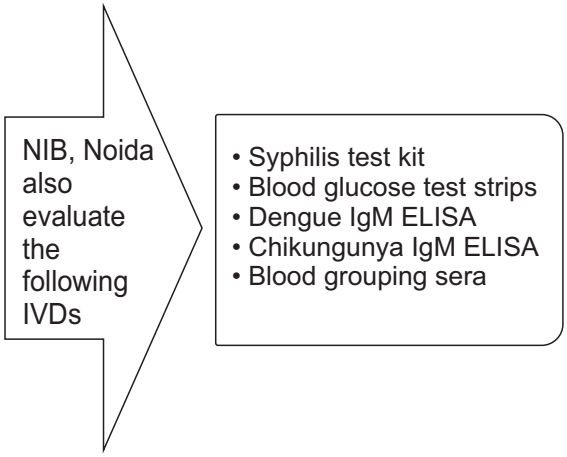
Specifications of Notified IVDs

Analyte	ELISA / CLIA /ELFA etc.		Rapid Kit	
	Sensitivity	Sensitivity	Sensitivity	Sensitivity
Anti HIV 1 / 2	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
Anti-HCV	100%	≥ 98%	100%	≥ 98%





Initiative taken by NIB, Noida



Medical Device Testing Laboratory

Serial No.	Name of Laboratory	Category of medical device
1	The National Institute of Biologicals, Noida	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent
2	The Central Drugs Testing laboratory, Chennai	Condoms
3	The Central Drugs Laboratory, Kolkata	Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant

Medical Device Testing Laboratory

Serial No.	Name of Laboratory	Category of medical device
4	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae
5	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings
6	SIPRA LABS LIMITED Sanathnagar, Hyderabad, Telangana-500018.	Copper-T, Condoms ,Sterile Hypodermic Needles, Tubal Rings ,Hypodermic Syringes and Blood Bags

Materio-vigilance Programme

- Materiovigilance programme of India was launched on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad.
- Indian Pharmacopoeia Commission functions as National Coordination Centre (NCC).
- Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram act as National Collaborating Centre,
- National Health System Resource Centre (NHSRC), New Delhi, act as Technical support partner

Materio-vigilance Programme

- Central Drugs Standards Control Organisation (CDSCO), New Delhi, support MvPI with experience of functioning as National regulator.
- Under MvPI, 13 Medical Devices Adverse Events Monitoring Centres have been identified in the country to report the events on voluntary basis (spontaneous).
- In addition to this, 250 ADRs Monitoring Centres which have been established under PvPI, have also been requested/solicited to report Adverse events/side effects associated with the use of drugs/medical devices

Recall of Medical Device (Rule - 89)

- If a manufacturer or authorised agent, considers that a medical device, which has been imported, manufactured, sold or distributed, is likely to be unsafe, such manufacturer or authorised agent shall immediately initiate procedures to withdraw the medical device in question from the market and immediately inform the competent authority.
- CDSCO is working on the registry of medical devices and also for drafting guidelines for recall of product.

Medical Device Innovation in India

Medical device innovation in India

"Innovation in India" can help drive

- Make in India
- Enhance Quality
- Reduction in Cost for Domestic and developed market.
- Increase of Export.
- The medical device sector in India needs to be empowered through private-public partnerships among the Indian Government, Indian researchers, Indian clinicians and MNCs

Status of non notified medical devices

- Quantity ?
- Value ?
- Quality & safety ?

In order to regulate all medical devices following steps have been taken:

1. Amendment in fifth schedule at par with ISO 13485:2016
2. To regulate surgical gowns, surgical drapes and incision drapes
3. Preparation of roadmap for the regulation of all medical devices

Key features of Roadmap

- Inclusion of Medical device definition

"All Medical Devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assisted in its intended function by such means for one or more of the specific purposes of,-

Key features of Roadmap...

a) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

b) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

c) Investigation, replacement or modification or support of the anatomy or of a physiological process;

d) supporting or sustaining life;

e) disinfection of Medical Devices;

f) control of conception;"

All medical devices should be regulated in Drugs & Cosmetics Act in a phase wise manner as following:

FIRST PHASE

- Registration of all non-regulated Medical Devices on SUGAM portal.
- Issue of notification of all medical devices under Section 3(b)(iv) and provisions for exemptions to obtain import/ manufacturing license and permission for clinical investigation.
- Such registration should be initially on voluntarily basis up to 18 months from the date of notification and thereafter, it should be made mandatory for all importers and manufacturers in the country.

- During this phase, all manufacturers and importers should report the Serious Adverse Events (SAEs) to CDSCO as well as Materiovigilance Programe of India (MvPI) so that these reports could be analysed to assess the safety and performance of the devices and take appropriate regulatory interventions to ensure patients safety.
- Similarly cases of complaints on such devices regarding failure in Quality Management System, design, product quality etc., should be reported to CDSCO for appropriate investigation and regulatory actions to ensure quality, safety and performance of the Medical Devices marketed in the country.

Documents required for registration

- Details of the manufacturer or importer and his products.
- Certificate of compliance with respect to ISO 13485 standard accredited by NABCB/IAF.
- Legal undertaking stating that device is complying with all relevant standards as per Rule 7 of Medical Devices Rules, 2017and all documents including ISO 13485 Certification submitted by the applicant are true and authentic.

Documents required for registration...

- Once applicant submits above information on special SUGAM portal, Registration will be generated which shall be printed on label by the manufacturer or importer.
- CDSCO shall verify the documents at any point of time and investigate quality / safety related failure / complaints and suspend/cancel the registration based on the findings / outcome of verification / investigation, after giving an opportunity to show cause to the registrant.

EXTENT AND CONDITION OF EXEMPTION UNDER RULE 90 OF MDR,2017

a) To obtain license for import / manufacturing for sale or for distribution

b) To obtain permission to conduct clinical investigation or clinical performance evaluation.

c) To obtain permission to import or manufacturing for sale or for distribution of medical device / new in-vitro diagnostic medical device which does not have predicate medical device.

d) To obtain license for import / manufacturing for the purpose of clinical investigation, test, evaluation, examination, demonstration or training

Theses exemptions are valid for medical devices of Class A & B upto 30 months and for medical devices of Class C & D upto 42 months from the date of notification of these exemptions.

SECOND PHASE

- Registration of Class A & B devices shall be followed by mandatory licensing within 12 months after 18 months of registration period.
- After 12 months period, no person, company, organization should be allowed to manufacture, import, sale or distribute Class A & Class B Medical Devices without prior license under the Medical Devices Rules, 2017.

THIRD PHASE

- Registration of Class C & D devices shall be followed by mandatory licensing within 24 months after 18 months of registration.
- After the 24 months period, no person, company, organization should be allowed to manufacture, import, sale or distribute Class C & Class D Medical Devices without prior license under the Medical Devices Rules, 2017.

Medical device vertical with respect to manpower and infrastructure

- The vertical under Drugs Controller General (India) should be lead by an Additional Drugs Controller (India).
- Four Joint Drugs Controller (India) one each for specific function like -
  - Invasive Medical Devices
  - Non-Invasive Medical Devices
  - In-vitro Diagnostic Medical Devices
  - MvPI, Enforcement, Legal and Training

Medical device vertical with respect to manpower and infrastructure...

- Twelve Deputy Drugs Controllers (India),
- Forty eight Assistant Drugs Controllers (India)
- One Hundred and ninety two Drugs Inspectors and Assistant Drugs Inspectors
- 71 data entry operators (3 for office of Additional Drugs Controller (I),(2 each for JDC(I), (1 for each for DDC(I), ADC(I) and 71 office assistants which may be hired through outside agency

Medical device Vertical..Cont..

Proposed Vertical for Medical Device in CDSCO under Drugs Controller General (India)

S. No.	Regulatory officials	Strength
1	Additional Drugs Controller (I)	1
2	Joint Drugs Controller (I)	4
3	Deputy Drugs Controllers (I)	12
4	Assistant Drugs Controllers (I)	48
5	Drug Inspector (Medical Device)	192
6	Assistant Drug Inspector (Medical Devices)	192
	TOTAL	449

Medical device Vertical..Cont..

There should be experts as given below on deputation / contractual basis

S. No.	Expert and Specialist (Scale)	Post proposed
1	Orthopedician (7600)	3
2	Dermatologist (7600)	2
3	Surgeon (7600)	2
4	Biomedical engineers (6600)	20
5	Biocompatibility expert (6600)	1
6	Cardiologist (7600)	3
	TOTAL	31

Medical device Vertical..Cont..

- 20 Research Associates having Post Graduate Qualification in areas of Bio-Medical Engineering/Bio-Technology/Microbiology to assist in developing various guidelines and review of materiovigilance data which may be hired through outside agency.
- Further, the list of panel experts from various clinical fields including specialists in In-Vitro Diagnostics evaluation shall be utilized on the basis of need for Medical Devices including In-Vitro Diagnostics evaluation on the lines of Subject Expert Committees.

Medical device Vertical..Cont..

- In addition to the above, following cells also need to be established utilizing the above mentioned permanent staff lead by Deputy Drugs Controller (I) and some outside expert on need basis namely:

I. Materiovigilance cell
II. IT cell
III. Field Vigilance cell and Enforcement cell
IV. Training cell
V. Information & Public education cell

- In order to accommodate the manpower of Medical Device Vertical, minimum of 60,000 sq. ft additional space is required at Head Quarters.

Medical device Vertical..Cont..

Five laboratories should be set up within a span of five years for testing of various Medical Devices and In-vitro Diagnostics Medical device. The verticals of Laboratory are given below:

Laboratories Personnel

S. No.	Designation (Scale)	Post proposed
1	Director (8700)	5
2	Dy. Director (7600)	20
3	SSO Grade-I (6600)	20
4	SSO Grade-II (5400)	20
5	JSO (4800)	80
6	SA (4200)	160
	TOTAL	305

Total of CDSCO regulatory officers and laboratories staff = 754

Medical device Vertical..Cont..

it is also proposed to recruit some experts on deputation or contractual basis for the following category

S. No.	Expert and Specialist (Scale)	Post proposed
1	Orthopedician (7600)	3
2	Dermatologist (7600)	2
3	Surgeon (7600)	2
4	Biomedical engineers (6600)	20
5	Biocompatibility expert (6600)	1
6	Cardiologist (7600)	3
	TOTAL	31

Make In India 10 D Formula

- Disease
- Diagnosis
- Device
- Development
- Design
- Distribution
- De-Regulation (Harmonization)
- Demography
- Democracy
- Demand

STANDARDS OF MEDICAL DEVICES - A BIS PERSPECTIVE

by

Mr. Prakash Bachani,
Scientist E & Head (MHD) Bureau of Indian Standards (BIS)
(Lecture Delivered during the Training Programme on "Management & Ensuring Safety of Medical Devices" held on 2nd & 3rd May 2019, conducted by IPC, NCC-MvPI)

BRIEFS

Indian Standards Institution 1947 | BIS Act 1986 | BIS Act 2016

- The Indian Standards Institution (ISI) was set up in 1947.
- Bureau of Indian Standards (BIS) Act 1986 gave statutory status to BIS on 1 April 1987.
- The BIS Act of 2016 enforced on 12th October 2017 makes BIS the National Standards Body of India.

