1. STRENGTHENING OF CDSCO

i. Manpower strengthening

CDSCO is being progressively strengthened. The sanctioned strength of 111 posts in 2008 has been increased to 474 by 2014. At present there are 220 regular officers in position. The post of Joint Drugs Controller (India) has been filled through UPSC. Other vacant posts are being filled through UPSC / SSC. A pharmacologist has been appointed as new drugs consultant to assist in processing of applications of new drugs and clinical trials. The Government has also sanctioned the appointment of 250 contractual staff to assist the organization in coping with the work load at the Head quarter as well as zonal offices.

ii. Training and workshops

Thirty six training programmes / workshops on the subject related to the drug control were held during 2014 for updating the information and sharpening of the skills of the concerned officials working in CDSCO.

iii. 12th Five Year Plan

The revised outlay under 12th Five Year Plan for strengthening of Central Drug Regulatory System provides an outlay of Rs. 900 crores for strengthening of infrastructure of CDSCO.

iv. Strengthening of Central Drug Testing Laboratories

For strengthening the testing capacities of the Central Drug Testing Laboratories, the sanctioned amount of 12,84,77,206/- has already been spent on account of procurement of various equipments for these laboratories.

v. Introduction of E-governance at CDSCO

An Memorandum of understanding (MoU) has been signed between CDSCO and Centre for Development Advanced Computing (CDAC), a scientific society under Department of electronics and information technology, Ministry of
communications and information technology for designing, developing and implementing E-governance project (information technology enabled services at CDSCO for discharging various functions at the cost of Rs. 923.40 lakhs. It includes a plan for Digitalization of various activities of CDSCO.

2. STRENGTHENING OF STATE DRUG REGULATORY SYSTEM UNDER 12TH FIVE YEAR PLAN

For strengthening the State Drug Regulatory mechanism, a new centrally sponsored scheme under National Health Mission (NHM) Umbrella has been proposed with 75:25 sharing pattern for providing financial and human resource support to the States / UTs. Under the Scheme there shall be requirement of Rs. 1079 crores, in which the States share would be of 229 crores and the Central Government share would be of Rs. 850 crores. The components of expense heads approved relates to up-gradation of State Labs, expansion of existing offices, manpower accommodation and creation of new labs or mobile labs.

3. DRUGS AND COSMETICS (AMENDMENT) BILL

The Drugs and Cosmetics (Amendment) Bill, 2013 to amend the Drugs and Cosmetics Act, 1940 for upgradation and restructuring of regulatory framework has been further revised in the light of recommendations of the Parliamentary Standing Committee and comments from other stakeholders. The Bill include separate chapters for clinical trials and medical devices. The draft Bill has been uploaded by the Ministry of Health and Family Welfare on its website for comments from the public. The Bill will then be placed before the cabinet for introduction in the Parliament.

4. PROF. RANJIT ROY CHAUDHURY EXPERT COMMITTEE FOR STRENGTHENING CLINICAL TRIAL REGULATIONS

The Expert Committee constituted by the Ministry of Health and Family Welfare under the Chairmanship of Prof. Ranjit Roy Chaudhury had made a number of recommendations in respect of regulating the conduct of clinical trials in the country in a most authentic and transparent way. The recommendations included accreditation of Ethics Committees, investigators and clinical trial sites, procedures to be followed for review and grant of permissions for clinical trials, use
of information technology to ensure transparency in the system, establishing a system of reporting of serious adverse events and compensations in case of injury or death related to clinical trials etc. Actions on various recommendations were initiated. CDSCO had issued necessary orders (14 in number) on 03.07.2014. These measures will ensure that data generated in the clinical trials is authentic while the rights of human subjects participating in the trial are well protected.

5. NATIONAL SURVEY ON TO ASSESS THE PREVALENCE OF SPURIOUS SUBSTANDARD DRUGS

An All India Survey is proposed to be conducted in the country with methodology prepared by Indian Statistical Institute, Hyderabad to assess the prevalence of spurious and sub-standard drugs in the country. In the proposed survey, around 42,000 samples would be drawn from across the country which would include 15 therapeutic categories of drugs which is listed in National List of Essential Medicines (NLEM), 2011. The exact quantity of drugs to be sampled will be finalized after discussion with Indian Statistical Institute (ISI), Hyderabad and National Sample Survey Office (NSSO), Delhi. The proposed survey is to be conducted in the year 2014 and 2015. In order to conduct the survey effectively the State Drug Inspectors, participating in the survey will be identified, trained by the National Institute of Biologicals, Noida.

6. REVISION OF NATIONAL LIST OF ESSENTIAL MEDICINES (NLEM), 2011

The National list of essential medicines (NLEM) is one of the key instruments in balanced healthcare delivery system of a country which inter alia includes accessible, affordable quality medicine at all the primary, secondary, tertiary levels of healthcare. NLEM was last revised in 2011.

A core committee has been constituted by the Government under the Chairmanship of Dr. V. M. Katoch, Secretary, HR & DG, ICMR for updating the NLEM, 2011. The National consultations are in progress for the purpose of finalization revision of NLEM.

