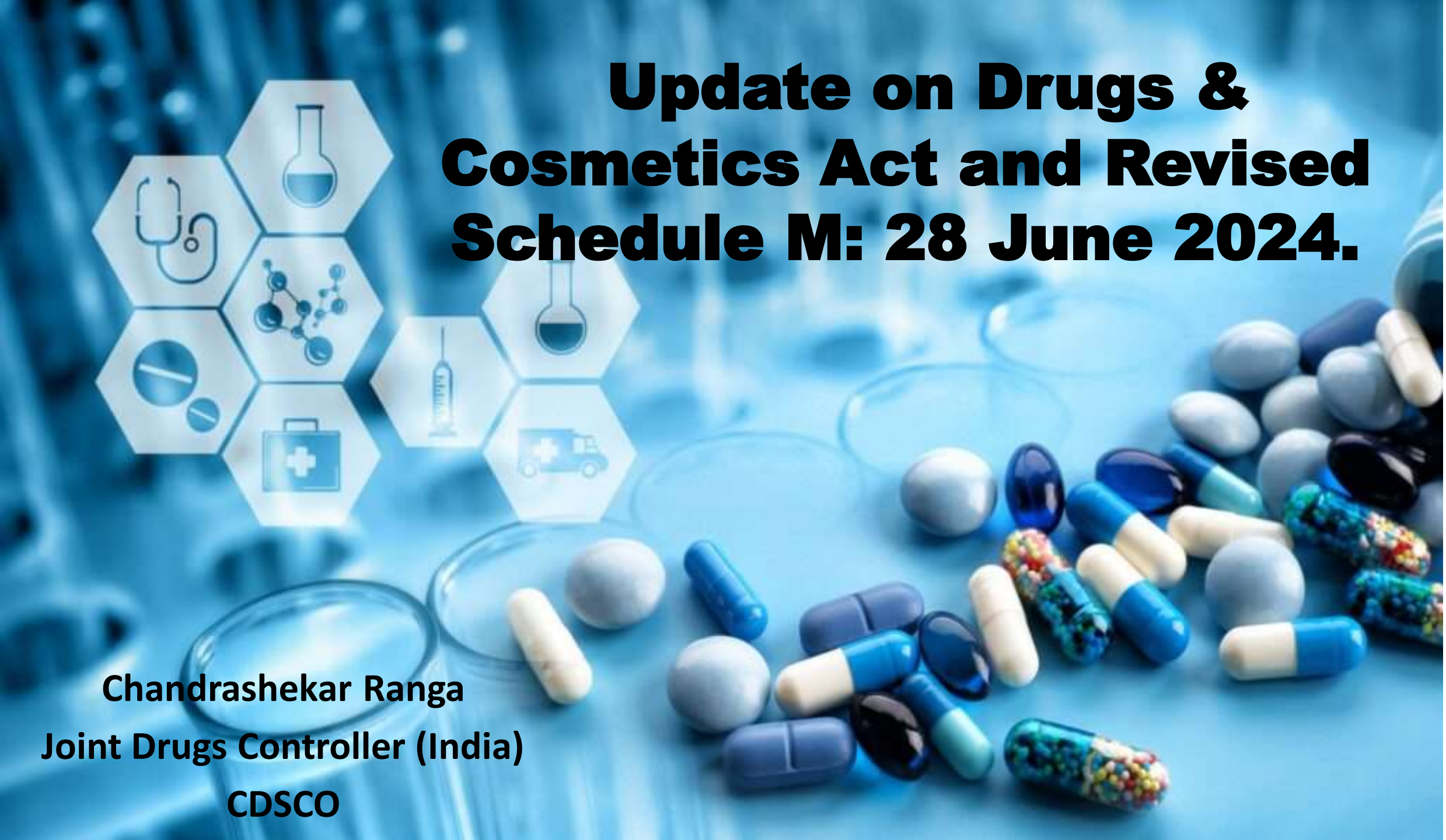
Update on Drugs & Cosmetics Act and Revised Schedule M: 28 June 2024.



