Chapter 14

QUALITY CONTROL IN FOOD & DRUG SECTOR, MEDICAL STORES

14.1 FOOD SAFETY & STANDARDS AUTHORITY OF INDIA (FSSAI)

The Food Safety & Standards Authority of India (FSSAI) has been established under the Food Safety & Standards Act, 2006, as a statutory body for laying down science based standards for articles of food and regulating, manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption. The Act aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multi-level, multi-departmental control to a single line of command. Various Acts and Orders that have hitherto handled food related issues in various Ministries and Departments have been integrated in the Act. The safety and quality of food is imperative to meet the country's aim of Universal Health Coverage and Food Security for all. A comprehensive, consolidated Food Safety and Standards Act aligned with the global practices was the first step to achieve this aim. The Food Safety and Standards Authority of India is making continuous efforts for effective implementation of the FSS Act. 2012-13 saw significant achievements in the field of food safety and standards. The following six regulations have been notified w.e.f. August, 2011.

i. Food Safety and Standards (Licensing & Registration of Food Business) Regulations 2011;

ii. Food Safety and Standards (Food Product Standards and Food Additives) Regulations 2011;

iii. Food Safety and Standards (Contaminants Toxins and Residues) Regulations 2011;

iv. Food Safety and Standards (Prohibition and Restriction on Sales) Regulations 2011;

v. Food Safety and Standards (Laboratory and Sample Analysis) Regulations 2011 and

vi. Food Safety and Standards (Packing and Labelling) Regulations, 2011.

Emphasis of the new law

- Safe and wholesome food for human consumption,
- Laying down Food Safety standards on scientific basis,
- Unified law encompassing seven different laws which were governing safety standards and regulations falling under separate nodal ministries,
- All issues relating to manufacture, import, storage, distribution and sale (including labelling) are addressed comprehensively,
- Creation of infrastructure for testing and certification procedures and
- Global standards for food, sanitary and phytosanitary measures, to promote recognition, co-ordination with governmental and non-governmental organisation world over.

Activities

Enforcement Division: FSS Act, 2006 is being implemented by all States/UTs Government w.e.f. 5th August, 2011. States/UTs Government have appointed Food Safety Commissioners, notified Designated Officers, Adjudication Officers and Food Safety Officers for respective areas within the State/UT. The number of licenses and registration issued by the States as on 31.03.2013 are 3,59,446 & 11,95,302 respectively.

Media (Print and Electronic): A lot of activities have been organised to make the stakeholders aware about

the essential elements of the Act, involving print and electronic media. Advertisement on licensing, labelling, are being released in multilingual mode across the country. Creatives are designed and released in newspapers/magazines/including advertorial etc. pamphlets, brochures on the procedure of licensing, registration, labelling, imported foods and similar literature were developed and distributed. Radio jingles were broadcast on various radio channels. Animated video spots were made out of the radio jingles and played in safal outlets in New Delhi. FSSAI branding was done in association with IRCTC.

Participated in events like AAHAR, to spread awareness through posters display, leaflet distribution and involving experts from FSSAI to clarify the queries raised by the Food business operators. Participated in Kumbh Mela by organising training programmes, lectures and street play. FSSAI has involved NGOs to generate awareness in the field of food safety with a broad spectrum of activities.

A dedicated website www.fssai.gov.in , blog and Social networking are in place to update the current happenings in the Authority. FSSAI, You tube channel has original videos to test adulteration in food stuff at the household level.

The IEC materials that are being developed in the Authority are shared with the State/UT Governments which the States can get translated into regional language, and appropriate channel of communication can be taken by the respective States to address various stake holders.

Imports: As per section 25 of the Food Safety & Standard Act, 2006, all imports of articles of food to be subject to the provision of the Act. It provides that no person shall import into India any article of food in contravention of the Act or any rules and regulations made thereunder. It also provides that the Central Government shall, while prohibiting, restricting or otherwise regulating import of article of food under the Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992), follow the standards laid down by the Food Authority under the provisions of this Act and the Rules and Regulations made thereunder. Further, as per section 47 (5) of the FSS Act, 2006, in case of imported articles of food, the Authorised Officer of the Food Authority shall take its sample and send to the Food Analyst of notified laboratory for analysis who shall send the report within a period of five days to the Authorised Officer.

Accordingly, under this Act, FSSAI has a clear mandate of ensuring safety of food items imported into the country. In view of this, FSSAI has already successfully operationalized the Imported food clearance process in a phased manner since August- September 2010 through appointment of Authorized officer in terms of section 47 (5) of the FSS Act, 2006 in 10 ports of entry at Delhi, Mumbai, Chennai & Kolkata Ports (including sea, air and land). Further FSSAI is in the process of operationalizing the additional ports of entry. On an average percentage of number of samples drawn at different ports has seen an increase in 2012-13.

Scientific Committee and Scientific Panels of the Food Authority: FSSAI under the provision of section 14(1) and 13(1) of the FSS Act has constituted a Scientific Committee and Nine Scientific Panels consisting of independent scientific experts for providing scientific opinion on various issues.

National Codex Contact Point: The Food Authority as the National Codex Contact Point (NCCP) has actively participated in various Codex Committees during the year 2012-13. The work proposals by the Food Authority-Standards for Okra & Potato, Development of Code of Hygienic Practices for the Street-Vended Foods and Code of Hygienic Practice for the Storage of Cereals were considered by the respective Codex Committees. India has also participated in a number of Electronic Working Groups.

International Cooperation, WTO/SPS/TBT: The Authority also serves as enquiry point for Sanitary and Phytosanitary (SPS) issues and thus regularly participates in bilateral cooperation with countries in food safety, standards, and capacity building of food testing laboratories, for instance, a Memorandum of Understanding (MoU) has been signed with Netherlands this year. Significant MoU with the Food and consumer Product Safety Authority of the Ministry of Economic Affairs, Agriculture and Innovation of the Kingdom of the Netherland on Cooperation in the field of Food Safety signed on 30th November, 2012.

