ACHIEVEMENTS OF CDSCO DURING YEAR 2015-2017

E-Governance

- E-Governance in CDSCO through SUGAM Portal has been launched. Following activities of CDSCO are presently performed through the Sugam Portal:

    - Import Registration and licensing of drugs and medical devices
    - Registration of Cosmetics
    - Registration of Ethic Committee
    - Permission to conduct Clinical Trial
    - Permission to conduct Bioavailability and Bioequivalence for export purpose
    - Personal permit for import of drug by individual patient
    - Test licence for import of small quantities of drugs for test and analysis purpose.

ISO Certification of CDSCO Offices

- In order to have a transparency, accountability, CDSCO (HQ) and its Zonal offices at Ahmedabad, Hyderabad, Ghaziabad and Kolkata and sub-zonal office at Chandigarh are certified Quality Management System (ISO 9001: 2008)

National Drugs survey

- National Drugs survey to access the extent of spurious and not of standard quality drugs in the country were conducted during 2014-2016. More than 47,012 samples drawn from the market at various levels including Govt. Hospitals, procurement channels were tested in Govt. laboratories. In the survey, the percentage of Not of Standard Quality drug is founded to be 3.16 % and spurious was found to 0.0245%.

Prohibition of Irrational FDCs

- 344 FDC's considered as irrational by the Expert Committee were prohibited on 10.03.2016 for manufacture, distribution and sale of drugs in the country. However, Delhi High Court quashed the notifications. The MOH&FW has filled application in Supreme Court against the High Court Order.

National List of Essential Medicines (NLEM)

- National List of Essential Medicines (NLEM), 2015 containing 376 medicines has been released. A total of 106 medicines have been added, and 70 medicines have been deleted from NLEM, 2011.

- Coronary Stent have been included in the NLEM, 2015 based on recommendation of Sub-committee of Core committee of NLEM.

Pharmacovigilance Programme of India (PvPi)

- The Pharmacovigilance Programme of India with IPC, Ghaziabad as National Coordination Centre is being continuously strengthened. Currently, there are 210 Adverse Drugs Reaction (ADR) Monitoring Centres across the Country. More than 2.5 lakhs ADRs have been reported to Uppsala Monitoring Centre (UMC), Sweden. IPC is going to be WHO collaborating Centre for Pharmacovigilance.

Capacity Building & Skill Development

- CDSCO & Ministry of Health & Family Welfare are continuously engaged in imparting training to the drugs regulatory officials and laboratory personnel from both State & Centre. During Oct-2015 to May-2017, 10 training programme including induction as well as advance level programme were organised. In the said training programme total about 700 officials from CDSCO, State Drug Authorities and Drugs Testing laboratories have been trained.
- In order to strengthen the drug regulatory system in the CDSCO, more than 200 new additional technical manpower has been sanctioned.

Monitoring of quality of drugs

- **Risk Based Inspection:** To ensure the safety, efficacy and quality of the drugs available in the country risk based inspection of Pharma facilities has been decided. Till date 250 risk based inspection were scheduled in 8 phases, out of which 170 inspections have been carried out.

- **Requirement of Bioavailability and bioequivalence study (BA/BE):** Drugs & Cosmetics Rules have been amended making it mandatory requirement of BA/BE studies for oral formulations of biopharmaceuticals classification System (BCS) Class II & IV drugs before licensing .

Clinical Trial

- Realizing the importance of clinical trial in development of new drugs to cope up with the challenges of disease burden in public health care, the CDSCO and the Ministry of Health and Family Welfare have taken various measures to promote the scientific and ethical clinical trials in the country. Details are annexed at Annexure-I.

Biopharmaceuticals

- Guidelines for similar biologics were first prepared in Oct., 2012 jointly by CDSCO & Dept. of Biotechnology specifying the regulatory requirements for marketing authorization of similar Biologic Products in India.

    - The guidelines were subsequently revised in December, 2016.

- The changes made to deliver a clear and precise development pathway for the approval of Similar Biologics product, which in turn will have a significant impact on the healthcare related to these products in India.