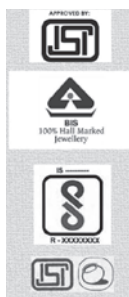
Our Presence

- BIS Head Quarter New Delhi
- 05 Regional Offices (ROs)
  - Kolkata (Eastern),
  - Chennai
  - (Southern),
  - Mumbai (Western),
  - Chandigarh (Northern)
  - Delhi (Central).
- 34 Branch offices
- 8 Laboratories (BIS)
- 200 Recognized OSL
- Training Institute at Noida

BIS Activities

In the interest of consumers as well as the industry, BIS is involved in various activities as given below:

- Standards Formulation
- Product Certification Scheme
- Compulsory Registration Scheme
- Foreign Manufacturers Certification Scheme



BIS Activities

- Hall Marking Scheme
- Laboratory Services
- Laboratory Recognition Scheme
- Sale of Indian Standards
- Consumer Affairs Activities
- Promotional Activities
- Training Services, National & International level

Standardization on Medical Devices

MEDICAL EQUIPMENT & HOSPITAL PLANNING DEPARTMENT

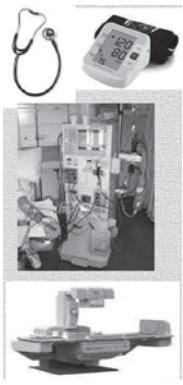
Benefits of Standards in Promoting Quality

- Fitness for Purpose
- Compatibility
- Interchangeability
- Variety Control
- Safety
- Protection of the Environment
- Product Protection

(ISO GUIDE 2)

Medical Equipment and Hospital Planning Department (MHD)

SCOPE : Standardization in the field of Medical Equipment, Surgical Dressings, Artificial limbs, Rehabilitation Equipment, Diagnostic Kits, Veterinary Surgery instruments, Dental Equipment, Laboratory Instruments and Equipment, Hospital Biomedical Waste Management and Infection Control, Medical Bio – technology & Medical Nano – technology, Hospital Planning and Health Care Services Biological and Clinical Evaluation of Medical Devices & Immuno – Biological Diagnostics Kits and Medical electrical equipment



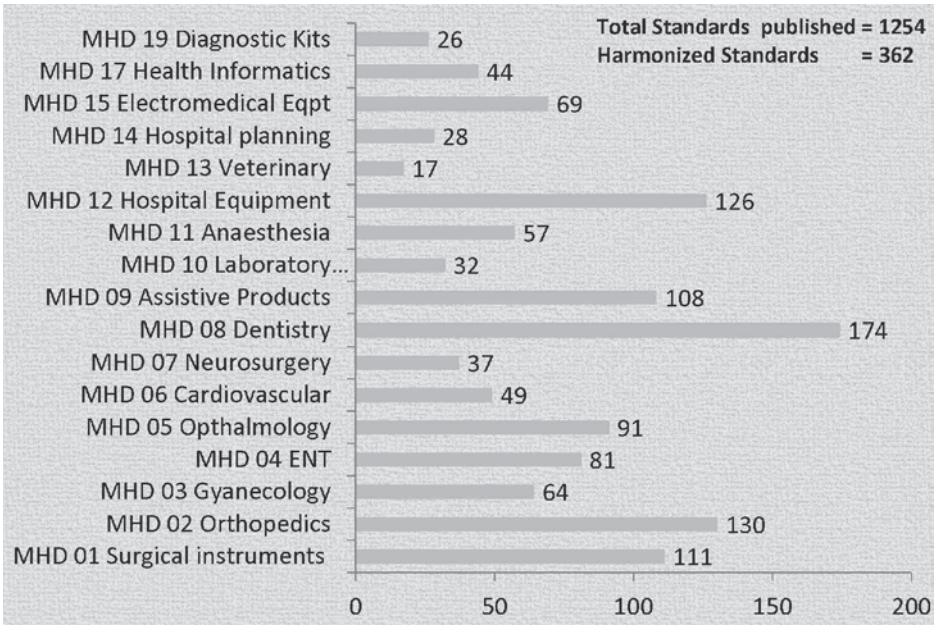
Setting National Standards on Medical Devices

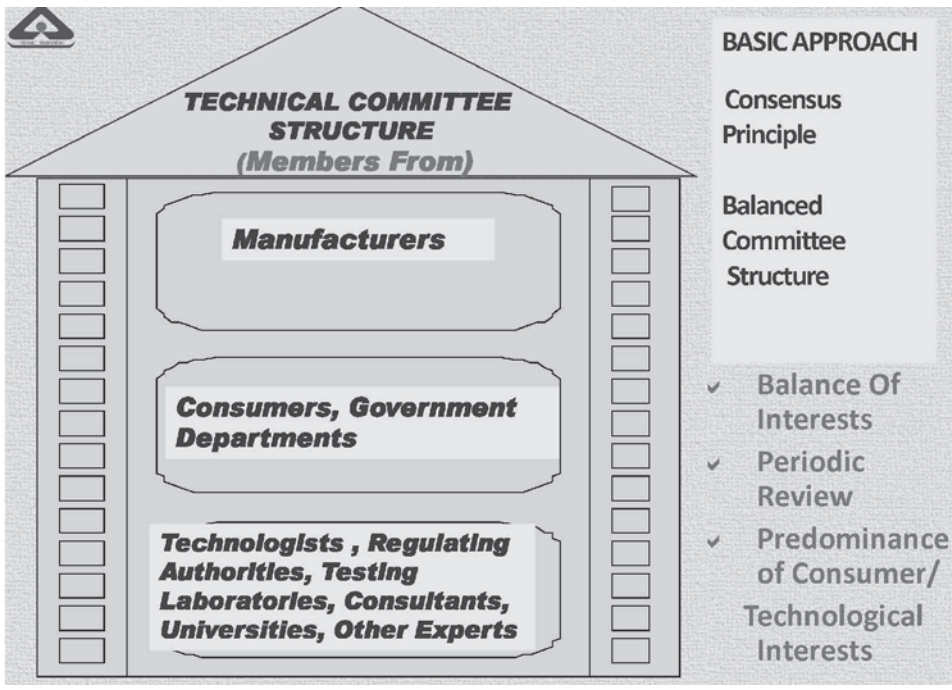
- 19 sectional committees + 1 on Anatomy and Forensic Equipment 1250 plus Indian Standards encompass product specifications in various branches of medicine

Standardization – A dynamic process

- Involvement of stakeholders – through consensus principle

National Standards on Medical Devices





Standards Formulation

OVERVIEW OF DIVISION COUNCIL / TECHNICAL COMMITTEES / PANELS.

Strength of Experts:

• Divisional Councils	01	
• Experts		46
• Technical Committees	19	
• Experts		549
• Panels	23	
• Experts		116

Collaborative approach with stakeholders

- Implementation of standards for bringing quality.
- Upgradation of standards from time to time.
- New items for standardization
- Conformity Assessment schemes of BIS

BIS Standards formulation activity in last few months

BIS has conducted a series of meetings during the last 4–5 months with following stakeholders for identification of gap areas:

1. Experts/Doctors
2. Medical Device Manufacturing industries (Manufacturers/Importers)
3. Association of Indian Manufacturers of Medical Devices (AiMED)
4. Association of Diagnostic Instruments Manufacturers of India (ADMI)

BIS Standards formulation activity in last few months

5. Medical Technologists Association of India (MTaI)
6. Drug Controller General of India
7. Department of Pharmaceuticals, Govt. of India
8. Department of Biotechnology, Govt. of India (BIRAC)
9. Meetings with Medical Device 'Startup' Industry in association with DHR (ICMR)
10. HITES Limited
11. WHO

Formulation of 'core group'.

Involvement of Innovators, Start–ups and Incubators in Standardization

- Strengthen existing harmonization/alignment process
- Boost local/regional production of medical devices.
- Identification of gap area and focused approach
- Ensuring quality products reach the customer

Outcomes of Start–ups Meets

- 1st meeting in association with ICMR held on 23 Jul 2018 at BIS Hq, New Delhi
  - Spec. on smart otoscope (ENTraview): M/s Medtronics
  - Electronics Health Record (EHR) notified by MoHFW.
- 2nd meeting in association with ICMR held on 19 Sept 2018 at ICMR Hq, New Delhi
  - Pedal operated resuscitator – M/s Windmill Health, New Delhi
  - Flexcrutch™ – M/s Flexmotive Technologies, New Delhi

- 3rd meeting in association with ICMR and BIRAC of Start–ups held on 4th Jan, 2019 at NIV, Pune
- 40 start ups, innovators
- Educational Utilization of Indian standards at MITADT University, Pune
- **New Subjects:**
  - Nanoparticle based hospital disinfectant.
  - All hospital surfaces to be infection free.
  - Nanoparticle disposal.
  - Adoption of IEC 60364–7–710: 2002 'Electrical installations of buildings Part 7–710: Requirements for special installations or locations – Medical locations'.
  - Disposable ECG Electrodes.