Chandrashekar Ranga

Joint Drugs Controller (India)

CDSCO

Status update on the revision of Drug Laws

Drugs, Medical Devices and Cosmetics Bill, 2023

- MoHFW published the draft Bill seeking suggestions/ objections from the public stakeholders.
- The purpose of the Bill is to consolidate the law relating to the import, manufacture, distribution and sale of drugs, medical devices and cosmetics.
- The objectives of the Bill is to –
  - ❖ ensure the quality, safety, efficacy, performance and clinical trial of new drugs,
  - ❖ clinical investigation of investigational medical devices and
  - ❖ clinical performance evaluation of new in vitro diagnostic medical devices,
  - ❖ for encouraging innovation in development,
  - ❖ protection and promotion of health, and
  - ❖ for matters connected therewith or incidental thereto
- The Ministry held consultation with the industry Associations on issues of concern

Features of the Bill

- Strengthened regulatory structures to ensure quality
- Better regulation of conduct of clinical trials and clinical investigations of new drugs
- Medical devices to be treated distinctly from drugs,
- Specific provisions for regulation of clinical trials of new drugs & clinical investigation of medical devices
- Provisions for obligating all officers of States and the Centre to assist each other to ensure Inter-state Coordination.
- Creation of certain quasi-judicial authorities to adjudicate certain procedural and minor offences.
- Provisions for issuance of improvement notices to manufacturers for improving deficiencies pointed out during inspection.
- Provisions for emergency use & accelerated approval of new drugs & investigational medical devices

Features of the Bill

- Provisions for recall of drugs, cosmetics and medical devices
- Provisions related to modes for service of notice order, decision, summons, notices, etc
- Regulation of sale by online mode.
- Provisions related to digital interventions for innovations, data management, data analytics and such similar technical activities.
- Enabling provision for collection of Records or Data from State Governments, or Union territory Administration, or any other Government Agency, or any other person, in a Digital Format.

Measures to ensure quality

Schedule M (Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products)

- The Ministry of Health and Family Welfare had published a draft notification G.S.R. 999 (E) dated 05.10.2018 regarding amendment in Schedule M of Drugs and Cosmetics Rules, 1945.
- Objections/ suggestions were received from stakeholders on the draft notification G.S.R. 999 (E) dated 05.10.2018 was deliberated and considered accordingly.
- The central Government has finalized the draft notification vide G.S.R. 922(E) dated 28.12.2023 after consultation with Drugs Technical Advisory Board.
- The central Government has provide a time period for implementation of the revised Schedule M as mentioned below:

Category of manufacturers	**Time line for implementation**
Large manufacturers (Turnover> 250 crores)	Six month from the date of publication of these rules. (i.e. 28/06/2024)
Small and Medium manufacturers (Turnover≤ 250 crores)	Twelve months from the date of publication of these rules. (i.e. 28/06/2024)

Salient features of Proposed Schedule M:-

The proposed Schedule M prescribes the following major additional features in addition to the existing Schedule M

- Pharmaceutical Quality System (PQS)
- Quality Risk Management (QRM)
- Product Quality Review (PQR)
- Qualification and Validation
- Establishment of system to recall the defective products
- Change control
- Self inspection team & Quality audit
- Suppliers audit and approval
- Stability studies
- Validation of GMP related computerized system
- Specific Requirements for Manufacturing of Hazardous products, Biological Products, Radiopharmaceutical and Phytopharmaceuticals.

Government support

- Various workshops are being conducted across the country for awareness of the stakeholders
- RPTUAS Scheme
  - ❖ Re-imbursement up to Rs One Crore on the amount spent on GMP upgradation subject to the conditions
  - ❖ Number of applications have been processed

UPDATES ON DRUGS RULES, 1945

- Bioequivalence and Stability Study is made mandatory for grant of manufacturing licence (G.S.R. 327 (E) dated 03.04.2017).
- Rule 84C Inspection for verification of compliance
  - ❖ Not less than once in three years or as needed as per risk based approach along with State authorities
  - ❖Significant improvement on GMP compliance
  - ❖Number of MSME have upgraded their facilities And become WHO GMP compliant
- Marketers are also made responsible for ensuring quality of the pharmaceutical products marketed by them around the world [G.S.R. 101(E), dated 11.02.2020]
- QR code/Bar code on all APIs and top 300 brands of formulations (GSR 20 (E) dated 18.01.2022 and GSR 567 (E) dated 13.08.2019)
- National Drug Data base built
  - ❖9,461 Firms
  - ❖759367 drug formulations out of which 178102 brand names

Recent initiatives to strengthen the regulatory system

- Risk Based Inspections :
  - ❖ About 375 RBI of manufacturing facilities conducted across country.
  - ❖ Phase wise RBI of testing facilities, 200 such RBI conducted across country.
  - ❖ Non compliance to applicable provisions were strictly dealt,
    - ❖ 67 mfg. permissions-cancelled,
    - ❖ 50 mfg. permissions-suspended
    - ❖ 01 testing facility cancelled
    - ❖ 10 testing facilities suspended
- Monthly review meetings with State Regulators.
- Regular meetings with industry associations.