7. Fixed Dose Combination

There were reports that certain Fixed Dose Combinations (FDCs) of drugs were licensed by the State Licensing Authorities (SLA) without due approval of
DCGI as required under the Drugs and Cosmetics Rules, 1945. The SLAs were requested by DCGI on 15.01.2013 to ask the manufacturers of such formulations to submit the data of safety and efficacy to the office of DCGI within 18 months. Office of DCG(I) had received approx. 7000 applications. 10 Expert Committees were constituted on 03.02.2014 with the approval of Ministry of Health and Family Welfare for examination of these cases. Subsequently another Committee under the Chairmanship of Prof. C. K. Kokate, VC, KLE University, Belgaum, Karnataka has also been constituted for examination of applications in a timely manner. The committees have done extensive work to examine the FDCs and the report of these committees is expected shortly.

8. PROHIBITION OF TESTING OF COSMETICS ON ANIMALS

i. The Drugs and Cosmetics Rules, 1945 has been amended vide Gazette notification G.S.R. 346(E) dated 21.05.2014 prohibiting the testing of cosmetics on animals in the country.

ii. These rules were further amended to prohibit import of cosmetics tested on animals vide Gazette notification G.S.R. 718(E) dated 13.10.2014.

9. RESTRICTION OF SALE OF OXYTOCIN BULK

To curb the misuse of Oxytocin by dairy owners for extracting milk from milch animals, the Ministry of Health and Family Welfare issued a notification under Section 26A of the Drugs and Cosmetics Act vide G.S.R. 29(E) dated 17.01.2014 restricting the manufacture and sale of oxytocin as under:

a. The manufacturers of bulk oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.

b. The formulations meant for veterinary use shall be sold to the veterinary hospitals only.

10. BANNING OF DRUGS

Drugs about which reports are received that these are likely to involve risk to human beings or animals in the present context of the knowledge are examined for
their safety and rationality through the expert committees and / or DTAB after due examination of their rationality and safety. Following drugs were prohibited during the period.

a. ‘Dextropropoxyphene and formulations containing Dextropropoxyphene for human use’ (G.S.R. 332(E) dated 23.05.2013).
b. ‘Fixed dose combination of flupenthixol + Melitracen for human use’ (G.S.R. 377(E) dated 18.06.2013) and 498(E) dated 11.07.2014.
c. Analgin and all formulations containing analgin for human use to be marketed for restricted indications only (GSR 86(E) dated 13.02.2014).

11. CLINICAL TRIALS

Various initiatives have been taken for further strengthening of clinical trial regulation to ensure the protection rights, safety and well being of Clinical Trial subjects and authenticity of bio medical data generated. Some of the initiatives are given below:-

i. The Drugs and Cosmetics Rules, 1945 have been amended vide Gazette notification G.S.R. 889(E) dated 12.12.2014 for making specific provisions in respect of compensation for ineffectiveness and placebo group trials and streamlining the system of reporting Serious adverse events and payment of compensation in case of injury or death during the clinical trial.

ii. A system of supervision of procedure for grant 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 in compliance to the Hon’ble Supreme Court’s order dated 03.01.2013.

iii. The procedure now followed for review of Clinical trial applications is a three tier review process. The applications are first evaluated by the New Drugs Advisory Committees, now renamed as Subject Expert Committees (SECs) / Investigational New Drugs (IND) committee. The recommendations of these committees are reviewed by the Technical Committee and then approved by the Apex Committee.
iv. 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 as per directions of the Hon'ble Supreme Court on 21.10.2013. The Drugs and Cosmetics Rules, 1945 are also being amended to make audio-video recording mandatory before enrolling the clinical trial subjects.

v. 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.

vi. Expert committees have also been constituted for examination of Serious Adverse Events other than death related to clinical trials.

vii. Another committee has worked out the formulae for determining the quantum of compensation in case of clinical trial related injury (other than death) and this has been approved by the competent authority.

viii. An administrative order was issued by DCG(I) making it mandatory for the sponsor or his representative to furnish the detail of the contract entered by the sponsor with the investigator / institution with regard to finance support, fees, honorarium, payments in kind etc. to be paid to the investigator.

ix. A system of accreditation of Ethics committees, investigators and clinical trial sites and guidelines specifying the requirements and procedures is required to be put in place. The job of accreditation has been assigned to the quality council of India.

x. The National Accreditation Board for Hospitals and Healthcare Providers (NABH) has finalized the report on Accreditation Standards for Clinical Trials for Ethics Committee, Investigator and Clinical Trials.

12. PROVISION FOR LABELING, STANDARDS ETC FOR MEDICAL DEVICES

The Drugs and Cosmetics Rules, 1945 were amended vide G.S.R. 690(E) dated 25.09.2014 for making provisions for the manner of labelling, qualification of competent persons to manufacture and test medical devices, shelf life, provisions
for standard to which these devices should adhere and exemptions for custom made devices for their import and manufacture.

13. SIGNING OF STATEMENT OF INTENT BETWEEN FDA USA AND MINISTRY OF HEALTH AND FAMILY WELFARE

The United States Food and Drug Administration (FDA) and the Ministry of Health and Family Welfare of the Republic of India sing a Statement of Intent to strengthened bilateral cooperation in the area of regulatory system of medical products to promote and protect public health on 10.02.2014.

14. VISIT OF INDIAN DELEGATION TO VIETNAM

A team of CDSCO officials visited Drug Administration of Vietnam (DV), Vietnam in June, 2014 to have first hand information on the quality complaints in respect of drugs exported from India by Indian Pharmaceuticals Companies and suggest suitable remedies.

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