India's participation in ISO/IEC Technical Committees relevant to MHD

BIS as a member of ISO
'P' (participating) member = 14 TCs and = 9 SCs
'O' (observing) member = 10 SCs

In IEC:
'P' (participating) member in = IEC TC 62 and its subcommittees 62A, 62B, 62C, 62D

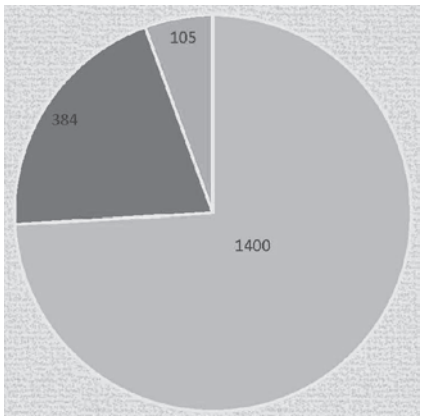
LIST OF ISO TECHNICAL COMMITTEES AND SUBCOMMITTEES AND NATIONAL MIRROR COMMITTEES OF (MHD) BIS

ISO/TC	Title	Status/Mirror committee of MHD	
TC 76	Transfusion, infusion and injection and blood processing equipment for medical and pharmaceutical	P	12
TC 84	Devices for administration of medicinal product and catheters	P	12
TC 106 Dentistry		P	8
SC 1	Filling and restorative materials	O	8
SC 2	Prosthodontic materials	O	8
SC 3	Terminology	O	8
SC 4	Dental instruments	O	8
SC 6	Dental equipment	O	8
SC 7	Oral care product	O	8
SC 8	Dental implants	O	8
TC 121	Anaesthetic and respiratory equipment	P	11
SC 6	Medical gas systems	P	11
SC 8	Suction devices for hospital and use emergency care	P	11
TC 150	Implants for surgery	P	2
SC 1	Materials	P	2
SC 2	Cardiovascular implants and extracorporeal systems	P	6
SC 4	Bone and joint replacements	O	2
SC 5	Osteosynthesis and spinal devices	P	2
SC 6	Active implants	O	2.6
TC 157	Non-systemic contraceptives and STI barrier prophylactics	P	3
TC 168	Prosthetics and orthotics	P	9
TC 170	Surgical instruments	P	1

ISO/TC	Title	Status/Mirror committee of MHD	
TC 172	Optics and photonics	O	5
Sc7	Ophthalmic optics and instruments	O	5
TC 173	Assistive products for persons with disability	P	9
SC 1	Wheelchair	P	9
SC 2	Classification and terminology	P	9
SC 3	Aids for ostomy and incontinence	P	9
TC 194	Biological and clinical evaluation of medical devices	P	19
TC 198	Sterilization of health care products	P	12
TC 210	Quality management and corresponding General aspects for medical devices	P	14

Harmonization Status – IS vs ISO/IEC Standards on Medical Devices

Harmonization Status



Standards Published by ISO/IEC = 1400

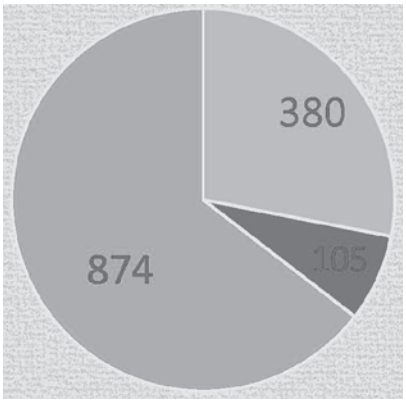
Standards adopted by BIS-Published = 380

ISO/IEC Standards adopted by BIS – Under process = 105

- Standards published by ISO/IEC
- Standards adopted by BIS – Published
- ISO/IEC Standards adopted by BIS – Under Process

Harmonization of Standards – Status (as on 30 April 2019)

No. of Indian standards



Total Standards Published = 1254

Standards adopted(Published) = 380

Standards adopted(Under process) = 105

Indigenous Standards(Published) = 874

- Standards Adopted (Published)
- Standard Adopted (Under Process)
- Indigenous Standards (Published)

MHD

HARMONIZATION POSITION

• IDENTICAL

ISO & IEC : 347

MODIFIED

ISO & IEC : 31
OIML : 02

TOTAL 380

Recent ISO meetings where MHD, BIS participated as convener/member

ISO TC 173 Assistive products – General requirements – 07 – 08 Feb 2018—Sweden

ISO TC 173 Assistive products – General requirements – 05 – 09 May 2018—Kenya

ISO TC 215 Health Informatics – 10 Nov 2017 – United Kingdom

ISO TC 215 Health Informatics – 01 – 04 May 2018 – Brazil

ISO TC 173 Assistive products – General requirements – 25 – 27 Sep 2018—Denmark

ISO/TC 157 Non – systemic contraceptives-17 – 20 Sep 2018—Chennai – BIS is the Host and STI barrier prophylactics (Plenary Meeting)

ISO/TC 150 Implants for surgery – 10 – 14 Sep 2018 – United States

ISO TC 198 Sterilization of Health Care Products – 17 – 21 Sep 2018—United kingdom

ISO TC 215 Health Informatics – 22 – 26 Oct 2018—Italy

ISO TC 210 Quality management and corresponding— 16 – 20 Nov 2018—South Korea general aspects for medical devices

ISO/TC 84 Devices for administration of medicinal products and catheters – 3 – 7 Dec 2018 – USA

ISO/TC 212 Clinical laboratory testing and in vitro – 12 – 16 Dec 2018 – Germany diagnostic test systems

ISO TC 215 Health Informatics – 13 – 17 April 2019—Sweden

ISO projects in Hand

ISO/TC 157/WG14	Guidance on the use of condom standards*
ISO/TC 157/WG17	Synthetic Male Condoms*
ISO/TC 157/WG24	Tubal ligation / Fallopian ring*
ISO/TC 173/WG12	Assistive Products - General requirements*
ISO/TC 215/WG2	Health informatics#

* BIS has convenorship of working group

BIS has membership of working group

IMEDICAL DEVICES RULES 2017

Notified by Ministry of Health and Family Welfare (MoHFW)
(Department of Health and Family Welfare) on 31st January, 2017

Implementation with effect from 1st of January, 2018

Cl 7. Product standards for medical device

1. The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 19861) (63 of 1986) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

2. Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for

Cl 7. Product standards for medical device...

Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeia standards.

3. In case of the standards which have not been specified under sub–rule (1) and sub–rule (2), the device shall conform to the validated manufacturer's standards.

Classification of medical devices

Medical devices other than in vitro diagnostic medical devices shall be classified on the basis of parameters specified in Part I of the First Schedule, in the following classes, namely:—

- (i) Low risk –
  Class A; e.g. surgical dressings
- (ii) Low Moderate risk –
  Class B; e.g. balloon type catheter
- (iii) Moderate High risk –
  Class C; e.g. bone cement
- (iv) High risk –
  Class D e.g. heart valve

Recently published ISS on Medical Devices – QMS with Essential Principles

IS 23485 Medical Devices –Quality Management System requirements and Essential Principles of safety & performance for Medical Devices

This standard has been formulated by a merger of:

- **ISO 13485 : 2016** 'Medical devices — Quality management systems — Requirements for regulatory purposes',
- **ISO 16142 – 1 : 2016** 'Medical Devices —Recognized essential principles of safety and performance of medical devices, Part 1 General essential principles and additional specific essential principles for all Non – IVD Medical Devices and Guidance on the Selection of Standards', and
- **ISO 16142 – 2 : 2017** Medical devices —Recognized essential principles of safety and performance of medical devices Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards.

The purpose of combining the three standards is to align these standards with the national regulations as well as harmonize the standards with the latest international practices implemented by IMDRF or EU MDR guidelines and keeping our national interest in focus.

Implementation of this standard by an organization would encompass compliance to "essential principles of safety and performance as well as to QMS requirements; which include risk evaluation and management for the designing and manufacturing of medical devices, clinical evaluation, bio compatibility verification, environmental effects' assessment, software validation and other safety and performance related aspects likely to be encountered during entire life cycle of a medical device.

Some Important Standards on Commonly Used Medical Devices

On Thermometers

- 1. IS 3055 (Part 1) : 1994 Clinical thermometers Part 1: solid stem type
- 2. IS 3055 (Part 2) : 2004 Clinical thermometers- Part 2: Enclosed scale type Specification
- 3. IS 15113 : 2002 Clinical Electrical Thermometers with Maximum Device - Specification

On Sphygmomanometers

- 4. IS 3390 : 1988 Sphygmomanometers, Mercurial
- 5. IS 7652 : 1988 Sphygmomanometers, Aneroid Type
- 6. IS/IEC 80601 – 2 – 30 : 2018 Medical Electrical Equipment Part 2 – 30 Particular Requirements for Basic Safety and Essential Performance of Automated Non – Invasive Sphygmomanometers

7. IS/ISO 81060 – 1 : 2007 Non – Invasive Sphygmomanometers Part 1 Requirements and Test Methods for Non – Automated Measurement Type

On Surgical Gloves

- 8. IS 4148 : 1989 Surgical Rubber Gloves
- 9. IS 15354(Part 1) : 2018 Single – Use Medical Examination Gloves Part 1 Specification for Gloves Made from Rubber Latex or Rubber Solution (First Revision)
- 10. IS 15354 (Part 2) : 2018 Single – Use Medical Examination Gloves Part 1 Specification for Gloves Made from Poly(Vinyl Chloride) (First Revision)
- 11. IS/ISO 15197:2013 In vitro diagnostic test systems Requirements for blood – glucose monitoring systems for selftesting in managing diabetes mellitus

- 12. IS 3319 : 1995 Blades, Surgical, Detachable (Bard Parker Type) and Handles
- 13. IS 13450 (Part 2/Sec 20) : 2018 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 20 Infant Transport Incubators
- 14. IS 17034 : 2018 Specification for Jaipur Foot
- 15. IS 8088 : 2019 Tricycle, Hand Propelled
- 16. IS 13450 (Part 1) : 2018/IEC 60601–1 : 2012 (Ed 3.1) Medical Electrical Equipment : Part 1 General Requirements for Basic Safety and Essential Performance (Second Revision)

Some recently published Standards by MHD

S. No.	IS NO.	Title
1	IS/ISO 21535 : 2007	IS/ISO 21535 : 2007 Non–Active Surgical Implants — Joint Replacement Implants — Specific Requirements for Hip–Joint Replacement Implants
2	IS/ISO 25539–2 : 2012	Cardiovascular Implants — Endovascular Devices : Part 2 Vascular Stents
3	IS 13450 (Part 2/ Sec 21) : 2018 IEC 60601–2–21 : 2009	Medical Electrical Equipment : Part 2 Particular Requirements for the Basic Safety and Essential Performance, Section 21 Infant radiant warmer
4	IS/ISO 21549 : Part 6 : 2008	Health Informatics – Patient Health Card Data : Part 6 Administrative Data
5	IS/ISO/TR 17791 : 2013	Health Informatics — Guidance on Standards for Enabling Safety in Health Software

Some recently published Standards by MHD...