FSSAI is also a part of India-EU Project on Capacity Initiative for Trade and Development (CITD). This agreement was signed by the Govt. of India on 30th November, 2011. The aim of the project as mentioned in the document is to "modernize and enhance the capacity of India's trade related regulatory institutions and enforcement system in order to meet International standards and requirements".

Quality Assurance: As per Sec. 43 (1) the Food Authority may notify food laboratories and research institutions accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) or any other accreditation agency for the purpose of carrying out analysis of samples by food analysts under this act. Till date 68 laboratories have been notified by FSSAI for a period of 1 year.

A manual regarding "Guidelines for Recognition of Food Testing Laboratories" was prepared. The document lays down the guidelines for general as well as the technical criteria for recognition, terms and conditions of recognition, withdrawal/cancellation of recognition and financial aspects of the Laboratory Recognition.

Achievements during the year 2012-2013

a) Standards for caffeinated beverages have been framed and the same draft has been notified for public comments.

b) Draft standards for Olive Oil have been notified for seeking public comments.

c) Laboratory parameters for food Products for analysis have been finalized.

d) Fifteen manuals of method of analysis of Food have been finalized.

e) Quick tests for analyzing the adulterants for the purpose of house hold and small industries have been developed and uploaded in the FSSAI's website.

f) Review of the existing standards and harmonization with Codex and other international best practices has been initiated.

g) Strategy paper on upgradation of the 72 public state food laboratory, establishment of one laboratory at each twenty districts has been developed.

Surveillance Division: The Surveillance Division of FSSAI had conducted a surveillance study of fruits and vegetables in Feb, 2013 in Azadpur fruit and vegetable market in early morning. Analytical tests for physical, chemical and microbiological parameters were carried out by NABL Accredited laboratories. The division has also started a nationwide survey on quality of packaged drinking water to ensure the quality and safety of packaged drinking water manufactured by various bottling units across country.

14.2 CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

The import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. The Central Government exercises regulatory control over these products imported into the country through the Central Drugs Standard Control Organization (CDSCO) headed by the Drugs Controller General (India) [DCG(India)]. The manufacture, sale and distribution of drugs in the country are primarily regulated by the State Drug Control Authorities appointed by the State Governments. The objective of the drug regulatory system is to ensure availability of safe, effective and quality drugs, cosmetics and medical devices based on scientific excellence and best possible regulatory practices.

Mission of CDSCO

The mission of Central Drugs Standard Control Organization (CDSCO) has been defined as under:

"To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices".

Organization: The Head-quarters of CDSCO are situated at Food and Drug Bhawan, Kotla Road, New Delhi - 110002. It has under its control zonal / sub-zonal offices, port offices and drug testing laboratories to perform various regulatory functions as prescribed under the Drugs and Cosmetic Act, 1940 and Rules.

There are six zonal offices situated at Mumbai, Ghaziabad, Kolkata, Chennai, Ahmadabad and

Hyderabad and three sub-zonal offices at Bangalore, Chandigarh and Jammu. The Port Offices of CDSCO are situated at notified port of entries. These Port offices are at Mumbai (Sea and Airport), Nava Sheva (Sea Port), Kolkata (Sea and Airport), Chennai (Sea and Airport), Hyderabad (Airport), Delhi (Airport), Kochi (Sea Port) and Ahmadabad (Air Port), Bangaluru (Air Port), Goa (Sea and Air Port).

There are seven functioning central drug testing laboratories under CDSCO, situated at Kolkata, Mumbai, Chennai, Guwahati, Chandigarh, Kasauli and Hyderabad. The testing capacity of these labs is around 8,000 samples per year. In addition, National Institute of Biologicals, Noida, is notified as Central Drug Laboratory for testing Blood Grouping Reagents and certain diagnostic devices. The Homeopathic Pharmacopoiea Laboratory, Ghaziabad tests homeopathic medicines and Indian Veterinary Research Institute, Izzatnagar tests veterinary medicines.

The Central Drug Laboratory, Kolkata is the appellate laboratory in matters of dispute regarding testing of drugs and is NABL accredited for chemical and biological testing. The Central Drug Testing Laboratory, Mumbai is a statutory laboratory involved in testing of samples of drugs from the ports, new drugs and oral contraceptive pills. It is an appellate laboratory for copper T- intrauterine contraceptive device and tubal rings. The Central Drug Testing Laboratory, Chennai is an appellate laboratory for condoms and is NABL accredited for both chemical and mechanical section. The Regional Drug Testing Laboratory, Guwahati tests samples of drugs received especially from States in the East Zone and is NABL accredited for both chemical and biological testing. The Regional Drug Testing Laboraotry, Chandigarh tests survey samples as well as samples sent by Drug Inspectors.

Regulatory Functions Performed at CDSCO

CDSCO is discharging the following functions at its hqrs, zonal/sub-zonal offices, port offices.