Regulatory Measures

- Risk Based Inspections have been initiated in order to assess the regulatory compliance.
- Dedicated PSUE/AE/AEFI division
  - ❖ PV audits
  - ❖ Online filing of PSUR through SUGAM portal
- Issue of NoC for export of Unapproved New Drugs/New drugs by CDSCO
  - ❖ Streamlining the application processing procedure
- NAP AMR 2.0
  - ❖ Dedicated consultations with the States
  - ❖ Monitoring of waste disposal of Antimicrobials during Inspections
  - ❖ Dedicated Nodal Cell at each State
  - ❖ Sharing of best practices
  - ❖ Sensitising the manufacturers and Chemsists
- Ayush vertical at CDSCO

Guidance Documents

Guidance document have been revised/issued on the following areas-

- Revised Guidance for Industry for Biologic products
- Pharmacovigilance Guidance document for MA holders
- Risk Based Inspections of Drug Manufacturing Sites.
- Submission of application by the Applicants for obtaining Manufacturing Licenses from the State Drug Authorities.
- Sampling of Drugs, Cosmetics & Medical Devices by Drugs Inspectors of Central and State Drug Authorities

Recent initiatives to strengthen the regulatory system

- Capacity Building:
  - ❖1837+ current strength of CDSCO (Regulatory and Quality control staff)
  - ❖Cadre expansion for Drugs and Medical Devices verticals.
  - ❖Dedicated Training Academy at NIHFW to impart classroom training to Central and State DC officials (21 such Sessions have already been organized and are many are oncoming)
  - ❖Online seminars, symposiums and trainings
  - ❖Various National and International collaborative capacity building programs

Recent initiatives to strengthen the regulatory system

- Skills and Competency building trainings and workshops:
  - ❖ Risk based inspections of Drugs manufacturing facilities
  - ❖ Investigation techniques and launching of prosecutions
  - ❖ Refresher course on New Drugs and Clinical Trials Rules 2019
  - ❖ NRA Assessment of Vaccines*
  - ❖ Clinical & CMC evaluation of New Drugs, Vaccine and Recombinant products. Biostatistics
  - ❖ Role of International Organizations viz. WHO, ICH, PIC/s/ICDRA/ ICMRA/IMDRA/MSM and Emergency Preparedness
  - ❖ Implementation of QMS in Medical Device
  - ❖ Regenerative Medicine and Gene therapy
  - ❖ GMP of Oral Solid Dosage and Topical formulation
  - ❖ Clinical Trials