S. No.	IS NO.	Title
6	IS/ISO 11607 – 2: 2006	Packaging for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming, Sealing and Assembly Processes
7	IS/ISO 14708 – 2: 2008	Implants for Surgery —Active Implantable Medical Devices Part 2 Cardiac Pacemakers (Superseding IS 11754:1986)
8	IS/ISO 15883 – 1: 2006	Washer – Disinfectors Part 1 General Requirements, Terms and Definitions and Tests
9	IS 13450 (Part 1) : 2018/IEC 60601 – 1 : 2012 (Ed 3.1)	Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (Second Revision)
10	IS/ISO 1942 : 2009	Dentistry– Vocabulary

11. IS 3758 : 2018 Hooks Aural – Specification (First Revision)

12. IS/ISO 3826 – 4 : 2015 Plastics Collapsible Containers for Human Blood and Blood Components Part 4 Aphaeresis Blood Bag Systems with Integrated Features

13. IS/ISO 6887 (Part 1) : 2018 Dentistry Base Polymers Part 1 Denture Base Polymers (First Revision)

14. IS 8346 : 2018 ISO 7493 : 2006 Dentistry Operator's Stool (Second Revision)

15. IS 10867 : 2018 ISO 6710 : 2017 Single – Use Containers for Human Venous Blood Specimen Collection (First Revision)

16. IS 10654 : 2018 ISO 7864 : 2016 Sterile Hypodermic Needles for Single Use Requirements and Test Methods (Fourth Revision)

17. IS 12375 (Part 2) : 2018 ISO 7206 – 2 : 2011 Implants for Surgery – Partial and Total Hip Joint Prostheses – Part 2 Bearing Surfaces Made of Metallic and Plastic Materials

18. IS 14239 (Part 1) : 2018 ISO 9714 – 1 : 2012 Orthopaedic Drilling Instruments Part 1 Drill Bits Taps and Countersink Cutters (First Revision)

19. IS 15732 (Part 1) : 2018 ISO 8600 – 1 : 2015 Endoscopes – Medical Endoscopes and Endotherapy Devices Part 1 General Requirements (First Revision)

20. IS 17034 : 2018 Specification for Jaipur Foot

21. IS 17063 : 2018 Specification for Rehabilitation Equipment Rough Terrain Active Wheelchairs Folding Rider I Adult and Child Size

22. IS/ISO 25539 – 2 : 2012 Cardiovascular Implants —Endovascular Devices : Part 2 Vascular Stents

Some important Standards under development by MHD

1. MHD 01 (13648) Surgical Stapler
2. MHD 05 (12430) Ophthalmic optics Chart displays for visual acuity measurement Printed projected and electronic first revision
3. MHD 06 (13125) Cardiovascular implants and artificial organs – Cardiopulmonary bypass systems – Arterial blood line filters
4. MHD 07 (12749) Implants for surgery Acrylic resin cement Flexural fatigue testing of acrylic resin cements used in orthopaedics
5. MHD 08 (13293) Dentistry Shanks for rotary and oscillating instruments
6. MHD 09 (11650) Battery Operated Motorized Tricycle – Specification
7. MHD 10 (13650) Biological Safety Cabinet, Class I
8. MHD 11 (13659) Non – invasive sphygmomanometers
9. MHD 12 (13423) Specification for Dissection Table
10. MHD 21 (13293) Non – chlorinated Polyethylene Bags for Storing and Transporting Bio – Medical Waste Specification
11. MHD 21 (13433) Sharps injury protection – Requirements and test methods – Sharps containers – Single Use

Product Certification Scheme

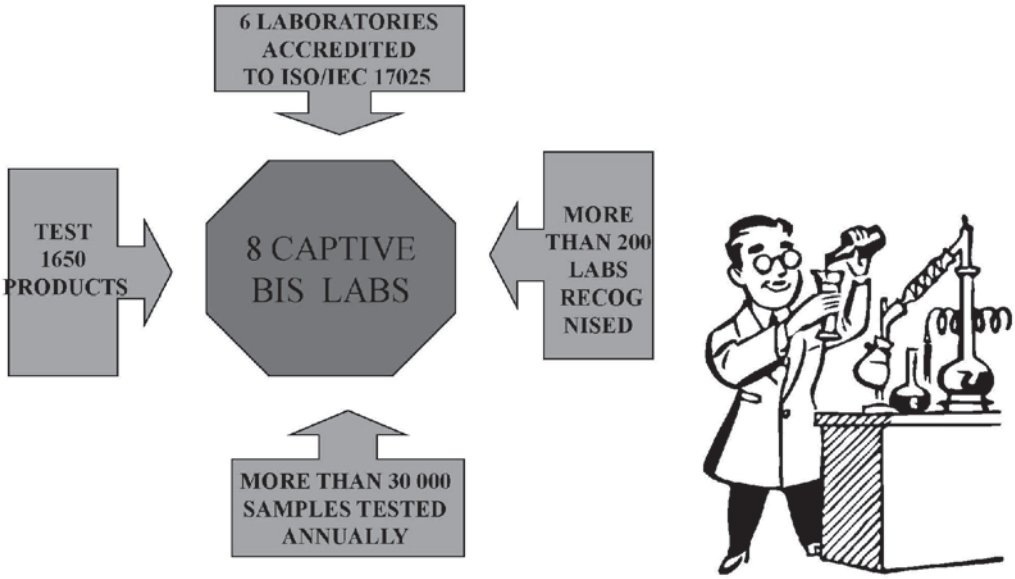
Voluntary in nature
About 960 Products under Certification
136 Products under Mandatory Certification
Total – End 2018; 34069 (Domestic), 865 (Foreign)
12576 (36%) – Mandatory, 22358 (64%) – Voluntary

First licence granted on 8 August 1955.
Operated through a network of 5 Regional, 33 Branches offices throughout India with Headquarters at New Delhi

STANDARDS [FORMULATED BY MHD] COVERED UNDER BIS PRODUCT CERTIFICATION SCHEME

- Standards covered under BIS Certification : 56
- Total No of licences granted : 234
- Standards under mandatory certification : 3
  - IS 3055(Part 1):1994 Clinical thermometers Part 1: Solid stem type - Specification (second revision)
  - IS 3055(Part 2):2004 Clinical thermometer : Part 2 Enclosed scale type - Specification (third revision)
  - IS 7620(Part 1):1986 Medical electrical equipment – Diagnostic medical X-ray equipment : Part 1 Mechanical and electrical safety requirements (first revision) Using elevated temperature to reduce analysis time further

LABORATORY TESTING - SUPPORT TO PRODUCT CERTIFICATION



National Institute of Training for Standardization (NITS)

- Provides training to industry, BIS employees and international participants
- 3 International Training Programmes related to 'Laboratory Quality Management System', 'Management Systems' and 'Standardization and Quality Assurance' for Developing Countries
- No. of Training programmes conducted annually: around 200
- Around 3000 participants trained annually

INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2018-19 AWARDED BY TNPSWT

Profile of 3rd Rank Projects

PHARMACEUTICS

Name: Ms. R. Priyadharshini

Project Title: Toxicity Assessment of Silver Nanoparticle Coated with natural pH stimuli Polymer in Ovarian Cancer Cell lines.

College: PSG College of Pharmacy, Coimbatore

Guide's Name: Dr. V. Sankar

PHARMACEUTICAL CHEMISTRY

Name: Mr. A. Sathish

Project Title: Design, Synthesis, Characterization and Biological evaluation of some novel 2,4- substituted Thiazolidine derivatives as Anti-Tubercular agents.

College: College of Pharmacy, Madurai Medical College, Madurai

Guide's Name: Dr. G. Umarani

PHARMACEUTICAL ANALYSIS

Name: Ms. Ann Raichel John

Project Title: Bio-Analytical Method Development and Validation for Simultaneous Estimation of Cefixime, Ornidazole, Ofloxacin & Dicloxacillin in Human Plasma by RP-HPLC

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. J.S.K. Nagarajan

PHARMACOLOGY

Name: Ms. M. Megala

Project Title: Neuroprotective potential of Naringenin on Rotenone Induced Drosophila Melanogaster Model for Parkinson's Disease

College: JSS College of Pharmacy, Ooty

Guide's Name: Mr. B. Shivaramakrishnan

PHARMACOGNOSY

Name: Mr. K. Muthukrishnan

Project Title: Pharmacognostical, Phytochemical studies including isolation of Quercetin and In vitro Anti-Tubercular activity of Tragia Involucrata Linn

College: College of Pharmacy, Madurai Medical College, Madurai

Guide's Name: Dr. A. Krishnaveni

PHARMACY PRACTICE

Name: Mr. Sidharth. C.S

Project Title: Impact of Clinical Pharmacist Intervention in Drug Related Problems in Patients with Chronic Kidney Disease

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Aneena Suresh

PHARM D- PHARMACY PRACTICE

Name: Ms. Akili Karuna

Project Title: Effect of Verapamil on lowering fasting blood glucose in Hypertensive type 2 diabetes patients.

College: School of Pharmaceutical Sciences, VISTAS, Vels University, Chennai

Guide's Name: Dr. P. Shanmugasundaram

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

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 17th July, 2019

G.S.R. 499(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sub-section (1) of section 12 and sub-section (1) of 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. 608(E), dated the 3rd July, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of Official Gazette were made available to the public on the 6th July, 2018;

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 sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Eleventh Amendment) Rules, 2019.
   (2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (herein after referred to as the said rules), after rule 76A, the following rule shall be inserted, namely:-

   "77.Duration of licence.- (1) A licence issued in Form 28, Form 28B and Form 28D shall remain valid, if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless it is suspended or cancelled by the licensing authority.

   (2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence excluding inspection fee paid for grant of licence.

   (3) If the licencee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part

thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

3. In the said rules, after rule 82, the following rule shall be inserted, namely:-

"83.Duration of loan licence.- (1) A loan licence issued in Form 28A and Form 28DA shall remain valid, if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee requiredfor the grant of such licence excluding inspection fee paid for grant of licence.

(3) If the licencee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

4. In the said rules, in rule 140, in sub-rule (1), for the words, figures and letters "Form 32, Form 32A and Form 33", the words, figures and letters "Form 32 and Form 32A" shall be substituted.

5. In the said rules, in rule 143A, in sub-rule (1), the words and figures "or Form 33" shall be omitted.

6. In the said rules, in rule 150E, in clause (e), the words "or renewal" shall be omitted.

7. In the said rules, rule 150J shall be omitted.

8. In the said rules, in Schedule A,

(a) In Form 24C,

(i) in the heading, after the words "GRANT", the words "OR RENEWAL" shall be inserted;

(ii) in paragraph 1, for the words "grant", the words "grant or renewal" shall be substituted;

(b) Form 26J relating to "CERTIFICATE OF RENEWAL OF LOAN LICENCE TO MANUFACTURE FOR SALE OF LARGE VOLUME PARENTERALS OR SERA AND VACCINE OR RECOMBINANT DNA (R-DNA) DERIVED DRUGS SPECIFIED IN SCHEDULE C AND C-1 EXCLUDING THOSE SPECIFIED IN SCHEDULE X" shall be omitted.

(c) in Form 37, under the sub-heading "Conditions of Approval", in paragraph 1, the words and figures "and any certificate of renewal in Form 38" shall be omitted.

[F. No. X.11014/9/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 317(E), dated the 18th April, 2019.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th July, 2019

S.O. 2607(E).—Whereas, it is brought to the notice of the Central Government that the use of the drug Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements is likely to involve risk to human beings;

And whereas, the Drugs Technical Advisory Board has considered the said matter and recommended for prohibiting the said drug and its formulations for food producing animals, poultry, aqua farming and animal feed supplements;

And whereas, the Central Government is satisfied that it is necessary and expedient in the public interest to prohibit the manufacture, sale and distribution of the drug Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements;

Now, therefore, in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby

(a) prohibits the manufacture, sale and distribution of the following drug with immediate effect, namely:

"Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements"; and

(b) directs that the manufacturer of Colistin and its formulations shall label the container of the drug and mention the words "NOT TO BE USED IN FOOD PRODUCING ANIMALS, POULTRY, AQUA FARMING AND ANIMAL FEED SUPPLEMENTS" in conspicuous manner on the package insert and promotional literature of the said drug and its formulations.