Functions discharged at CDSCO headquarters:

- Grant of approval to manufacture and/or import new drugs and to conduct clinical trials as per provisions of the Drugs and Cosmetics Act and Rules.
- Approval of the licenses to manufacture certain categories of drugs as Central License Approving Authority (CLAA) i.e. Blood Banks, Large Volume Parenterals, Vaccines/Sera, r-DNA derived products, in-vitro diagnostic kits for detection of HIV 1 & 2, HCV & HBsAg and notified medical devices.
- Registration of foreign manufacturers of drugs and medical devices whose products are to be imported into the country, grant of licences to import drugs and medical devices along with regulatory control over the quality of these products imported into the country.
- Grant of Test Licences for import of drugs for the purpose of examination, test and analysis.
- Grant of licences to import drugs by Government hospitals or Medical Institutions for the use of their patients.
- Convening the meetings of Drugs Technical Advisory Board (DTAB) to discuss matter arising out of the administration of the Act and processing its recommendations especially related to amendments to the Drugs and Cosmetics Rules, 1945.
- Convening the meetings of the Drugs Consultative Committee (DCC) to secure uniformity throughout the country in the administration of this Act.
- Review and recommend to the Government to regulate, restrict or prohibit manufacture etc. of drug or cosmetics in public interest under section 10A and/or 26A drugs and Cosmetics Act, 1940.
- Conduct workshops and training programmes for skill development in respect of various issues related to quality control of drugs, medical devices and cosmetics.

Functions of the Zonal/Sub-Zonal Offices

Inspection of manufacturing premises jointly with State Governments for drugs covered under the CLAA Scheme i.e. I V Fluids, Large Volume Parenterals, Vaccine &

Sera, Blood & Blood Products, r-DNA products (Biotech Products) etc. for the purpose of grant/renewal of licenses.

- Inspection of private testing laboratories in coordination with the State Drug Inspectors for approval of these laboratories for carrying out tests on drugs/cosmetics on behalf of the licensees.
- Inspection of manufacturing facilities of the firms under WHO GMP Certification Scheme.
- Inspection of drug manufacturing firms for capacity assessment and other provisions at the request of the Central Government.
- Inspections to investigate complaints received from various forums.
- Coordination with the State Drug Controllers to sort out problems involved in the investigations of drugs manufactured in one State and declared not of standards quality in another State and other such matters.
- Launching of prosecutions in cases detected by the zonaloffices.
- Drawing of sample of drugs for test and analysis by the Government Analysts.

Functioning of Airport & Seaport Offices

To control the quality of imported drugs, notified medical devices and cosmetics, the port offices check documents (bill of entry) and draw samples on random basis to check their quality and verify shipping bills of export of drugs as requested by the customs authorities.

Strengthening of CDSCO

The CDSCO is being continuously strengthened to ensure that only safe and effective medicines of standard quality are made available in the country. The sanctioned strength of the organization has increased from 111 posts in 2008 to 475 posts in 2013. Presently it has 197 regular officers, namely, the Drugs Controller General (India), 01 Joint Drugs Controller (India), 15 Deputy Drugs Controllers, 19 Assistant Drugs Controllers, 143 Drug Inspectors, 08 Technical Officers, 04 Senior Technical Assistants and 6 Technical Assistants. The remaining posts are being filled through the UPSC. Thirty one posts of Assistant Drug Inspectors are also being filled up through the Staff Selection Commission. The Government 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.

An ambitious plan has been made under the 12th Five Year Plan for further strengthening of the CDSCO as well as State Drug Regulatory Authorities including enhancement of testing capacities. Outlays of Rs. 1800 crore for Centre and Rs. 1200 crore for States/UTs have been made in the 12th Plan.

Training/workshops conducted with WHO support in the country

Various training programmes/workshops on different topics were held during the period for updating the knowledge and sharpening of the skills of the concerned officials working in CDSCO. Some of such workshops conducted with WHO support are mentioned below.

- Two Workshops on "Quality Risk Management Approach applied to GMP (Advanced)' were conducted by CDSCO in collaboration with WHO, from 18th February 2013 to 22ndFebruary, 2013 at Hotel Mount View, Sector-10 Chandigarh and from 6th May to 10th May, 2013 at Hotel Sagar Plaza, Pune (Maharashtra).
- Two Induction Training programme for newly recruited Drugs Inspectors of CDSCO were conducted in July, 2013 and August, 2013.
- A Workshop on Harmonization of Schedule-Y, ICMR, GCP guidelines on Ethical issues was conducted from 24th - 25th June, 2013 at New Delhi.
- Two Workshops on GMP Regulatory Inspection (Basic)" in collaboration with WHO were conducted at Hyderabad from 23rd and 27th September, 2013, and at Pune from 18th to 22nd November, 2013 for Drugs Inspectors of CDSCO, States and CDL, Kasauli.
- An Interpol Training Programme on investigating traffics of Spurious and Medical Products was conducted for the Drug Control Officers from 08-10 October, 2013 at CBI Academy, Ghaziabad.

- A Lead Audit Course on quality management system as per IS/ISO 9001:2008 for officers of CDSCO was conducted in coordination with the Bureau of Indian Standard from 02-06 December, 2013.

Regulatory Activities at the Headquarters

a) Quality Control over import of drugs

The CDSCO regulates the quality of drugs imported in to the country through the system of registration and licensing as provided under the Drugs and Cosmetic Rules, 1945. This includes registration of overseas manufacturing sites and the drug products (bulk drugs and finished formulations). Import licences are granted to the Indian importers for the import of the drugs from these manufactures as provided under the rules. The quality of imported drugs is further monitored at the port offices when the drugs are actually imported.

During the year 2013, upto November, 2013, the office of Drugs Controller General (India) granted 333 Registration Certificates in respect of manufacturers of the drugs who intend to export their products to India. During the same period, 2419 licences in Form 10 for import of drugs in to the country were also granted.

Permissions were also granted for import of small quantities of drugs for test and analysis in Form 11 of the Drugs and Cosmetics Rules. The office of DCG(India) granted 11,465 test licences for the import of drugs in small quantities for test and analysis upto November, 2013.

b) Quality Control over import of cosmetics

The registration of cosmetics imported into the country was initiated from 1st April, 2013 to ensure that products imported into the country are not only of standard quality but also have been manufactured under Good Manufacturing Practices by genuine/licensed manufacturers. This provision would ensure that only genuine and safe cosmetics are permitted to be imported in the interest of public health safety. The office of DCG(I) granted 265 Registration Certificates by the end of November, 2013.

c) Quality Control over Notified Medical Devices

Medical Devices notified by the Government of India under the Drugs and Cosmetics Act, 1940 are regulated by CDSCO as 'drugs' under the provisions of the Drugs and Cosmetics Rules. The quality control over these devices is regulated through the system of registration and import licences.

