

MAJOR ACHIEVEMENTS OF CDSCO (JANUARY, 2012 TO FEBRUARY, 2014)

- A 16 member International team of WHO, after conducting an extensive four day audit from 10-14 December, 2012 in respect of the vaccine regulatory system, has declared the National Regulatory Authority i.e. CDSCO as functional. The team includes regulatory officials from USA, France, Indonesia, Thailand, Iran and WHO (HQ), Geneva.
- Serodiagnostic test kits for diagnosis of tuberculosis' have been prohibited to be manufactured /imported in to the country with effect from 07.06.2012.
- Drugs & Cosmetics Rules have been amended on 17.07.2012 providing loan licensing system for Drugs under Central Licence Approving Authority.
- Goa port, Marmugao port in Goa and Air ports of Goa & Bangaluru have been notified on 17.07.2012 as port of entry for import of drugs.
- The Ministry of Health & Family Welfare has received the approval of 165 additional posts sanctioned to the Central Drugs Standard Control Organization in 2013 raising the sanctioned strength to 492 with 279 Drugs Inspectors. Earlier, from a total sanctioned strength of 111 posts in 2008 with 32 Drugs Inspectors, CDSCO had increased its sanctioned strength to 327 posts with 169 Drug Inspectors in 2011.
- A system of issuance of Written Confirmation Certificates by DCG (I) for active pharmaceutical ingredients (API) to be exported to EU has been introduced in 2013.
- Haemovigilance Programme has been launched on 10th December, 2012 under Pharmacovigilance programme of India to track adverse reactions events and incidences associated with blood transfusion and Blood product administration (Haemovigilance). National Institute of Biologicals is the coordinating centre, for Biovigilance programme (BvP) including Haemovigilance across the country.
- A system of requirement of registration of Cosmetics to be imported into the country has been introduced with effect from .1.04.2013.
- . A new Schedule H1 containing specified antibiotics, anti-TB drugs and habit forming drugs has been incorporated under the Drugs and Cosmetics Rules, 1945 for having stricter regulatory control over these drugs. This will be effective from 01.03.2014

- Drugs & Cosmetics Rules have been amended on 07.11.2013 deleting the clause 'or its inclusion in Indian Pharmacopoeia whichever is earlier' in the explanation of rule 122E. This implies that a new drug shall be considered as new drug for four years of its first approval irrespective of whether it is included in the Indian Pharmacopoeia or not.
- Drugs & Cosmetics Rules have been amended on 07.11.2013 incorporating a clause under Schedule D specifying the requirement of permission of DCG(I) for import of dual purpose items by the importers.
- Sindoor has been included under Schedule S of the Drugs & Cosmetics Rules on 07.11.2013 so that it conforms to the standard prescribed by BIS.
- Ketamine hydrochloride has been shifted from Schedule H to Schedule X of the Drugs & Cosmetics Rules on 07.11.2013 to prevent the misuse of the drug.
- Under Pharmacovigilance Programme of India (PvPi), 60 more ADR monitoring Centre have been setup taking the total to 150ADRs Centres in the country.
- It has been made mandatory Under 26 A that oxytocin shall be manufactured for sale or for distribution or sold in the manner as under w.e.f. 17.01.2014;
 - The manufactures of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufactures licenced under Drugs & Cosmetic Rules 1945 for manufacture of formulations of the said drug.
 - The formulation meant for veterinary use shall be sold to the veterinary hospitals only.
- The regulatory compliance at port entry for labeling requirements has been strongly enforced by vide notice dated 04.03.2014.
- A international cell dedicated to address the export related issues including investigation of complaint with respect to quality of drugs was created in January 2014. The complaints are dealt by establishing expedited mechanism for enforcements vide Order No. DCG(I)/MISC/2014 (31) dt. 05.03.2014.
- Various measures have been taken to strengthen regulation of clinical trials. Details are as under:
 - Amendment in the Drugs & Cosmetics Rules vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

- Amendment in the Rules vide Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.
- Amendment in the Rules vide Gazette Notification G.S.R. 72(E) dated 08.02.2013 specifying requirements and guidelines for registration of Ethics Committees.
- An Expert Committee has been constituted to examine the reports of deaths in clinical trials. The committee has prepared a formula for determining the quantum of compensation in case of clinical trial related deaths which is available in CDSCO website.
- The committee setup under the Chairmanship of Prof.Ranjit Roy Chaudhury on clinical trial and new drugs has submitted its report. The Ministry of Health & Family Welfare has examined the recommendations and finalized the action to be taken on various recommendations, the details of which have been posted on the CDSCO website.
- In compliance to the Hon'ble Supreme Court's order dated 03.01.2013, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under Chairmanship of Secretary, Health and Family Welfare and a Technical Committee under Chairmanship of DGHS.
- The present procedure followed for review of Clinical trial applications is a three tier review process. As per the process applications are evaluated by the New Drugs Advisory Committees (NDACs)/ Investigational New Drugs (IND) committee. The recommendations of these committees are finally reviewed by the Technical Committee and then approved by the Apex Committee on the basis of recommendations of the Technical Committee.
- Further, in compliance with the order of Hon'ble Supreme Court dated 26.07.2013, consultations have been made with the Principal / Health Secretaries of the States / UTs, NHRC, Civil Societies and other stakeholders who have submitted their suggestions which are under consideration for further strengthening of regulations on clinical trials.
- DCG (I) through an administrative order dated 30.08.2013 has made it mandatory for the sponsor or his representatives to furnish the details of the contract entered by the Sponsor with the Investigator/Institutions with regard to financial support, fees, honorarium, payments in kind etc., to be paid to the Investigator.
- In light of the order of Hon'ble Supreme Court dated 21.10.2013, it has been made mandatory with effect from 30.11.2013 that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, is required to be done.
- Draft guidelines for audio-visual recording of informed consent process have been prepared. Comments/ suggestions on the draft guidelines received from the stakeholders are under examination for finalization of the guidelines.