[F. No. X. 11014/8/2019-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th September, 2019

G.S.R. 652(E).—Whereas the draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required by sub-section(1) of section 12 and sub-section(1) of 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. 188(E), dated the 6th March, 2019, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Official Gazette were made available to the public on 8th March, 2019;

And whereas no objections or suggestions were received from the public on the said rules for consideration 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 Medical Devices Rules, 2017, namely:—

1. (1) These rules may be called the Medical Devices (Fourth Amendment) Rules, 2019.

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

2. In the Medical Devices Rules, 2017, in the Appendix, in Form MD-10, for the words "State Licensing Authority", the words "Central Licensing Authority" shall be substituted.

[F. No. X. 11014/31/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 318(E), dated the 18th April, 2019.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th September, 2019

G.S.R. 653(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sub-section (1) of section 12 and sub-section (1) of 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. 214(E), dated the 11th March, 2019, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of Official Gazette were made available to the public on the 12th March, 2019;

And whereas, no objections or suggestions were received from the public on the said rules for consideration by the Central Government;

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

1. (1) These rules may be called the Drugs and Cosmetics (Twelfth Amendment) Rules, 2019.

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

In the Drugs and Cosmetics Rules, 1945, in rule 43A, after the words “Mundra Port in Gujarat”, the words “and Inland Container Depot Dhannad, Indore in Madhya Pradesh” shall be inserted.

[F. No. X.11014/5/2019-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No. F. 28-10/45-H (1), dated 21st the December, 1945 and last amended vide notification number G.S.R. 499(E), dated the 17th July, 2019.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th October, 2019

G.S.R.787(E).— Whereas a draft of certain rules further to amend the Medical Device Rules, 2017, was published as required by sub-section (1) of section 12 and sub-section (1) of 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. 87 (E), dated the 4th February, 2019 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 5th February, 2019;

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 and 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 Medical Devices Rules, 2017, namely:

1. (1) These rules may be called the Medical Devices (Fifth Amendment) Rules, 2019.

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

2. In the Medical Devices Rules, 2017, in rule 19, after the proviso, the following proviso shall be inserted, namely:

"Provided further that the testing laboratories of State Governments and Central Government shall be exempted from the requirement of the accreditation by the National Accreditation Board for Testing and Calibration Laboratories for a period of two years from the date of coming into force of the Medical Devices (Fifth Amendment) Rules, 2019.".

[F.No.X.11014/1/2019-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note:- The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R. 652(E), dated the 13th September, 2019.

File No. 15-35/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(DTAB-DCC Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 09.08.2019

To
All State/ UT Drugs Controllers

Subject: Advisory on labeling requirements for combi kit of Misoprostol and Mifepristone tablets for Medical Termination of Pregnancy (MTP) -Reg.

Sir/ Madam,

Combi kit of Misoprostol and Mifepristone tablets (1 uncoated mifepristone 200 mg tablet + 4 uncoated misoprostol 200 mcg tablets) for MTP was approved on 24.12.2008 by CDSCO with following warning:

"Warning: product is to be used only under the supervision of a service provider and in a medical facility as specified under MTP Act 2002 & MTP Rules 2003"

The issue of labeling requirements for combi kit of Misoprostol and Mifepristone was deliberated in 56th Drugs Consultative Committee (DCC) meeting held on 01.06.2019. In meeting, the DCC suggested that a letter should be issued by CDSCO to all State Drugs Controllers about the labeling requirements and also to ensure the effective implementation of labeling requirements as per MTP provisions.

You are therefore, requested to ensure the effective implementation of labeling requirements for Combi kit of Misoprostol and Mifepristone tablets as per the provisions of Drugs and Cosmetics Act, 1940 & Rules, 1945 and MTP Act, 2002 & MTP Rules, 2003.

Yours Faithfully

(Dr.S.Eswara Reddy)
Drugs Controller General (I)

Copy to:

1. Joint Secretary (R), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi.
2. All Zonal/ Sub-Zonal/ Port Offices of CDSCO.
3. CDSCO Website.

File No: Import/Misc/129/2019-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Import and Registration Division)

FDA Bhawan, Kotla Road,
New Delhi
Date: 18/10/2019

Office Memorandum

Subject: Monitoring the end use of drugs which are meant for dual use- Regarding.

This is in reference to the OM of even no dated 05th July 2019 issued by this office wherein a list of dual use APIs was enclosed and all zonal/ Sub zonal/Port offices of CDSCO were requested to strictly monitor the end use of dual use Active Pharmaceutical Ingredients.

In this regard, this office has received representations from various stakeholders requesting for waiving of requirement of dual use NOC.

Accordingly, the matter was examined and it has been decided that if the manufacturer himself is importing such products for their end use (other than medicinal use), one time dual use NOC may be granted for one year to such manufacturers under the intimation to this office based on the assessment of at least one year data and written undertaking by the manufacturer justifying the quantity proposed for one year. The period of one year may be further relaxed if the data submitted and the operations carries out by the operators indicate to prove that it is for self consumption for further manufacturing.

However, you are requested to strictly monitor the end use of dual use Active Pharmaceutical Ingredients and action taken in this matter shall be communicated to this office.

(Dr. V. G. Somani),
Drugs Controller General (India)

To:

All Zonal, Sub-zonal and Port offices of CDSCO.

Copy to:

1. Joint Secretary (R), Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.
2. Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Shastri Bhawan, New Delhi.

No. IVD/Clarification/247/19
Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Diagnostic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002,
Dated:- 11.10.2019

Circular

Subject: External Performance evaluation of IVD's under MDR – further guidance

With reference to subject cited above, it is clarified that as per the Guidance on Performance Evaluation, SLA / CLA may require the Performance Evaluation Report from the external lab for three batches for the purpose of grant of Import/ Manufacturing license only for the following In-vitro Diagnostics;

In-vitro Diagnostic Medical Devices intended for:- 1. HIV, 2. HBV, 3. HCV, 4. Blood Grouping reagent, 5. Cancer, 6. Tuberculosis, 7. Malaria, 8. Dengue, 9. Chikungunia,10. Syphlis, 11. Typhoid, 12. Influenza, 13. ToRCH (Toxoplasma gondii, Rubella virus, Cytomegalovirus, Herpes simplex virus) 14. Chlamydia 15. Pneumonia, 16. Methioilline-Resistant Staphylococcus Aureus, 17. Entero virus. 18. Marker for congenital disorder e.g. Screen test for Down's Syndrome 19. Sexually transmitted agent i.e. Treponema pallidurn, Neisseria gonorrhoeae, Human Paoliloma Virus, Herpes Virus 20. Other life threatening Infections / agent.

In case of In-vitro Diagnostics mentioned at s.no 13 to 20 which are licensed and available in the Indian market for long time and manufactured in lesser number of batches per year, SLA / CLA may initially require the Performance Evaluation Report from the external lab for one batch for the purpose of grant of license, however, the subsequent two consecutive batches satisfactory PER shall be submitted by the manufacturer to the concerned authority as an when it is manufactured.

Further, with respect to the question that, where performance evaluation by External lab can be carried out for the consideration of grant of license for IVDs specified above, it is to clarify that it may be carried out at place as per the rule and it is generally expected that testing is performed at laboratory indicated in the guidance document on PER and If there is any problems including inability of lab or longer testing time etc., other options for testing like any Central Government or State Government Laboratory of any hospital or of any institute laboratory accredited by NABL or by any hospital accredited by NABH are also available as provided in the Medical Device Rules.

V.G.S.

Dr. V. G. Somani
Drugs Controller General (India)

EVENTS

Pharma Knowledge and Training Institute (Finishing School)
8th Training on
Industrial Orientation Training for Production and Quality Management Personnel

The 8th Training programme for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at Trust premises in Spencer Plaza, Anna Salai, Chennai from 9th to 30th September 2019. The total 36 trainees from Karpagam College of Pharmacy, Coimbatore, PSG College of Pharmacy, Coimbatore and School of Pharmaceutical Sciences, VISTAS (Vels University) Chennai students were trained in this training programme.

The students were given training both theoretically and practical on the subject of "Industrial Orientation Training on Production and Quality management Personnel". The following subjects were taught as theory and practical during this training programme.

Theoretical Training Programme

- Overview of the Pharmaceutical Industry and Job opportunities for the Pharmacy graduates.
- Regulatory Requirements of Production and QC under Drugs & Cosmetics Act and Rules, Role of Govt. Drug Testing laboratories.
- Good Manufacturing Practices under Schedule "M" of Drugs & Cosmetics Act in respect of Production, Quality Control, and Maintenance of record of Drugs & Pharmaceuticals.
- Salient features of Drugs & Cosmetics Act and Rules in respect of Manufacture of Pharmaceuticals, Cosmetics, Medical Devices and Licensing procedure of sales establishment.
- Procedure of Pharmacist Registration
- Plant Design & Site Master File
- cGMP's for manufacturing including entry & exit procedures.-
- ICH guidelines for production & Quality Control of Pharmaceuticals
- Good Laboratory Practices - Schedule L1
- IQ, OQ, PQ and DQ of equipments of Production & QC, Validation, Qualification and calibration
- Market complaints, CAPA, OOS and OOT etc., what is containment? Essential steps to control contamination, handling of deviation, Risk Assessment.
- Change control, Deviation control and their importance.
- Documentation and records in Production and QC
- Standard Operating Procedures
- Sampling of Raw Materials, Packing materials, In- process Materials and Finished products.

- Analytical method validation
- Introduction to Theory of Chromatography & Spectrophotometry.
- TLC Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC) a brief introduction.
- Calibration of QC equipments
- Tablets - Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets.
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated tablets, Delayed Release tablets etc, their advantages, How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production, Different types of Coating of Tablets, Materials used for coating & coating process. nd DQ of equipments of Production & QC, Validation, Qualification and calibration
- Preventive maintenance, Predictive maintenance & Break down maintenance.
- Basic Calculations in Quality Control, Dilutions and Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis.
- General requirements for Tablets, Capsule, Oral liquids & external preparations.
- Air Systems, Water Systems, their sampling and testing.
- Quality by Desigh (QbD)
- Dissolution & its Importance, Methods used in Dissolution Testing.
- Microbiology - An Introduction, Microbiology for non-sterile preparations.
- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions & Emulsions etc. Facilities required and their methods of manufacture, in process tests to be carried out during their manufacture.
- Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing etc and selection of different materials according to stability of products Viz: tablets & Capsules, Powders etc.
- What is Pharmacopoeia, various Pharmacopoeias used world over, how to use pharmacopoeia, monographs, their explanation & General Notices in pharmacopeia and Reference Standards.
- Reference Standards and Working Standards, Reference retention samples storage
- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability.
- Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above products.