During the year 2013, (upto November, 2013), the office of DCG(I) granted 302 Registration Certificates to the manufacturers of the Medical Devices intending to export their medical devices to India while 915 licences in Form 10 for import of medical devices to the country were granted during the same period. In addition, 122 permissions for import of Medical Devices and diagnostics devices for test and analysis were also granted during the same period.

The manufacture of the notified devices is approved by the DCG(I) as Central Licence Approving Authority (CLAA) under the Drugs and Cosmetics Rules. During the year 2013, (upto November, 2013), the office of DCG(I) granted CLAA approval in 75 cases in respect of manufacturing licences for manufacture of medical devices.

d) Grant of permission for introduction of new drugs in the country

New Drugs are permitted to be marketed in the country in accordance with the permission granted by the Drugs Controller General (India) after ensuring that these are safe and efficacious and comply with the requirements of the Drugs and Cosmetics Rules. The applicants are required to provide technical data in respect of safety and efficacy before these could be permitted to be marketed in the country. Fixed Dose Combinations which are required to be marketed for the first time in the country are also considered as new drugs under the Drugs and Cosmetics Rules, 1945.

Vaccines are considered as new drug unless certified otherwise. During the year 2013, (upto November, 2013), permission to import finished formulations of vaccines was given in 4 cases and permissions for manufacture of vaccines as New Drugs was granted in 18 cases. During the same period, in 9 cases new licences for manufacture of vaccines were also granted.

e) Clinical trials

Clinical trials of new drugs are conducted on human subjects in the country to discover or verify the clinical,

pharmacological (including pharmacodynamics/ pharmacokinetics), and/or adverse effects with the object of determining their safety and/or efficacy. The Drugs and Cosmetics Rules provide that clinical trials for a new drug, whether for clinical investigation or any clinical experiments are required to be conducted under and in accordance with the permission granted by the Drugs Controller General (India). The applications for grant of permission to conduct clinical trials on new drugs in the country are examined by the office of DCG(India). Permissions are also required for conducting bioequivalence studies on drugs in chemically equivalent drug formulations to study whether they produce identical therapeutic response in patients or not. During the year 2013, the office of DCG(India) granted no objections for conduct of clinical trials on new drugs in 26 cases upto November, 2013.

In order to strengthen the regulatory provisions over the conduct of clinical trials in the country, following initiatives have been taken.

i. Twelve New Drug Advisory Committees (NDACs) related to different therapeutic areas, consisting of medical experts drawn from various Government medical colleges and institutes from all over the country help in evaluation of applications for marketing of new drugs in the country or to conduct clinical trials on new drugs. 78 meetings of these committees have taken place since 2011, wherein a total of 1122 applications were evaluated. Out of these 331 applications were related to global clinical trials including clinical trials of new chemicals entities.

ii. All Investigational New Drug applications are evaluated by the Investigational New Drug committee under the Chairmanship of Secretary, Department of Health Research & Director General of ICMR.

iii. Under the directions of the Hon'ble Supreme Court of India, in the case of Swasthya Adhikar Manch Vs. Government of India (W.P. Civil 33 of 2012), the Ministry of Health and Family Welfare also constituted two committees for supervising the clinical trials of new chemicals entities. While the first Committee - the Technical Committee is headed by the Director General of Health Services and the second i.e. the Apex Committee, for overall supervision, is headed by the Secretary, Ministry of Health and Family Welfare.

iv. In light of the order of the Hon'ble Supreme Court dated 21.10.2013 directions were issued on 19.11.2013 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, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering the principle of confidentiality. This is applicable to all new subjects to be enrolled in all clinical trials including global clinical trials.

v. Registration of clinical trial in ICMR registry is mandatory.

vi. Guidelines for conducting clinical trial inspection of clinical trials sites and sponsor/Clinical Research Organizations (CROs) have been prepared and are available at the website of CDSCO.

vii. Drugs and Cosmetics Rules have been amended to strengthen the regulations relating to clinical trials in the country. Details are as under:

- Introduction of rule 122 DAB and APPENDIX XII in Schedule Y 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.
- Introduction of rule 122 DAC regarding permission and conditions for conduct of clinical trials vide Gazette Notification G.S.R. 63(E) dated 01-02-2013. The rule provides authority for conducting clinical trial inspections and actions in case of non-compliance by the CDSCO.
- Introduction of rule 122 DD for registration of Ethics Committees by the office of

DCG (India) vide Gazette Notification G.S.R. 72(E) dated 08.02.2013. The amendment includes providing the requirements and guidelines for registration of Ethics Committees.

viii. Independent Expert Committees have been constituted to examine the reports of deaths in clinical trials and recommended to DCG(India) to decide the cause of deaths and to determine the quantum of compensation in each clinical trial related death. A formula has been developed for determining the quantum of compensation in case of clinical trial related deaths which is available in CDSCO website.

ix. The Committee set up under the Chairmanship of Prof. Ranjit Roy Chaudhury on approval of clinical trials and new drugs has submitted its report. The Ministry of Health & Family Welfare has examined the recommendations for taking action. The details of the recommendations and the decision of Government thereon are available on the website of CDSCO (www.cdsco.nic.in).

f) Blood Banks

Licences for the Blood Banks are also granted by the office of DCG(India) as Central Licensing Approving Authority. During the year 2013 upto November, 2013, fresh licences were granted in 127 cases while endorsement of blood components on the existing licences were issued in 85 cases.

g) National Regulatory Authority (NRA) Assessment by WHO

India has a Rs. 19,000 crore worth vaccine industry which is exporting two thirds of the vaccines manufactured in the country while one third is domestically consumed. The major international procurement agencies for vaccines are WHO, UNICEF, Gates Foundation, Clinton Foundation, etc. which purchase vaccines for the use across the world. These agencies procure vaccines on the basis of assurance by the WHO that these are of high quality and safe and efficacious for use.

