14
Chapter

QUALITY CONTROL IN FOOD & DRUG SECTOR, MEDICAL STORES

14.1 FOOD SAFETY & STANDARD AUTHORITY OF INDIA (FSSAI)

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. Ensuring the safety and quality of food for the citizens is imperative. A comprehensive, consolidated Food Safety and Standards Act, aligned with the global practices, was the first step towards achieving this objective. The Food Safety and Standards Authority of India is making continuous efforts for effective implementation of the FSS Act.

14.1.1 Activities of the FSSAI

1. Enforcement

Regulation of Food Safety in States: FSS Act, 2006 has been operationalized in India since 5th August, 2011. Central Licensing has been started from five regional offices (Chennai, Delhi, Kolkata, Mumbai and Guwahati) and two sub-regional offices (Chandigarh and Lucknow) of the Authority. All the States/UTs have appointed Food Safety Commissioners, notified Designated Officers, Adjudicating Officers and Food Safety Officers for respective areas within the State. A total of 17,465 licenses were issued by Central Licensing Authority and 5,29,426 licenses by the States/UTs till 12.11.2014. Further, a total of 23,09,055 Food Business Operators (FBOs) have been registered in the system by the States/UTs Governments. The FSSAI has held 12 meetings of the Central Advisory Committee till date wherein the representatives from States/UTs participated and discussed their issues.

2. Codex

2.1 The Codex Contact Point of India i.e. National Codex Contact Point (NCCP) is set up at Food Safety and Standards Authority of India (FSSAI). The NCCP of every Country coordinates with the Codex Secretariat for all the matters related to Codex Alimentarius.

2.2 **Participation in various committee meetings and submission of comments on time:** The Food Authority and the concerned Ministries/Departments have actively participated in the following Codex

Committee Meetings held during April 2014 to November 2014:

SN	CODEX Committee	Dates
1	8th Session of Codex Committee on Contaminants in Foods (CCCF)	31st March, 2014 to 4th April, 2014 in The Hague, Netherlands
2	28th Session of Codex Committee on General Principles (CCGP)	7th to 11th April, 2014 in Paris, France
3	46th Session of Codex Committee on Pesticide Residues (CCPR)	5th to 10th May, 2014 in Nanjing, China
4	37th Session of Codex Alimentarius Commission (CAC)	14th to 18th July, 2014 in Geneva, Switzerland
5	21st Session of Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)	13th to 17th October, 2014 in Brisbane, Australia
6	42nd Session of Codex Committee on Food Labelling (CCFL)	21st to 24th October, 2014 in Rome, Italy
7	19th Session of FAO/WHO Coordinating Committee for Asia (CCASIA)	3rd to 7th November, 2014 in Tokyo, Japan
8	46th Session of Codex Committee on Food Hygiene (CCFH)	17th to 21st November, 2014 in Lima, Peru Hygiene

2.3 Submission of new work proposals: India has submitted two new work proposals on the following items:

- Labelling Standard for Non-Retail Containers in Codex Committee on Food Labelling (CCFL) and
- Establishment of Maximum Levels for Aflatoxins in Spices (CCCF).

2.4 Participation in Electronic Working Groups (eWGs)

India has participated in 38 Electronic Working Groups (eWGs) and significant comments were submitted in the eWGs. India was also the leader of 08 eWGs.

2.5 Workshops in the country

In an effort to bring in more stakeholders into the Codex fold, FSSAI conducted the third workshop in the series on the theme of '***Codex Alimentarius: Principles and Procedures***' in collaboration with the Institute of Chemical Technology (ICT) on 12th September, 2014 at Institute of Chemical Technology (ICT), Mumbai. The workshop was inaugurated by Shri K. Chandramouli, Chairperson, FSSAI.

2.6 India as the Regional Coordinator of FAO/WHO Coordinating Committee for Asia (CCASIA)

- The Coordinating Committee for Asia (CCASIA) was established at the 11th Session of the Codex Alimentarius Commission

(CAC) held in Rome, Italy, in July 1976 and has 23 Asian Member countries as of 2014. Main objective of CCASIA is to promote mutual communication among the Asian members and CCASIA has been working under the purpose of the Codex Alimentarius of protecting the health of the consumers and ensuring fair practices in the food trade since its beginning in 1978.

- At the 19th Session of CCASIA, on the proposal of the Delegation of Indonesia, the Coordinating Committee of Asia unanimously agreed to recommend to the 38th Session of Codex Alimentarius Commission that India be appointed as Coordinator of Asia. All the members supported the proposal of the Committee. As a result, India would occupy the position of Regional Coordinator from July 2015 onwards for a period of three years.

3. Standards

3.1 Scientific Panel on Functional Foods, Nutraceuticals, Dietetics Products and other similar products

- FSSAI has constituted a Scientific Committee and Nine Scientific Panels, comprising of independent scientific experts for providing scientific opinion on various issues, in terms of the provisions conatined in Section 14(1) and 13(1) of the FSS Act. The FSSAI has successfully organized several meetings of Scientific Committee and all the Scientific Panels in which various scientific opinions and several food standards have been developed.
- During the period April 2014 to November 2014, the Nutraceuticals Panel conducted 3 meetings and 5 meetings of the working groups.