- Capsules - Processes involved in the production of Capsules such as size reduction, sieving, granulation, Filling, Cleaning & Polishing etc., Various components of Capsules with examples of different materials used. Different sizes of Capsules available in the market,Filling of Capsules: hand filling, Machine Filling High speed filling Machines, In process tests to be carried during production of Capsules, How to control and rectify (in case of failure) weight variation, Disintegration time, Dissolution etc during production of Capsules.
- Batch Manufacturing Records, Batch Packing Records and importance of online recording Basics of production planning & Inventory Control.
- BA / BE studies of Drugs & Pharmaceuticals
- Powders for Dry Syrups: Main ingredients with examples of various materials used, equipment used for their manufacture, In process tests to be done, and their packaging Effervesant Powders their main ingredients their manufacture and packing.
- Oral Rehydration Powders(ORS), Equipment used for their manufacture, WHO approved formula, Materials used for formulation of ORS, in process tests to be done and packing of ORS powders-
- Preparation and Standardization of Herbal Formulations.
- Soft Skill

The above subjects were taught by well experienced senior level pharma industry manufacturing and quality assurance technical personnel through power point presentation. The faculties who had taken theory classes on the above subjects are as follows.

Mr. J. Jayaseelan, Managing Director M/s. Saimirra Innopharm Pvt Ltd.
Dr. G. Selvaraj, Director of Drugs Control (Retd), Tamilnadu.
Mrs. P. V. Vijayalakshmi, Deputy Director of Drugs Control, Tamilnadu
Mr. T. Ilango, Registrar, Tamilnadu Pharmacy Council
Mr. Sanjay Kumar Dasmohapatra, Vice President – Technical & Operations, M/s. Medopharm
Mr. K. Saravana Kumar, Associate Vice President, Corporate-QA, M/s.Fourrts (India) Labs Pvt.Ltd.
Mr. G.T. Arularasu, Head – Quality Control (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. R. Ramadhas, Deputy Manager – Analytical Development, M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. S. Saravanan, IICMS (Indian Institute of Chromatography and Mass Spectrometry)
Mr. V. Saravanan, IICMS, Chennai
Dr. Devasena Kannan, IICMS, Chennai
Dr. Balaji, IICMS, Chennai
Ms. Soujanya, IICMS, Chennai
Mr. S. Sridhar, Vice President – Woks, M/s. Medopharm (Malur Plant).
Mr. V. Arul Selvan - Manager – QC, M/s. Apex Laboratories P Ltd .
Mr. S. Jaya Kumar, Head – Quality, M/s. Apex Laboratories Pvt Ltd.
Dr. R. Venkidesh, M/s. AtoZ Pharmaceuticals Pvt. Ltd.,

Lecture by Mr. T. Ilango,
Registrar, Tamilnadu Pharmacy Council

Lecture by Mr. Sanjay Kumar Dasmohapatra,
M/s. Medopharm

Lecture by Mr. S. Jaya Kumar,
M/s. Apex Laboratories Pvt Ltd.

Lecture by Mr. M. K. Thinakar Krishna,
M/s. Fourrts (India) Labs Pvt. Ltd.

Lecture by Mr. D. Srinivasa Rao,
M/s. Apex Laboratories Pvt. Ltd.

Lecture by Mrs. Sujatha Ravi,
M/s. Tablets (India) Ltd.

Group Photo

Address by Mr. R. Narayanaswamy,
Director – PKTI

Address by Mr. S. V. Veerramani,
Chairman, TNPSW Trust

Certificate Distribution

Certificate Distribution

Group Photo

Mr. K. M. Sridhar, Head – Quality Control (Plant I), M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. Mujibur Rahman, Asst Manager – Microbiology, M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. M. Radhakrishnan, Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.
Dr. D. Natarajan, Pharma Consultant
Dr. N. Murugesan, Director (Retd), CDTL, Chennai.
Mr. M. Ramalingam, Head (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. D. Srinivasa Rao, GM – Plant Operations, M/s. Apex Laboratories P Ltd.
Mr. M. K. Thinakar Krishna, Head – R & D, M/s. Fourrts (India) Labs Pvt. Ltd.
Mr. D. Satish Kumar – Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.
Dr. S. D. Rajendran, Director and Head-Operations, Scitus Pharma Services, Chennai
Mrs. Sujatha Ravi, GM – QC, M/s. Tablets (India) Ltd., Chennai
Dr. R. Ilavarasan, Dr. R. Ilavarasan, Deputy Director, Institute In-charge,
Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute, Chennai.
Mrs. Swathi, Manager, L & D, Ripe Consulting Services Pvt. Ltd., Chennai

Practical Training

M/s. Fourrts (India) Laboratories Pvt. Ltd., Plant 1 & Plant 2, Chennai, M/s. Apex Laboratories Pvt. Ltd., Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Tablets (India) Ltd., T H Road, Chennai, M/s. Sai MirraInnopharm Pvt. Ltd., Ambattur, Chennai and M/s. The Madras Pharmaceuticals, OMR, Chennai, offered their facilities for practical training to the trainees for 6 days.

Evaluation

All the trainees were evaluated after each of the lecture programme as well as on the final date of completion of the programme on the basis of the evaluation these students were given 3 merit awards given during the valedictory function.

Valedictory Function

The Valedictory function was held on 30th September 2019. The Chief guest of the function was Mr. S. V. Veerramnai, Chairman of our Trust and M/s. Fourrts (India) Labs Pvt Ltd., Mr. A. Krishna Dev, Vice Chairman, TNPSW Trust, Mr. K. Prafulla Chandra, Trustee, Dr. S. Jayakumari, HOD, Pharmacognosy, Vels University, were the guest of honours. R. Narayanaswamy, Director, PKTI Welcomed the gathering and explained about the 8thtraining programme. Certificates were distributed all the trainees. Mr. N. Sreenivasen, Secretary, TNPSWT proposed vote of thanks.

Placement Interview

Placement interview conducted for the trainees on 30th September 2019 and the participants companies were M/s. Apex Laboratories Pvt. Ltd., Alathur, Chennai, M/s. The Madras Pharmaceuticals, OMR, Chennai and M/s. Saimirra Innopharm Pvt. Ltd., Chennai.

Award of Excellence


Prof. Dr. R. Senthamarai receiving the Award of 'Excellence in Education'

Prof. Dr. R. Senthamarai, Principal, Periyar College of Pharmaceutical Sciences, Tiruchirappalli, Tamil Nadu has been conferred with " Award of Excellence in Education" on the occasion of National Convention on Vitiligo organized by the Leucoderma Awareness Movement - India on 23rd June 2019 at St. Joseph's College , Tiruchirappalli for her relentless achievements in academia. Earlier she received the "Munnodi Pennmani" award from Bharathidasan University, Tiruchirappalli and "Women Achiever" award from Tamil Nadu Progressive Women Advocates' Association, Tiruchirappalli consecutively during 2017 and 2018. All these credentials have been bestowed in recognition of her exuberant performance throughout her career over 30 years in Periyar organizations both in academics and for the welfare of the society especially for her interest towards the womenfolk for their upliftment and well being.

PCPS Student Honoured with University Gold Medal


T. Indhumathi receiving Gold Medal with certificate of Appreciation during the Convocation

Ms. T. Indhumathi student of Periyar College of Pharmaceutical Sciences, Tiruchirappalli, Tamil Nadu secured State First Rank in Final B.Pharmacy University Examinations held in August 2018 and received a Gold Medal and "Prof. K. Chinnaswamy Endowment Award" during the 31st Convocation held on 29th June 2019 from The Tamil Nadu Dr. M.G.R Medical University, Chennai . Thiru. Banwarilal Purohit, Hon'ble Governor of Tamil Nadu and Chancellor of The Tamil Nadu Dr. M.G. R. Medical University presented the Gold Medal and Certificate of appreciation. Thiru. V. Ramasubramanian, Chief Justice of the High Court of Himachal Pradesh was the Chief guest and Dr. C. Vijayabaskar, Hon'ble Minister for Health & Family Welfare and Dr. Sudha Seshayyan, Vice - Chancellor graced the occasion. The Management, Principal, faculty and students of PCPS congratulated the student for her outstanding performance.

NEWS

Found: A Way to Make Cancer Cells Self-destruct

In a new hope for cancer patients, researchers have found a way to cause some cancer cells to self-destruct. Million of cells in our bodies 'kill' themselves every day to help protect us from potentially harmful ones. Cancer cells, on the other hand, ignore our immune system's signals – and finding a way to stop this has been the 'Holy Grail' of cancer research.

The research team has identified a new pathway that works as a partner to a gene called MYC which controls normal cell growth, but when it is mutated or amplified in cancer, it sets off a chain reaction that helps tumours grow uncontrollably.

The pathway involves a protein called ATF4, and when it's blocked, it can cause cancer cells to produce too much protein and die

Published in the journal Nature Cell Biology, the study done on mice points the way towards a new therapeutic approach as inhibitors that can block synthesis of ATF4 already exist.

"What we've learned is that we need to go further downstream to block tumour growth in a way that cancer cells can't easily escape, and our study identifies the target to do just that," said Constantinos Koumenis, Professor at the University of California.

According to researchers, this finding shows the alternative approach is to target ATF4 itself, since it's the point where both signal pathways converge, meaning there's less redundancy built in to allow cancer to survive.

Lead author Dr Feven Tameire said: 'This shows us the potential impacts of targeting ATF4 in MYC-dependent tumours — something we're already studying. 'We're also working to confirm this approach will not cause any serious off-target effects.' It also shows that ATF4 turns on the genes MYC needs for growth and also controls the rate at which cells make specific proteins called 4E-BP. This study also found that when tumours in humans are driven by MYC, ATF4 and its protein partner 4E-BP are also overly expressed, which is further evidence that these findings may point to an approach that could work for humans.

Source: *The Times of India,* 3rd July 2019

Moratorium on New Pharmacy Colleges for Five Years, HC Told

The Madras High Court was on Monday told that the Pharmacy Council of India (PCI) had imposed a moratorium on the opening of new pharmacy colleges throughout the country, except the northeastern region, for five years from the year 2020-21 since there were enough degree and diploma holders in the field.

The submission was made in the wake of a tussle between degree and diploma holders in the subject in being considered for the post of pharmacist in government service. The court on Monday called for all relevant records to find out what the other avenues available for degree holders were apart from the post of pharmacist.

Interim order

A Division Bench of Justices S. Manikumar and Subramonium Prasad sought details while passing interim orders on a writ petition filed by S. Naveen Kumar, a degree holder, who accused the State government of appointing only diploma holders to the post of pharmacist much to the disadvantage of the unemployed degree holders.