WHO had conducted an extensive four day audit from 10-14 December, 2012 in respect of the vaccine clearance procedures adopted by the National Regulatory Authority (NRA) i.e. office of the Drugs Controller General (India), and was satisfied that the procedures adopted by the NRA which are stringent enough and the international community can be assured that the vaccines permitted for manufacture by the said authority are of high quality, safe and efficacious.

Subsequent to NRA assessment, WHO continues to accept the applications of Indian vaccines manufacturers for pre-qualification programme for supply of vaccines to UN agencies. Japanese Encephalitis, Pentavalent and OPV vaccines manufactured by Indian vaccine manufacturers have been pre-qualified by WHO in 2013.

h) Amendments to the Drugs and Cosmetics Rules, 1945

Apart from the amendments relating to clinical trials mentioned above, the following amendments have been incorporated under the Drugs and Cosmetics Rules, 1945 in the year 2013 to make it responsive to the present day needs of the society.

i. A new Schedule H1 containing certain 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 vide Gazette notification G.S.R. 588(E) dated 30.08.2013.

ii. The amendments to the Drugs and Cosmetics Rules, 1945 made vide Gazette notification G.S.R. 724(E) dated 07.11.2013 are as under:

- Revision of the definition of loan licence.
- Deletion of the clause 'or its inclusion in Indian Pharmacopoeia whichever is earlier' in the explanation of rule 122E for a new drug to be considered as a new drug.
- Incorporation of a clause under Schedule D specifying the requirement of permission of DCG(India) for import of dual purpose items by the importers.
- Inclusion of Sindoor under Schedule S so that it conforms to the standard prescribed by BIS.
- Shifting of Ketamine hydrochloride from Schedule H to Schedule X.

i) Drugs and Cosmetics (Amendment) Bill, 2013

The Ministry of Health and Family Welfare introduced the Drugs and Cosmetics (Amendment) Bill, 2013 in the Rajya Sabha for the amendments to the Drugs and Cosmetics Act, 1940 on 29th August, 2013 for upgradation and restructuring the Drugs Regulatory framework for ensuring the manufacture and sale of safe and efficacious drugs in the country. It has been proposed to create a Central Drug Authority headed by the Secretary, Department of Health and Family Welfare and introduction of a new Schedule under the Act, containing drugs for which Central Licensing Authority would be empowered to issue manufacturing licences. The Bill also contains separate chapters on clinical trials and regulation of medical devices in the country. The Bill was referred to the Department Related Parliamentary Standing Committee on Health & Family Welfare for examination and report. The report of the Committee, the Seventy-Ninth Report on the Drugs & Cosmetics (Amendment) Bill, 2013 has been received and the same is under, examination in the Ministry.

j) Drugs Technical Advisory Board (DTAB)

The Drugs Technical Advisory Board is a statutory body under the Drugs and Cosmetics Act, 1940 to advice the Central Government and the State Governments on technical matters arising out of the administration of the said Act and Rules made thereunder. The Board is headed by the Director General of Health Services and DCG(I) acts as Member Secretary. Four meetings of the DTAB were held during the year 2013 as under:

i. 62nd meeting of DTAB was held on 30th January, 2013.

ii. 63rd meeting of DTAB was held on 16th May, 2013.

iii. 64th meeting of DTAB was held on 19th July, 2013.

iv. 65th meeting of DTAB was held on 25th November, 2013.

k) Drugs Consultative Committee

The Drugs Consultative Committee is also a statutory committee under the Act, consisting of Central and State Drug Controllers to advice the Government on matters relating to uniform implementation of the Drugs and Cosmetics Act and Rules made thereunder. DCG(I) acts as Chairman of the Committee. Two meetings of the Drugs Consultative Committee were held during the year 2013 as under:

i. 45th meeting of DCC was held on 4th & 5th February, 2013 at New Delhi.

ii. 46th meeting of DCC was held on 12th & 13th November, 2013 at New Delhi.

l) Banning of Drugs

The Drugs and Cosmetics Act, 1940 provides powers to Central Government to prohibit manufacture etc., of any drug or cosmetic in public interest. Drugs about which reports are received, 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/DTAB. Manufacture and sale of the drug if considered necessary is prohibited by Central Government in public interest through a gazette notification.

During the year 2013, following notifications under Section 26A were issued by the Government of India:

i. The manufacture for sale, sale and distribution of 'Dextropropoxyphene and formulations containing Dextropropoxyphene for human use' was suspended with immediate effect vide G.S.R. 332(E) dated 23.05.2013.

ii. The manufacture for sale, sale and distribution of 'Analgin and all formulations containing analgin for human use' was suspended with immediate effect vide G.S.R. 378(E) dated 18.06.2013.

iii. The manufacture for sale, sale and distribution of 'Fixed dose combination of flupenthixol + Melitracen for human use' was suspended with immediate effect vide G.S.R. 377(E) dated 18.06.2013.

iv. The manufacture for sale, sale and distribution of 'Pioglitazone and all formulations containing Pioglitazone for human use' was suspended with immediate effect vide G.S.R. 379(E) dated

18.06.2013. The matter was reviewed by the DTAB and it recommended that the suspension be revoked and the drug formulations allowed to be marketed subject to certain conditions. The Ministry of Health and Family Welfare had accordingly issued a revised Gazette notification G.S.R. 520(E) dated 31.07.2013 permitting the manufacture for sale, sale and distribution of Pioglitazone and all formulations containing Pioglitazone for human use subject to the conditions recommended by DTAB.

m) Good Distribution Practices for Pharmaceutical Products

The Guidelines on Good Distribution Practices for Pharmaceutical Products have been prepared by CDSCO. These guidelines have enumerated detailed procedures for organization and management, personnel, quality system, warehousing, temperature controls, transportation, documentation etc. including guidelines for recalls and returns. The draft guidelines are being finalized in consultation with the State Drug Control Authorities and other Stakeholders.

