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

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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)

- 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:

<table>
<thead>
<tr>
<th>Category of manufacturers</th>
<th>Time line for implementation</th>
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<tbody>
<tr>
<td>Large manufacturers (Turnover&gt; 250 crores)</td>
<td>Six month from the date of publication of these rules. (i.e. 28/06/2024)</td>
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<tr>
<td>Small and Medium manufacturers (Turnover≤ 250 crores)</td>
<td>Twelve months from the date of publication of these rules. (i.e. 28/06/2024)</td>
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</table>
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 Chemists
- 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: 403349
- 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.**

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Timelines</th>
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</thead>
<tbody>
<tr>
<td>CT (innovated in India):</td>
<td>within 30 days</td>
</tr>
<tr>
<td>CT (if drug is already approved by other country):</td>
<td>within 90 days</td>
</tr>
<tr>
<td>New drug</td>
<td>within 90 days</td>
</tr>
<tr>
<td>Processing of Import License</td>
<td>90 days</td>
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</tbody>
</table>

If the central licensing authority does not communicate, the “permission to conduct the clinical trial shall be deemed to have been granted”.

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NEW DRUGS AND CLINICAL TRIALS RULES

3
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

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Country Name</th>
<th>Drug Regulatory Agency</th>
<th>MoU/MoC/MoI</th>
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<tbody>
<tr>
<td>1</td>
<td>United States America</td>
<td>US Food and Drugs Administration</td>
<td>MoU</td>
</tr>
<tr>
<td>2</td>
<td>United Kingdom</td>
<td>The United Kingdom Medicines and Healthcare Products Regulatory Agency</td>
<td>MoU</td>
</tr>
<tr>
<td>3</td>
<td>Sweden</td>
<td>The Swedish Medical Products Agency (MPA)</td>
<td>MoI</td>
</tr>
<tr>
<td>4</td>
<td>Japan</td>
<td>The Ministry of Health, Labour and Welfare of Japan</td>
<td>MoC</td>
</tr>
<tr>
<td>5</td>
<td>Brazil</td>
<td>ANVISA</td>
<td>MoU</td>
</tr>
<tr>
<td>6</td>
<td>Argentine</td>
<td>The National Administration of Drugs, Food &amp; Medical Devices</td>
<td>MoU</td>
</tr>
<tr>
<td>7</td>
<td>Saudi Arabia</td>
<td>Saudi Food and Drug Authority</td>
<td>MoU</td>
</tr>
<tr>
<td>8</td>
<td>Afghanistan</td>
<td>The National Medicines and Healthcare products regulatory authority</td>
<td>MoU</td>
</tr>
<tr>
<td>9</td>
<td>Germany</td>
<td>Drugs Regulatory Authority, Germany</td>
<td>MoU</td>
</tr>
<tr>
<td>10</td>
<td>Suriname</td>
<td>Medicines Regulatory Authority, Ministry of Health</td>
<td>MoU</td>
</tr>
<tr>
<td>11</td>
<td>Dominican Republic</td>
<td>Directorate General for Medicines, Foods and Sanitary Products</td>
<td>MoU</td>
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<tr>
<td>12</td>
<td>Ecuador</td>
<td>ARCSA</td>
<td>MoU</td>
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<tr>
<td>13</td>
<td>Russia</td>
<td>Federal Service on Surveillance in Healthcare &amp; Social Development (Russian Federation)</td>
<td>MoU</td>
</tr>
<tr>
<td>14</td>
<td>The Netherlands</td>
<td>THE MINISTRY OF HEALTH, WELFARE AND SPORT, KINGDOM OF THE NETHERLANDS</td>
<td>MoU</td>
</tr>
<tr>
<td>15</td>
<td>BRICS</td>
<td>BRICS Drugs regulatory authorities</td>
<td>MoU</td>
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<tr>
<td>16</td>
<td>Denmark</td>
<td>DKMA</td>
<td>JDI</td>
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**Note:** More than 30 MoUs are under negotiations & MoU with Chile, Peru is ready for signing.
19th International Conference of Drug Regulatory Authorities
New Delhi, India | 14th October - 18th October 2024
<table>
<thead>
<tr>
<th>Time</th>
<th>Pre-ICDRA</th>
<th>ICDRA</th>
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<tbody>
<tr>
<td>14 October 24</td>
<td><strong>Opening Ceremony</strong></td>
<td><strong>Plenary 1</strong></td>
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<tr>
<td>9:00-10:30</td>
<td>(Palash Hall, Grand Ball Room A, B and C, 6th Floor)</td>
<td>(Palash Hall, Grand Ball Room A and B, 6th Floor)</td>
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<tr>
<td>10:30-11:00</td>
<td>Coffee break</td>
<td>Coffee break</td>
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<td>(Prefabrication area 6th Floor)</td>
<td>(Prefabrication area 6th Floor)</td>
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<tr>
<td>11:00-12:30</td>
<td><strong>Plenary 2</strong></td>
<td><strong>Plenary 2</strong></td>
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<tr>
<td></td>
<td>Smart Regulation: The New Era of MLA and Increased Reliance</td>
<td>Effective Regulatory Harmonization and Convergence Through Regional/Continental Networks</td>
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<tr>
<td></td>
<td>(Palash Hall, Grand Ball Room C, 6th Floor)</td>
<td>(Palash Hall, Grand Ball Room A and B, 6th Floor)</td>
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<td>13 October 24</td>
<td><strong>WS 5</strong></td>
<td><strong>WS 8</strong></td>
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<tr>
<td></td>
<td>Access to Medical Products: CRP, FRP, Joint Assessment Procedures</td>
<td>Replacing, Reducing and Refining Dependence on Animal Studies</td>
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<td>(Palash Hall, Grand Ball Room A and B, 6th Floor)</td>
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<td>16 October 24</td>
<td><strong>WS 6</strong></td>
<td><strong>Plenary 2</strong></td>
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<td></td>
<td>Quality of Pharmaceutical Starting Materials</td>
<td><strong>WS 7</strong></td>
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<td></td>
<td>Regulation of Advanced Therapy Medical Products</td>
<td>Strengthening and Promoting Networking of NCLS</td>
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<tr>
<td>17 October 24</td>
<td><strong>WS 9</strong></td>
<td><strong>WS 2</strong></td>
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<td></td>
<td>Plenary 1, Recommendations from 18th ICDRA: How Well We Are Doing</td>
<td>Clinical Trials: From WHA Recommendations to Action</td>
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<td></td>
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<td>Regulation of Medical Devices (including IVDs): Global, Regional and Country Trends</td>
<td>GxP Inspections</td>
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<td>(Palash Hall, Grand Ball Room A and B, 6th Floor)</td>
<td>(Palash Hall, Grand Ball Room C, 6th Floor)</td>
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<td>18 October 24</td>
<td><strong>WS 8</strong></td>
<td><strong>WS 9</strong></td>
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<td></td>
<td>Paediatric Medicines and Maternal Health</td>
<td>IMS for Regulators (Including the Role of AI)</td>
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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 !!