When the petition was heard in March this year, Additional Government Pleader (AGP) E. Manoharan told the court that the government had decided to appoint diploma holders as pharmacists in government service since degree holders had many other opportunities of employment in government as well as private sector.

However, not in agreement with such a submission, the judges passed an interim order directing the Director of Medical Services Recruitment Board to permit degree holders to apply for the post.

However, they made it clear that the interim order would be subject to the final result of the writ petition.

Subsequently, when the case was heard on Monday, Tamil Nadu Marundhalunargal Nala Sangam, an association of pharmacists, brought it to the notice of the court that only diploma holders were suitable for the post since they undergo 91 days of practical training, compared to B. Pharm. graduates who undergo only 16 days of such training.

'Chief Secretaries told'

The court was told that the Pharmacy Council on Wednesday wrote to Chief Secretaries of all States, except those in the northeastern region asking them not to grant permission for any new pharmacology college for the next five years since there were enough number of degree and diploma holders across the country.

When the judges wanted to know how many B. Pharm. graduates had been accommodated in posts other than that of pharmacist, the AGP told the court that 106 out of 146 posts of drug inspectors and 27 out of 35 posts of junior analysts had been filled with such graduates. He sought time till Friday to submit details.

Accepting his plea, the judges adjourned the case to Friday.

Source: *The Hindu,* 23rd July 2019

New Cure for Deadly Strain of Tuberculosis

The regimen has shown to drastically cut down treatment time in a clinical trial in South Africa

Four years ago, South African fashion designer Innocent Molefe, 38, was diagnosed with tuberculosis. A year ago, it developed into multi-drug resistant strain requiring painful injections and heaps of pills.

Three months after the first round of treatment, he relapsed and started a second round. At the end of it he still wasn't cured.

Thanks to a new treatment — approved on Wednesday by the U.S. Food and Drug Administration, he is now cleared of the disease, has bounced back to work and has even resumed night-clubbing, something he has stopped four years ago.
"I was willing to beat TB and I'm living proof. I can move around... I can still go clubbing till the early hours," said the designer.

The announcement was especially welcomed in South Africa, one of the countries with the highest number of TB cases. Of the more than 1.6 million TB deaths recorded every year, more than 75,000 are in South Africa alone. In 2017, South Africa recorded more than 3,22,000 active TB cases."

The new treatment which cures highly drug-resistant strains of tuberculosis will drastically shorten the treatment period.

Three-drug combination

The three-drug regimen consists of bedaquiline, pretomanid and linezolid — collectively known as the BPaL regimen.

Pretomanid is the novel compound developed by the New York-based non-profit organisation TB Alliance and which received the FDA greenlight on Wednesday.

The treatment regimen was studied at three sites in South Africa involving 109 patients and achieved a 90% success rate after six months of treatment and six months of post-treatment follow-ups.

With the treatment involving five pills of the three drugs daily taken over just six months, it is easier to administer.

This compares to between 30 and 40 drugs that multiple-drug resistant TB patients take each day for up to two years.

"Usually and in many places in the world the treatment for (multiple) ... drug resistant TB would take anything between 18 to 24 months," said Pauline Howell, principal investigator of the clinical trial at Sizwe Tropical Disease Hospital in Johannesburg.

'Huge difference'

" This still includes daily injections for six months, which are extremely painful," Ms. Howell said, adding that taking only five pills would make a huge difference.

The FDA approval represents a victory for those suffering from highly drug-resistant forms of the world's deadliest infectious disease, said Mel Spigelman, president and CEO of TB Alliance.

Last year, there were more than half a million drug resistant TB cases in the world.

Source: *The Hindu,* 16th August 2019

Leprosy Drug to Treat Cancer? Doctors Hunt for New Uses of Old Medicines

Can a leprosy tablet priced at Rs 2 each be the 'miracle cure' to treat blood-cell cancer? Or can expensive injections given to treat osteoporosis in post-menopausal women be replaced with a pill that costs as little as Rs 100 for a month's supply?

These are some of the questions Indian scientists have set out to answer as they look towards repurposing 'old' drugs as affordable treatments for new diseases. Repositioning of old drugs is an attractive proposition given substantial costs and the slow pace of new drug discovery and development. Sample this: To successfully launch a prescription drug in the US after taking it through preclinical studies and clinical trials requires $2.6 billion on an average and takes 12 years. And what are the chances of US Food and Drug Administration (FDA) approving the drug? Only 14%.

In contrast, existing drugs have already been shown to be safe in patients and if they can be used to treat other diseases, it can reduce drug development costs. It can also help meet the growing demand for new drugs, especially in developing countries like India which currently depend on advanced nations to come up with new drugs and launch them in their markets.

Using drugs originally meant for one condition for treatment of another is not a new concept. Viagra, a little blue pill prescribed to men all over the world for erectile dysfunction, was actually supposed to treat chest pain or discomfort due to coronary heart disease. Minoxidil was developed to treat ulcers but is now used to treat hair loss. Aspirin, one of the most widely used drugs in the world, originally meant to ease inflammation and pain is now also used to treat and prevent heart attacks and strokes.

Indian doctors are also sifting through old drugs to find new uses and cheaper alternatives to current treatments. At the Central Drug Research Institute (CDRI) in Lucknow, scientists have

recently found that certain leprosy drugs might help treat myeloma, a type of blood cancer. Sabyasachi Sanyal, a researcher at CDRI, in collaboration with clinical haematology department of King George's Medical University, Lucknow, screened FDA-approved drugs in chronic myeloid leukemia (CML) cells and found that a leprosy drug — clofazimine, priced at Rs 2 per tablet — was a potent inhibitor of these cells.

Sanyal's colleague and chief scientist at CDRI, Lucknow, Dr Naibedya Chattopadhyay, screened a library of over 1,000 clinically approved drugs with the aim to discover an oral substitute for teriparatide — an injectable given to women suffering from post-menopausal osteoporosis. "Our pre-clinical studies found that Pentoxifylline, a drug prescribed for the treatment of a disease of peripheral artery also referred to as intermittent claudication, when given to osteoporotic female rabbits mimicked all the skeletal effects of teriparatide including restoration of bone mass, strength, micro-structure and quality," Dr Naibedya told TOI.

While the minimum treatment cost with teriparatide is Rs 7,000 per month, treatment with pentoxifylline would cost Rs 100 per month, said Naibedya. "Moreover, since pentoxifylline does not require refrigeration, post-menopausal women having no access to a refrigerator will also benefit from the treatment," he said. Researchers, however, added that both clofazimine and pentoxifylline were yet to undergo human trials for their new indication.

If proven successful in human trials, the potential benefits are huge. The cost of launching a repurposed drug is approximately 85% less than that incurred on launching a new drug, according to Dr Naibedya. "Strategic repurposing of old drugs for new uses can save time as their pharmacology formulation and potential toxicity are already available. In the US, this strategy typically includes a demonstration of its efficacy in in vitro or in vivo animal model systems for new indications and then filing an investigational new drug application with the FDA, where following approval it typically enters into human trials," he said.

Doctors at the All India Institute of Medical Sciences, New Delhi, are also conducting clinical trials on repurposed drugs. Dr Kameshwar Prasad, professor of neurology at AIIMS, recently wrote to the Indian Council of Medical Research (ICMR) to set up a task force to identify and validate low-cost alternatives to expensive drugs.

Dr Prasad said that doctors are already prescribing certain cheaper therapies in place of expensive drugs in some cases. For instance, a single cycle immune therapy for treatment of the Guillain-Barre-Syndrome (GBS), an acute inflammatory disorder of the peripheral nervous system, currently costs between Rs 3 lakh and Rs 8 lakh. To those who can't afford it, physicians are recommending steroids that cost less than Rs 5,000 and are equally affective.

"One of our residents, Dr Bhavna Kaul, recently conducted a survey of physicians across India to assess the use of cheaper alternatives for GBS. We were surprised to find that most physicians and neurologists were prescribing them since the standard treatment, in this case immunoglobin, was not affordable. They also claimed that the response of patients was satisfactory," he added. In Bengaluru as well, a pharmaceutical company is studying the impact of a type 2 diabetes drug on cardiovascular diseases.

The significance of repurposing drugs is considerable. Global spending on medicines is predicted to reach $1.4 trillion in 2020. Drug repositioning can help curb expenditure while safeguarding access to quality healthcare. But roadblocks remain.

New indications for a drug need huge investment to move from 'proof of concept' to registered therapeutic use. Many times, researchers lack funding to undertake clinical trials and pharmaceutical companies can be disinterested in repurposing generic drugs as it would fetch them little financial returns, experts said.

Like in Australia, Canada or Europe, India does not offer patent protection for new uses of known drugs. Experts said that companies which hold a current patent for a medicine could invest in the discovery of additional indications. But if pharmaceutical companies aren't interested, governments could step in.

Dr Naibedya said that financial support from the government could help teaching institutions conduct clinical trials of drugs that can be repurposed. "Successful public-funded demonstration of efficacy of a repurposed drug in clinical trials approved by the Drug Controller General of India may pave the way for far more affordability where the patients do not have to bear the burden of extra cost of development by the industry."

Source: *The Times of India,* 1st Sept 2019

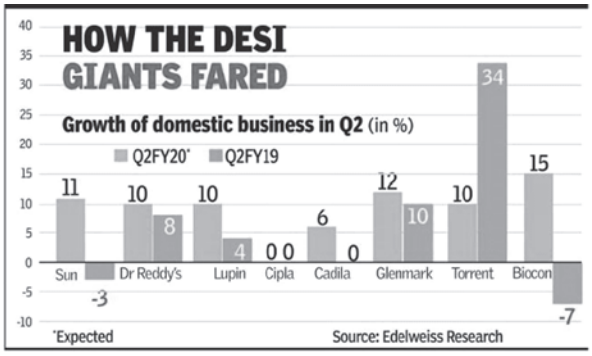
Domestic Pharma Market Grows 11.5% in July-September

The organised domestic pharma market grew in double digits last month, resulting in one of the best quarters in over a year, with 11.5% growth across July-September, buoyed by higher volumes (3.2%) and price growth (5.5%).

The robust monsoon seems to have helped in reviving growth during the quarter ended September, with all key therapies exhibiting double-digit expansion, data from pharma research firm AIOCD Awacs showed..

Earlier this year, the market seemed to be slowing down with the previous six quarters registering muted single-digit growth, pulled down by multiple factors including increase in use of low-cost generics, and lower sales in acute segment.

Significantly, regulatory hurdles impacted the sector as major companies received warning letters, flagging manufacturing concerns. The US Food and Drug Administration (USFDA) issued observations to companies like Cipla (for Goa, Bengaluru API), Lupin (Tarapur, Mandideep), Biocon (Bengaluru, Malaysia), Torrent Pharma (Dahej) and Dr Reddy's (Bollaram API, Duvvada).