14.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

The Indian Pharmacopoeia Commission is poised to publish periodically the Indian Pharmacopoeia, the official and authentic book of standards. Its seventh edition of Indian Pharmacopoeia i.e. IP 2014 was released by Hon'ble Health & Family Welfare Minister, Government of India on 04/11/2013. The book will come into effect from 01/01/2014. The work of publishing the book was completed within the stipulated time schedule.

The Indian Pharmacopoeia Commission was successful in achieving the target of coming out with 300 Indian Pharmacopoeia Reference Substances (IPRS) and is on way to achieve the target of 400 IPRS by 31/03/2014. The Commission is striving vigorously for preparing, certifying and distributing Indian Pharmacopoeia Reference Standards which will go a long way to save valuable foreign currency which the Country is forced to incur on account of import of Reference Standards of life saving drugs. IPC for the first time has come out with IPRS Impurities, which in turn help in generating more revenue and save foreign currency.

The Commission intends to promote the use of generic drugs rationally. The work of publishing of the 5th edition of National Formulary of India, the book of reference, for the use of clinicians, pharmacists and nurses is under way in IP Commission. The Apex Body and Core Committees has been constituted and approved by the Ministry for bringing out the 5th edition of NFI. The Commission has procured high end scientific and technical instruments which are very essential to cope up with international parameters of efficiency, efficacy and quality of drugs.

The 2nd World Pharmacopoeia Summit was held in New Delhi on 18-19th April, 2013. The summit was attended by many pharmacopoeial bodies across the world.

The Pharmacovigilance Programme of India which was recasted to Indian Pharmacopoeia Commission by the Ministry from All India Institute of Medical Sciences, New Delhi have collected approximately 56,000 Adverse Drug Reactions (ADR) till date. Out of which 50,000 ADRs have been committed to UPPSALA, Monitoring Centre, Sweden. The Commission is in process of enhancing the number of Adverse Drug Reaction Monitoring Centres from 90 to 150. The Commission is briskly analysing and validating the Certificate of Analysis (COA) of new Drugs.

14.4 DRUG DE-ADDICTION PROGRAMME (DDAP)

The Constitution of India under Article 47 enjoins that the state shall endeavour to bring about prohibition of

the consumption of intoxication drinks and drugs, which are injurious to health. The activities to reduce the drug use related problems in the country could broadly be divided into two arms - supply reduction and demand reduction. The supply reduction activities which aim at reducing the availability of illicit drugs within the country come under the purview of the Narcotics Control Bureau under the Ministry of Home Affairs and the Department of Revenue as the administrator of the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988. The demand reduction activities focus upon awareness building, treatment and rehabilitation of drug using patients. These activities are run by the Ministry of Social Justice and Empowerment as the nodal Ministry and to some extent by the Ministry of Health and Family Welfare. The Ministry of Health & Family Welfare operates a limited Drug De-addiction Programme by providing financial grants for augmenting post abuse treatment facilities in select Central Government hospitals / institutions and the Government hospitals / institutions in North-East States. Under this programme, a National Nodal Centre, the "National Drug Dependence Treatment Centre (NDDTC), Ghaziabad (U.P.)", has been established under the All India Institute of Medical Sciences (AIIMS), New Delhi. The NDDTC receives regular annual recurring grants-in-aid from the Ministry. Other institutions receiving regular annual recurring financial assistance under this programme are Dr. Ram Manohar Lohia Hospital, New Delhi, Sucheta Kriplani Hospital, New Delhi, PGIMER, Chandigarh, JIPMER, Pondicherry and NIMHANS, Bangalore. The purpose of these centres is not only to provide de-addiction and rehabilitation services to the patients but also to conduct research and provide training to medical doctors in the area of drug de-addiction.

14.5 DRUG DE-ADDICTION & TREATMENT CENTRE, DEPARTMENT OF PSYCHIATRY, PGIMER, CHANDIGARH

Drug De-Addiction and Treatment Centre (DDTC), PGIMER, Chandigarh, established in 1988, has a 20 bedded inpatient section, an outpatient department and a community clinic at Kharar, Punjab. In 2013, an Urban Outreach Clinic has also been started in Manimajra, U.T. Chandigarh. At the Centre, nearly 11304 patients have been seen in walk-in and follow-up clinics and admitted around 226 patients. Counselling sessions were done to 12196 patients. Laboratory services were provided to 3872 patients. A total of 280 yoga sessions and 268 Art of Living sessions had also been provided to patients. In community clinics, around 22 camps were conducted and a total of 396 patients were seen. Various training programmes have also been initiated for various categories of professionals and para-professionals. A number of original pieces of research have been carried out in areas relevant to alcohol, drug abuse and dependence. Various research publications have come out from research conducted at the DDTC and published at reputed national and international scientific journals. Post-doctoral course i.e. DM in Addiction Psychiatry has also been approved and it is being started from January, 2014. It is first such course in the country which will create a newer cadre of de-addiction experts and specialists.