- The broad framework of the guidelines remains unchanged. However, the revision seek to enhance the scientific utility of the guidelines to ensure robust quality and clinical evaluations by:

    - Defining similar biologics,
    - Identifying critical and key Quality Attributes for establishing similarity,
    - Specifying lower limits of minimum sample size 100 for clinical evaluations,
    - Making phase IV safety evaluations compulsory and specifying lower limits of minimum sample size 200 for it,
    - Recognizing innovators' product as Reference Biologic (approved in ICH countries)
    - Enabling parallel submission of applications to CDSCO and Review Committee on Genetic Manipulation (RCGM), DBT
    - Incorporating procedural simplification
    - Enumerating the applicability /scope of Guideline
    - Clarifying on key technical terms and providing additional details.

Medical Devices

- For regulation manufacture, import, clinical investigation, sale of medical devices, new Medical Device Rules, 2017 have been published on 31.01.2017 which will come into effect from 01.01.2018. Salient features of the said rules are annexed at Annexure II

International cooperation

- CDSCO, Ministry of Health & Family Welfare has signed MOU/SOI/MOC with USFDA, MHRA (UK), EMA, PMDA (Japan), ANVISA (Brazil) for extending regulatory cooperation with these countries.

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Annexure-I

Measures to promote the scientific and ethical clinical trials in the country

- To ensure evaluation of applications in expedited manner without compromising the quality of review, twenty-five panels consisting of experts have been prepared, which is updated from time to time. For evaluation of applications of Global Clinical Trial and New Drugs Subject Expert Committees (SECs) are constituted taking experts from the panels on need basis.

- Subsequent to the amendment in Drugs & Cosmetics Rules on 30/01/2013 inserting provisions relating to the reporting & examination of Serious Adverse Events (SAEs) concerns were raised on some of these provisions like criteria for deciding the relatedness of the SAEs to clinical trial and payment of compensation. Therefore, the rules were further amended on 12/12/2014, with effect from 11/06/2014 addressing these concerns.

- Earlier requirement of Audio-Visual (AV) recording of Informed Consent Process (ICP) of all subjects in all clinical trials have been revised by amending the Drugs & Cosmetics Rules on 31/07/2015 wherein the Audio-Visual (AV) recording of ICP has been made mandatory only in case of vulnerable subjects in clinical trials of New Chemical Entity (NCE)/New Molecular Entity (NME) and in case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the ICP is required.

- The Drugs and Cosmetics Rules have been amended on 16.03.2016 providing that no permission is required from DCG(I) for conduct of clinical trial of approved drug formulation for new indication, route of administration etc. for Academic / Research purposes subject to conditions that the trial has been approved by the Ethics Committee and the data generated will not be submitted to the regulatory Authority for new drug approval purpose and certain other conditions.

- Earlier restriction that number of clinical trials an Investigator can undertake should be not be more than three has been removed providing that the number of clinical trials should be decide by the respective Ethics Committee.

- Earlier requirement of at least 50 bedded hospitals for conduct of clinical trial have been revised providing that centres irrespective of number of beds, could be allowed to conduct clinical trials after the Ethics Committee approval.

- For addition of new clinical trial site or investigator in clinical trial, no NOC from DCG (I), in the normal course, would be necessary. The respective Ethics Committee after due diligence can approve such proposals for addition of site(s) and investigator(s). However the applicant would inform the DCG (I) about any such addition/deletion and if, no objection was received from DCG (I), it would be deemed to have concurrence of CDSCO.

- To improve transparency and efficiency in evaluation of clinical trial applications, IT enabled system for online submission and processing of such applications have been developed.

- “Handbook for Applicants and Reviewers of Clinical trials of New Drugs in India” is published in January, 2017.

Annexure-II

Salient features of the Medical Device Rules, 2017

- Medical devices shall be notified under the provisions of the Act and classified in Class A, Class B, Class C and Class D based on the risk based classification criteria where Class A being the lowest and that of the Class D is of highest risk medical device.

- Manufacture licence of Class A medical devices may be granted without prior audit of manufacturing site by a Notified Body.

- Manufacture of Class A and Class B will be regulated by the State Licensing Authority Concerned.

- Manufacture of Class C and Class D will be regulated by the Central Licensing Authority.

- Import of all medical devices will be regulated by the Central Licensing Authority.

- Notified Bodies will be registered with the CLA to assist the SLA concerned in the verification and assessment of Quality Management System of Medical Device Manufacturers who manufacture Class A and Class B devices.

- Manufacture and Import Licence shall remain valid till it is suspended or cancelled from its date of issue provided that a licence retention fee needs to be deposited in every five years.

- Separate provisions for regulation of Clinical Investigation of investigational medical devices.

- Central Government may establish medical device testing laboratory for testing and evaluation of medical devices.