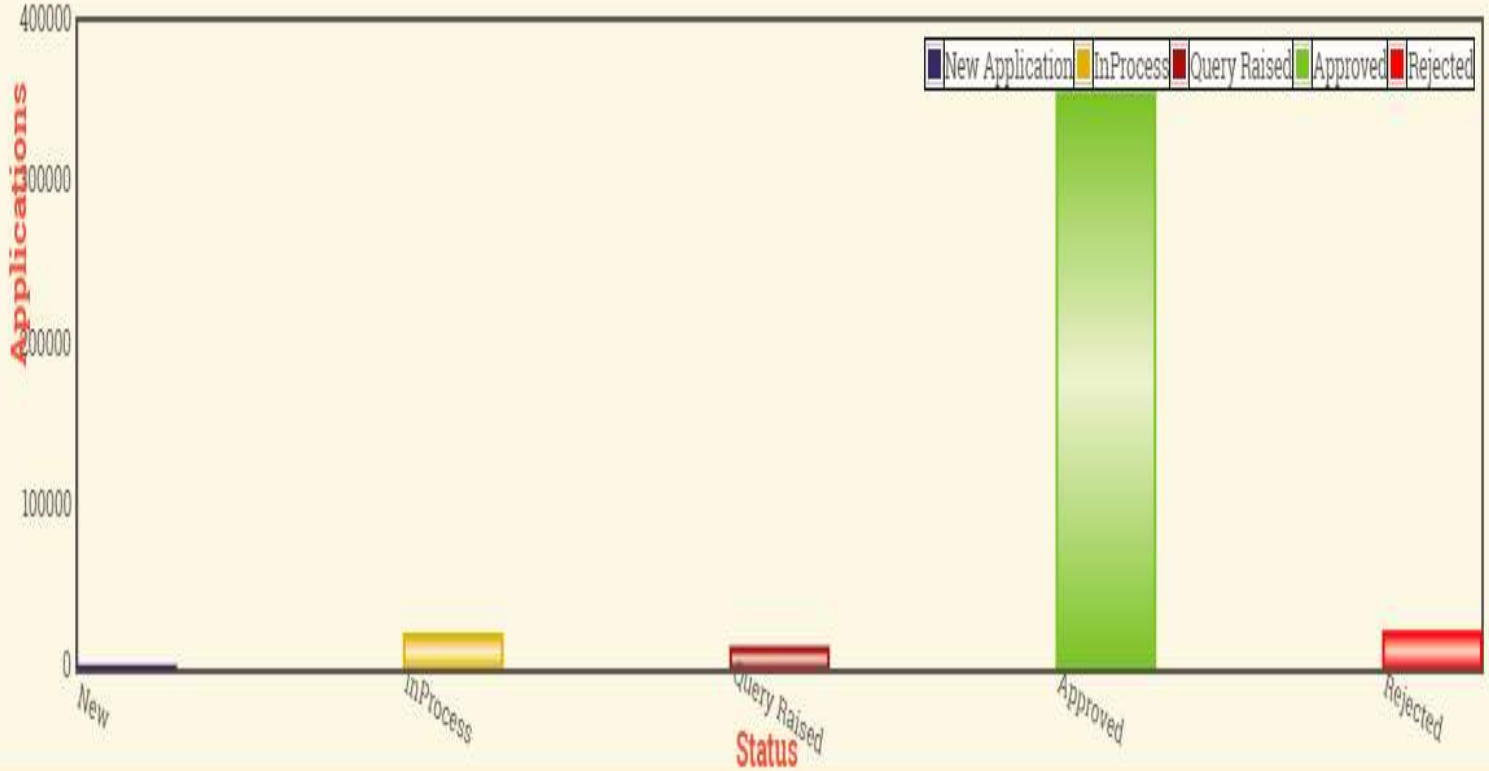
E-Governance

- Four Portals
  - ❖SUGAM for drugs
  - ❖MDONLINE for devices/IVDs
  - ❖ONDLS for States & CLAA
  - ❖SUGAM Labs
- NSWS Portal developed by DPIIT
- New modules developed under SUGAM portal
  - ❖Submission of PSURs
  - ❖Post Approval Changes for Vaccines
  - ❖Manufacturing license for Vaccines
  - ❖Blood centre and components licensing

Registered Users

Total Registered Users on SUGAM Portal: 25189

Applications received



Applications Count

Total	: 409349
New	: 399
Approved	: 355287
Rejected	: 21475
Inprocess	: 20235
QueryRaised	: 11953

Ease of Doing Business

In order to improve transparency, accountability and fast tracking the approval:

- E-governance through **SUGAM Portal**,
- Establishment of **Public Relation Office** at all offices of CDSCO,
- Video Conferencing facility for **Start Ups**, **Innovators, etc.**
- Providing **prompt and predictable** services to the stakeholders,
- **Streamlining** of regulatory process with global pharma. ecosystem
- **Accelerating** the regulatory approvals by **regulatory reliance**

NEW DRUGS AND CLINICAL TRIALS RULES

- Pre-defined timelines.

Type of Application	Timelines
CT (innovated in India):	within 30 days
CT (if drug is already approved by other country):	within 90 days
New drug	within 90 days
Processing of Import License	90 days
If the central licensing authority does not communicate, the “permission to conduct the clinical trial shall be deemed to have been granted”.	

Initiatives under consideration

- OTC drugs
  - ❖DTAB sub-committee
- Registration of CROs
  - ❖Registration
  - ❖Requirements of CROs
  - ❖Suspension/cancellation
- Confusing brand names/similar brand names
  - ❖DTAB lr to the Registrar of Trademarks
- Development of a Unified Portal
- Substitution of drugs
  - ❖Branded vs Generic
- Rules under Jan Vishwas Bill
  - ❖Govt examining if other violations can be brought under the Bill

Initiatives under consideration

- Compliance with GDP
- Prohibition to import and manufacture of Chloramphenicol and Nitrofurantoin in food producing animal rearing system
- Approval of plant layout before issue of Manufacturing License
- Guideline for disposal of unused/expired drugs
- Requirements for post approval changes to ensure quality throughout their lifecycle

INTERNATIONAL COLLABORATION

Broad Areas of Cooperation:

- Promoting an understanding between the Parties of each other's regulatory framework, requirements and processes and facilitating future regulatory strengthening initiatives for both parties.
- Exchange of information and cooperation on Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) and Good Pharmacovigilance Practices (GPvP).
- Recognition of Indian Pharmacopeia.
- Participation in scientific and practical conferences, symposiums, seminars and forums organized by the Parties.
- Exchange of safety information, including Pharmacovigilance, and adverse events where there is a particular safety concern related to the other party. This includes safety concerns relating to medicines and medical devices.
- Coordination at the international fora.
- Capacity building in mutually agreed areas
- Any other areas of common interest