14.6 NATIONAL DRUG DEPENDENCE TREATMENT CENTRE (NDDTC), AIIMS, GHAZIABAD (U.P.)

The National Drug Dependence Treatment Centre (NDDTC) has continued to provide leadership in the management of drug dependence in the country by its multi-faceted activities through this year. The NDDTC has been in forefront in the country to develop models for treatment of drug dependence in the country. Opiate Substitution Therapy and Methadone Maintenance Treatment programme have got a major boost this year, with more and more centres in the country starting these treatment modalities for opiate drug dependence.

Besides providing clinical care at its Centre at Ghaziabad in its outpatient and inpatient services, it has strengthened its outreach services for the management of drug and alcohol dependence in the community through its outreach clinics at Sundar Nagari and Trilokpuri in Delhi. The number of new cases registering at all facilities has been increasing steadily, with more cases coming for follow-up and less number dropping out of treatment. To aid the clinical services, the Laboratory services at the

NDDTC provides timely and accurately the screening results of body fluids for detecting presence of abused drugs, and also the investigations like biochemical, haematological, and also HIV screening.

The Centre has been carrying out research with the priority aim of providing much needed solutions to find out cost-effective interventions that can help in establishing practising guidelines for other centres. This is being done through many funded and non-funded projects. The NDDTC has attracted funding for these research project from NID, ICMR, UNODC, NCPCR, NACO, GFATM and others.

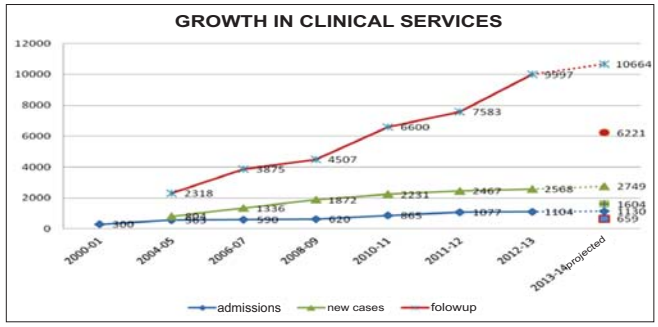
The NDDTC has continued to contribute towards capacity building of medical officers and other health professionals at the national level. It has also been playing a key role at the international level, by helping in capacity building in countries like Bhutan, Maldives, Bangladesh etc.

The NDDTC has been regularly publishing research articles in peer-reviewed journals of national and international repute. This year it also brought out 9 manuals for various substance abuse disorders for benefit of different levels of health workers. Its faculty members are involved in a number of national and international committees, taskforces, governmental and non-governmental agencies towards management and policy framework issues of substance abuse.

14.7 CENTRE FOR ADDICTION MEDICINE, NATIONAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES, BANGALORE

The Centre for Addiction Medicine (CAM), has completed more than two decades of clinical service, training and resource generation, research and advocacy in the area of addictive disorders.

The activities of the CAM were audited by the team from Voluntary Health Association of India as part of the Evaluation of the Drug DE addiction Programme under the Ministry of Health and Family Welfare.



**Plotted With Projected Scores For The Year 2013-14. Projection based on the growth in first 7 months of the year.*

A. Clinical Services

The CAM has registered 1609 new patients and 6221 patients in out-patient follow up over the period of 7 months from April to October 2013, during the review year 2013-14. 659 patients were admitted to the CAM in-patient ward during the above period for in-patient treatment. 118 of them were admitted in general psychiatry wards.

There is a comprehensive inpatient programme consisting of individual and family assessment, individually tailored treatments which involve pharmacological treatments for withdrawal and long term prevention of relapse, individual and group counseling, family counseling and intensive aftercare.

Impact of after care workers and tele-health facilities

Aftercare programme includes (a) measures for lapse management, including a novel and effective option for brief admission to prevent lapses converting to relapse; and (b) active tele-health and home-visit contacts run by the special cadre of after-care workers. These measures have been able to dramatically increase patient retention rates (from 21% to 69%) and rapid return to functioning after lapses.

Special Clinics:

a. The CAM runs a separate Opioid substitution Clinic for buprenorphine maintenance programme using international best practices.

b. The CAM has also integrated the tobacco cessation clinic along with drug de-addiction activities.

Expansion during the current year

In response to the growing public demand for patient care, public awareness, community activity, research and policy, several new initiatives have been initiated during the current year.

1. The 20 bedded in-patient facility for substance using women, the first of its kind in the country is almost complete and the services will be started from January 2014.

2. The drug-toxicology laboratory which tested more than 6000 samples for drugs and alcohol in urine and blood has had to add one more e-machine for testing samples to keep up with the growing demand. The lab has been receiving requests from outside agencies for tests to be done, since it is the only facility for such testing in the region.

3. The CAM conducted several research studies on behavioral addictions such as pathological gambling, internet and cell phone addiction and finding that the still under-recognised problem is quite common, has begun offering services for treatment of behavioral addictions.

4. The gym facility which was started during last year has received great response and is used by patients regularly.

5. Social workers who work in the community have been successful in educating the community regarding addiction and recovery and are providing preventive strategies for drug and alcohol related problems. Their main objective is:

    - Early recognition of substance users,
    - Offering treatment for the needy people,
    - Offering preventive counseling,
    - Community level education for addiction and high risk population.

They have communicated to around 2800-3000 people in Bhovi colony and around 2000-2500 people in Someshwara colony. They are coordinating with the corporate and private health services, school and education departments like anganwadi, nursery, primary and high schools, law enforcing services, religious institutions, NGOs, self-help groups and youth clubs.

The community team has identified more than 400 persons with substance use problems and have motivated them to avail treatment from the centre.

B. Training and Training-Resource Generation

Intramural Training: As in previous years post-graduate trainees in psychiatry, psychology, psychiatric social work, psychiatric nursing from the National Institute of Mental Health and Neurosciences, Bangalore received hands-on training in management of persons with addiction.