"These actions continued to erode pharma valuations: Lupin corrected about 20% year-to-date (YTD), following an official action initiated at Somerset, and a warning letter at Mandideep; Cipla slid 30% YTD, following observations at Bengaluru API and Goa; and Biocon is down 35% YTD, following observations at Bengaluru and Malaysia," a note from Edelweiss Research dated October 7 said.

Further, the USFDA issued a warning letter to Glenmark Pharma for its manufacturing plant in Baddi (Himachal Pradesh), and flagged concerns at Aurobindo's facility in Telangana recently. Analysts say, going forward, there could be an impact on valuations of certain companies due to rising regulatory risk.

Domestic sales are likely to grow about 8% year-on-year (YoY) driven by acute therapies as a heavy rainy season led to a surge in vector-borne diseases. The market registered a robust double-digit growth of 11.9% for September 2019, while for the corresponding month in the previous year it was 7.5%, and in August 2019 the market grew 9.4%.

Acute therapy, which accounts for nearly half of the market, registered 11.7% growth, while chronic (31% of the market) grew by 13%, and sub-chronic by 10.7%. Sales of anti-infectives grew 10.9%, gastro Intestinal 12.1%, vitamins & minerals 11.4%, and pain/analgesics at 12.6%. In the chronic segment, anti-diabetics recorded 14.2% growth, cardiac 13.7% and neuro/CNS 11.9%. Derma registered a growth of 10.3% and respiratory 7.8%.

Analysts estimate a decent Q2FY20 performance, with a 12% YoY sales growth in the second quarter — strongest across sectors — on a favourable base, and 7% YoY earnings growth. US sales are likely to grow 11% YoY, but slip 4% quarter-on-quarter on lack of new approvals and non-recurrence of one-time opportunities at Sun Pharma, Cipla and Lupin.

Source: *The Times of India,* 12th Oct 2019

New Definition of Med Devices to Include Nebulisers, Syringes

The health ministry is set to notify a new definition of medical devices which will expand the span of regulation to cover all such products, including diagnostic equipment, nebulisers, syringes as well as stents and other implants.

The notification, already approved by the ministry, is expected to be notified by the end of this week, official sources told TOI.

"The new definition for medical devices will be aligned with that of the International Medical Device Regulators Forum (IMDRF) and one which is globally accepted," an official said.

Once the new definition is notified, all medical devices will fall under the health ministry's regulatory purview and will have to undergo scrutiny by the Central Drugs Standard Control Organisation (CDSCO) before entering the market.

This means companies will have to seek approval from CDSCO for manufacture, import and distribution of any medical device. Besides, they will also have to report adverse events and carry out clinical trials for new products as per regulatory requirement. All medical devices manufactured or sold in the country will also be monitored for quality, safety and efficacy.

At present, only 35 medical devices are notified as drugs in India, of which 23 are regulated and the rest will come under regulatory purview from next year, according to the ministry's earlier notification.

The regulator has also prepared a roadmap for regulating these products after consultations with various international regulators under IMDRF and inter-ministerial consultation.

"The idea is to have a roadmap for medical devices so that manufacturing of products can be promoted in the country. Approval, certification and registration from a central authority under the health ministry will help in strengthening the credibility of 'Made in India' medical devices," the official said.

The government is also working to bring a separate law to regulate medical devices.

Besides, it is mulling an overarching pricing policy to cap trade margins of all medical devices.

The medical devices industry, currently pegged at around $7 billion in India, is growing at a CAGR of 4.5%. The sector is projected to touch $9.6 billion by 2022.

The implementation of regulation will start with licensing, which will be voluntary for 18 months and become mandatory after 12 and 24 months, depending on their classifying category based on risks.

Companies will be required to give details of products including design, shelf life and raw material along with other proof of evidence that their products are safe and efficacious.

According to sources, all medical devices in the country - whether manufactured locally or imported - will be completely under the regulatory framework within three-four years.

Medical device manufacturers, lobbying for a separate regulation for their products distinct fom drugs, say all devices must be regulated to create a level-playing field and ensure patient safety.

Source: *The Times of India,* 14th Oct 2019

241 Gujarat Pharmacists Lose Registration for Renting Licences

Gujarat State Pharmacy Council (GSPC) on Wednesday said it has cancelled the registration of 241 pharmacists in the state in the last six months for giving their licenses on rent to drug stores and taking up a job elsewhere, which is "illegal" as per norms.

Gujarat State Pharmacy Council (GSPC) on Wednesday said it has cancelled the registration of 241 pharmacists in the state in the last six months for giving their licenses on rent to drug stores and taking up a job elsewhere, which is 'illegal' as per norms.

Apart from suspending their licenses, the GSPC also imposed fine on these pharmacists for indulging in this malpractice prohibited under the Drugs and Cosmetics Act.

Of these, 103 pharmacists faced suspension very recently following a decision taken in this regard during the executive committee meeting of the GSPC, its president Montubhai Patel said.

Many other pharmacists are also under the scanner and warnings have been issued to them already, he added.

"This is the first time in India when such large number of pharmacists have been penalised. We have also issued warnings to around 3,000 pharmacists who were found guilty of giving their licenses on rent to drug stores and taking up another job, which is illegal," Patel said in a statement.

These erring pharmacists also include employees of several pharma companies, it added.

"Being a pharmacist is a noble profession. A drug store can sell medicines only after consulting a pharmacist present in the store. However, many of them were found to be working in companies after giving their license to these drug stores. We are in no mood to tolerate such malpractice which is bringing disrepute to this profession," Patel added.

Source: *ET Healthworld,* 17th October 2019

All Medical Devices to be Regulated from December 1

The health ministry has proposed to notify all medical devices from December 1, expanding the span of regulation to ensure safety and efficacy of a variety of such products used for diagnosis.

The health ministry has proposed to notify all medical devices from December 1, expanding the span of regulation to ensure safety and efficacy of a variety of such products used for diagnosis, treatments and other medical interventions in human beings and even in animals.

The ministry published a gazette notification on Friday with the proposal defining all medical devices as drugs and seeking public comments within one month. It later also notified a separate set of draft rules under which these devices will be regulated once the final notification is issued. Once the final notification is in place, all medical devices including software, equipments, accessories and contraceptives will be regulated under Drugs and Cosmetics Act and firms will have to seek an approval from the Drugs Controller General of India to manufacture, import and sell any medical devices in the country.

Source: *ET Healthworld,* 19th Oct 2019

Govt Issues Norms for Nanopharmaceuticals

The 'Guidelines for Evaluation of Nanopharmaceuticals in India' – released by the department of science and technology on Friday - are expected to aid research towards development of new nano-formulations that are more efficacious, less toxic and safer than conventional drugs.

Aiming to promote nanotechnology - based research, while also ensuring safety of medicines coming out of it, the government has rolled out guidelines to regulate nano-pharmaceutical products.

The 'Guidelines for Evaluation of Nanopharmaceuticals in India' – released by the department of science and technology on Friday - are expected to aid research towards development of new nano-formulations that are more efficacious, less toxic and safer than conventional drugs.

As per the guidelines, the requirement of special or additional tests for safety and efficacy evaluation of a particular nanopharmaceutical should be decided on a 'case-by-case approach' which will depend upon various factors such as physiochemical and biological nature, and other aspects, including the background data available on the

raw material - active pharmaceutical ingredient (API) or nanocarrier, the regulatory status in other countries, etc.

At present, there are no globally accepted uniform guidelines for nano-pharmaceuticals. Though these products are not completely new drugs but are more efficacious than the conventional pharmaceutical products because of their nanotechnology - based delivery mechanisms.

The guidelines stated that all nano-pharmaceutical products will have to comply by the New Drugs and Clinical Trials Rules, 2019 for seeking approval for manufacturing or import of any new drug or to undertake clinical trial.

"'Guidelines for Evaluation of Nanopharmaceuticals in India' is one of the most important steps for delineating quality, safety and efficacy assessment of the novel nanoformulations. These guidelines are intended to provide transparent, consistent and predictable regulatory pathways for nanopharmaceuticals in India," science & technology minister Harsh Vardhan said.

S Eswara Reddy, joint drugs controller said the guidelines assume significance as there is no strict regulatory pathway to assess the quality of the product by the health ministry at the moment. "Nanotechnology intervention has opened a new horizon for targeted delivery of approved drugs and repurposing of drugs. Every year several new nano-pharmaceuticals are being introduced into the market globally. The guidelines will encourage Indian innovators and industries to develop and commercialise new nano-pharmaceuticals, which will make our country a global leader in this area," the guidelines state.

The guidelines have been framed jointly by the department of biotechnology, Indian Council for Medical Research (ICMR) and Central Drugs Standard Control Organisation (CDSCO).

Source: *ET Healthworld,* 26th Oct 2019

Prices of cancer, cardiac drugs may be slashed

The Standing National Committee on Medicines, which has been tasked with preparing the shortlist, will meet stakeholders on November 4 to consider their views before the National List of Essential Medicines (NLEM) 2019 is updated and finalised.

The prices of some antibiotics and drugs used to treat cancer and cardiac diseases are likely to be cut as the government inches closer to updating the list of essential medicines and bring some of them under price control.

In a departure from the usual practice, not all essential drugs will find their prices capped. The Standing National Committee on Medicines, which has been tasked with preparing the shortlist, will meet stakeholders on November 4 to consider their views before the National List of Essential Medicines (NLEM) 2019 is updated and finalised.

The committee headed by Balram Bhargava, secretary in the department of health research and director-general of the Indian Council of Medical Research, will decide which medicines should be available in adequate numbers and assured quality.

"This meeting will look into shortlisting drugs on oncology and cardiovascular diseases as lots of drug development has happened in these categories. Also, antimicrobial resistance is a priority area for the experts. Those drugs which have become resistant to Indian population will be deleted from the NLEM and new ones will be added," a senior government official said.

This list will then be sent to a second committee, comprising Rajiv Kumar, vice-chairman of NITI Aayog, Preeti Sudan, secretary in the health ministry, and PD Vaghela, secretary in the department of pharmaceuticals, which will decide which drugs are to be under price control.

This is a departure from the existing mechanism in which all essential medicines automatically go under price control.

Under the earlier mechanism, the health ministry prepared a list of drugs eligible for price regulation, following which the department of pharmaceuticals under the ministry of chemicals and fertilisers incorporated them into Schedule 1of the Drug Price Control Order. The National Pharmaceutical Pricing Authority then fixed the prices of drugs.

Medicines and devices listed in the NLEM must be sold at prices set by the NPPA, while those in the non-scheduled list are allowed a maximum annual price increase of 10%.

The first stakeholder meeting on NLEM was held in July and included representatives from drug makers, pharma lobby groups and non-profit organisations. The experts were asked for their feedback on cancer drugs, cardiology drugs, penicillin preparations, information on anti-microbial resistance and a review of NLEM 2015.

Source: *ET Healthworld,* 29th Oct 2019

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