INTERNATIONAL COLLABORATION

Sr. No.	Country Name	Drug Regulatory Agency	MoU/MoC/MoI
1	United States America	US Food and Drugs Administration	MoU
2	United Kingdom	The United Kingdome Medicines and Healthcare Products Regulatory Agency	MoU
3	Sweden	The Swedish Medical Products Agency (MPA)	MoI
4	Japan	The Ministry of Health, Labour and Welfare of Japan	MoC
5	Brazil	ANVISA	MoU
6	Argentine	The National Administration of Drugs, Food & Medical Devices	MoU
7	Saudi Arabia	Saudi Food and Drug Authority	MoU
8	Afghanistan	The National Medicines and Healthcare products regulatory authority	MoU
9	Germany	Drugs Regulatory Authority, Germany	MoU
10	Suriname	Medicines Regulatory Authority, Ministry of Health	MoU
11	Dominican Republic	Directorate General for Medicines, Foods and Sanitary Products	MoU
12	Ecuador	ARCSA	MoU
13	Russia	Federal Service on Surveillance in Healthcare & Social Development(Russian Federation)	MoU
14	The Netherlands	THE MINISTRY OF HEALTH, WELFARE AND SPORT, KINGDOM OF THE NETHERLANDS On behalf of MEB, IGJ, CCMO	MoU
15	BRICS	BRICS Drugs regulatory authorities	MoU
16	Denmark	DKMA	JDI

NOTE: More than 30 MoUs are under negotiations & MoU with Chile, Peru is ready for signing.

India 2024

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19TH INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES

World Health Organization

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19th International Conference of Drug Regulatory Authorities

New Delhi, India | 14th October - 18th October 2024

19th ICDRA: Programme Overview

Theme: "Smart Regulation: Delivering Quality Assured Medical Products for All"

14 - 18 October 2024, New Delhi, India

Time	Pre-ICDRA			ICDRA				
	14 October 2024	**15 October 2024**		**16 October 2024**	**17 October 2024**		**18 October 2024**	
9.00-10.30	Plenary 1 **Opening Ceremony** **(Palash Hall, Grand Ball Room A, B and C, 6th Floor)**	WS 5 **Access to Medical Products: CRP, FRP, Joint Assessment Procedures** **(Palash Hall, Grand Ball Room A and B, 6th Floor)**	WS 6 **Quality of Pharmaceutical Starting Materials** **(Palash Hall, Grand Ball Room C, 6th Floor)**	Plenary 1 **Opening. Recommendations from 18th ICDRA: How Well We Are Doing?** **(Palash Hall, Grand Ball Room A and B, 6th Floor)**	Plenary 4 **Regulation of Medical Devices (including IVDs): Global, Regional and Country Trends** **(Palash Hall, Grand Ball Room A and B, 6th Floor)**		WS 7 **Paediatric Medicines and Maternal Health** **(Palash Hall, Grand Ball Room A and B, 6th Floor)**	WS 8 **GxP Inspections** **(Palash Hall, Grand Ball Room C, 6th Floor)**
10.30-11.00	Coffee break (Pre fabrication area 6th Floor)	Coffee break (Pre fabrication area 6th Floor)		Coffee break (Pre fabrication area 6th Floor)	Coffee break (Pre fabrication area 6th Floor)		Coffee break (Pre fabrication area 6th Floor)	
1100-12.30	Plenary 2 **Smart Regulation: The New Era of WLA and Increased Reliance** **(Palash Hall, Grand Ball Room C, 6th Floor)**	WS 7 **Regulation of Advanced Therapy Medicinal Products** **(Palash Hall, Grand Ball Room A and B, 6th Floor)**	WS 8 **Replacing, Reducing and Refining dependence on animal studies** **(Palash Hall, Grand Ball Room C, 6th**	Plenary 2 **Effective Regulatory Harmonization and Convergence Through Regional/ Continental Networks** **(Palash Hall, Grand Ball**	WS 1 **Strengthening and Promoting Networking of NCLs** **(Palash Hall, Grand Ball Room A and B,**	WS 2 **Clinical trials: from WHA Recommendations to Action** **(Palash Hall, Grand Ball Room C, 6th Floor)**	WS 9 **IMS for Regulators (Including the Role of AI)** **(Palash Hall, Grand Ball**	WS 10 **Regulators' Role in Containing AMR** **(Palash Hall, Grand Ball**

Exhibition booth

- Booth of size 3m X 3m
- For Indian exhibitors INR 1,05,000+18%GST for Pre ICDRA for 2 days
- These registration charges include complimentary registration for 2 personnel (including refreshment and lunch)

Thank You !!