Extra-Mural Training:

a. Regional Technical Training Centre for the capacity building of Injecting Drug Users- Targeted Intervention staff of the Southern Region including the four southern states [Tamil Nadu, Kerala, Andhra and Karnataka] has been commissioned from October 2013.

b. Medical officers, Social Workers and Psychologists of the state of Himachal Pradesh, under the auspices of the National Rural Health Mission were trained in early recognition, assessment and management of addictive disorders. This is part of an ongoing process to facilitate management of alcohol, tobacco and other drug problems along with consultations for routine consultations for non-communicable disorders as well as set up specialized treatment facilities in each district of Himachal Pradesh.

c. During the year more than 55 post-graduate trainees from institutions across the country, across the disciplines of psychiatry, psychology, and psychiatric social work were posted for periods from 2 weeks to 3 months for specialized training in addiction management.

The following workshops and training activities were conducted at the CAM.

1. A one month orientation programme on Substance Abuse Management is being conducted during the month of November 2013. This programme is

conducted for both medical and non-medical personnel including lay counselors who are interested in substance abuse management. This year around 11 participants who have registered for the programme from across the country, along with 24 psychologists and social workers from Himachal Pradesh.

Figure 1: Orientation Programme on Substance Use Management

2. Medical Officers in the Southern District "National capacity building - Fourth training workshop of Training of doctors on substance use disorders was held between 17th to 30th July 2013 at NIMHANS, Bangalore. This activity has been funded by Department of Revenue, Ministry of Finance, Government of India.

3. Sixth training workshop for medical officers from Himachal Pradesh was conducted during 16th to 30th April 2013. This programme which was very well received has been appreciated and now a batch of 12 psychologists and 12 social workers from Himachal Pradesh are posted here for training.

4. The Tobacco Cessation (TCC) team have conducted more than 5 to 6 awareness programmes in the community during the year and also had a 2 day training programme for Dentists from different hospitals where more than 25 doctors were trained.

5. The CAM, TCC staff from NIMHANS conducted awareness programme under collaboration of Central Board of Workers Education. The topic was covered on tobacco related problems, behavioral counseling and treatment.

6. Technical session on "Tobacco Cessation" in the Karnataka state level consultation on ban on 'Tobacco Advertising Promotion and Sponsorship' (TAPS) on 05/07/2013.

7. Workshop "Tobacco related problem and its Intervention"on 24th and 25th September, 2013 at Centre for Addiction Medicine, NIMHANS.

a. Prof. Pratima Murthy and Prof. Vivek Benegal in their capacity as visiting professors at the Lokopriya Gopinath Bordoloi Regional Institute of Mental Health,Tezpur delivered 5 training lectures and conducted 2 skill workshops.

b. Faculty members from the CAM conducted training sessions and workshops as part of different Continuing Medical Education Programmes, in different regions of the country. Some important ones are listed below:

- Alcohol Control Measures at course on NCD Prevention and Control for Harvard School of Public Health Scholars and Lown Foundation Fellows. New Delhi (January, 2013).
- "Assessment in SUD" and "Management of Opioid Use Disorders" at NRHM- NIMHANS conducted training programme in February 2013.
- Invited talk on Counselling for Alcohol and Drug Addicts, RRTC South Zone II, sponsored by NC-DAP (National Centre for Drug Abuse Prevention), National Institute of Social Defence, Ministry of Social Justice and Empowerment, Govt of India, 13 April 2013, Bangalore.
- Two day workshop on Tobacco Cessation services for Dentists in September 2013.

Training Resources Created

A Treatment Providers manual for family based relapse prevention and a work-book for relapse management for persons seeking treatment for addictive disorders and their care-givers was published and is currently in routine use with in-patients at the CAM.

14.8 MEDICAL STORE ORGANIZATION (MSO)

Medical Stores Organisation under the Directorate General of Health Services is a century old Organisation.

Originally, it was created primarily to meet the need of Medical Stores of the troops and Military based Hospital and to hold reserves in the event of hostilities with other countries. In 1942, the Army authorities established their own depot and MSO came under civil administration of the central government. The Medical Stores consists of seven Medical Store Depots located at Mumbai, Kolkata, Chennai, Hyderabad, Guwahati, Karnal and New Delhi. The main function of Medical Store Organisation is to procure store and supply of quality medicines to its indenters at a competitive price through its seven GMSDs located at various places.

The Depots at Mumbai, Chennai and Kolkata have Quality Control Laboratories attached to them for quality testing before dispatch of medicines to the indenters.

The MSO operates through two formularies, one for proprietary/branded drugs and other for generic drugs. During 2013-14 it has undertaken rate contract for 514 branded drugs and 157 generic drugs. As per the indents made by its about 1800 indenters, it supplied medicine to them. An exhaustive new formulary consisting of 1447 Generic drugs has been finalized.

The Medical Stores Depot had arranged immediate medical relief supply of ORS, and other essential lifesaving medicines for flood affected areas of the States of Uttarakhand and cyclone affected area of Odisha during 2013-14. The medical store depots also arranged 196350 doses of quadrivalent meningococcal meningitis vaccine and 13899 doses of influenza vaccine for Haj Pilgrims during 2013-14.

To bring transparency and accountably in the working of MSO online programme has been developed by NIC. Procurement and supply of proprietary & generic drugs for all the indenters is being done online.

GMSD, Karnal, Mumbai, Chennai and Kolkata are having cold chain facilities and handling storage & distribution of vaccines. It has been decided to improve and modernize cold chain facilities in all existing seven GMSDs so that the storage and distribution of vaccine can be undertaken more effectively.

The GMSDs are also storing and distributing the material for National Programme like T.B Programme, Family Welfare Programme etc. & necessary provision of enhancing their storing capacity for the store relating to these National Programme is being carried out by GMSDs.