4. Laboratory

- As per Section 43(1) of the Act, 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. As on 03.12.2014, 68 laboratories have been notified by FSSAI. Further, FSSAI framed a procedure in respect to inviting applications for Recognition/ Authorization/Notification of NABL Accredited Food Testing Laboratories for analysis of samples under the FSSAI. The scrutiny of received applications has been completed and a few MoUs signed and activity for renewal is ongoing. A few parameters for the testing of all food articles have also been compiled.
- The Individual lab reports, State Reports and National Report related to the baseline assessment of the State/Public Laboratories have been compiled by the three-member expert committee. The Lab Reports and State Reports were sent to the personnel of individual labs and all Food Safety Commissioners respectively.
- As per sub-section (2) of section 43 of FSS Act, 2006, the Food Authority is required to establish or recognise by notification, one or more referral food laboratory or laboratories to carry out the functions entrusted to the referral food laboratory by this Act or any rules and regulations made thereunder. A total of 11 referral laboratories have been authorised by FSSAI.

5. **Surveillance**

- As per recommendations of 11th CAC meeting held on 7th March, 2014, a working group comprising of Food Safety Commissioners (FSCs) of Assam, Goa, Maharashtra, Tamil Nadu and UP has been constituted on 26th March, 2014 to finalize Standard Operating Procedure (SOP) and a structured programme of surveillance.
- The first meeting of the Working Group was held on 9th April, 2014 for suggesting a structured programme of surveillance activities including SOPs. The second meeting of working group was held on 4th July, 2014 for the finalization of SOPs for Surveillance. Draft Surveillance plan was prepared by the working group and circulated to all the Food Safety Commissioners of States to conduct surveillance activities in their States. State FSCs have been instructed to conduct Surveillance on seasonal fruits and vegetables, fats & oils, dairy products, ready to drink juice etc. and festive food commodities in their respective States.
- 2014-15 has also been declared as the year of surveillance.

6. **Information, Education and Communication (IEC)**

- Information, Education and Communication (IEC) combines strategies and approaches that enable the organisations, communities and stakeholders to play key roles in achieving and sustaining their defined goals. There are various means of communications using print media, social media tools, digital media, audio-video visuals, mass contact awareness programme, outdoor publicity, Official website etc. through which the stakeholders may be informed and educated about the various aspects of food safety.
- IEC activities carried out during 2014-2015 are as follows:
  - An MoU (Memorandum of Understanding) for undertaking Mass Contact Activation Programme on food safety in 08 districts of Uttar Pradesh on behalf of FSSAI has been signed with the State Institute of Rural Development (SIRD), Lucknow.
  - FSSAI has started a joint awareness campaign with the Department of Consumer Affairs under the aegis of "Jago Grahak Jago" and first creative under this campaign was released vide print media in November, 2014
  - FSSAI has its Facebook page wherein the general tips related to food safety are being provided on a regular basis in order to make stakeholders aware about the importance of safe food.
  - 1st edition of FSSAI bi-monthly e-newsletter has been published in November-2014.
  - FSSAI participated in the India International Trade Fair-2014 by putting up a stall wherein various posters displayed and IEC materials on registration, licensing, Import, food product approval system, food safety at home, food safety for children, adulteration of food products and method of its detection etc. were distributed as well as the queries of the stakeholders were also addressed on the spot.
  - Radio jingles on labelling of food were aired PAN India w.e.f. 13th November, 2014 for a period of 15 days to coincide with FSSAI's participation in India International Trade Fair-2014.
  - FSSAI has a dedicated and well maintained website i.e. www.fssai.gov.in, wherein the FSS Act/Rules/Regulations along with other articles, Advisories, Notifications etc. are available and it is

updated on regular basis as and when required.

7. Training

- As per section 30(2)(c) of FSSA, 2006, it is the responsibility of the States/UTs to organise/conduct training programmes for food safety regulators. The Authority supports these programmes by providing funds, faculties (Resource Person) and training material.

8. Harmonization of Indian Standards with Codex and other International Best Practices:

- It is the responsibility of FSSAI under the Food Safety and Standards Act, 2006 and the FSS Regulations of 2011 to frame standards for food products and for food safety and to monitor their implementation in the country. Several standards have been notified and more are required to be framed and notified. However, there is an on-going demand for review of these standards taking into account the latest developments in food science, food consumption pattern, new specifications, presence of new contaminants and toxins as well as use of new food additives and ingredients required by the producers and manufacturers. In light of this, it was considered appropriate to review India's standards and harmonise them with the Codex Alimentarius standards and other international best practices to the extent possible.
- Currently, three organisations i.e., FSSAI (mandatory standards) and BIS & AGMARK (voluntary standards) are working in collaboration for reviewing and formulating food product standards.

9. Capacity Building Initiative for Trade Development in India (CITD): Food Safety & SPS, Technical Regulations & Standardization & Support to Post Clearance Audit (PCA) in Customs.

- The overall objective is to support India in strengthening its capacity to achieve economic growth and sustainable development, through further integration into the global trading system, by increasing the safety and quality of products, and by reducing costs and impediments to trade. Training of 18 Designated Officers and Food Safety Officers of western zone States has been conducted in west Zone (Pune) from 20-23 May, 2014 in auditing HACCP, GHP and GMP. 2nd training has been held from November 25-28, 2014 in Bengaluru for Southern Zone.

10. Imports

- As per section 25 of the Food Safety & Standard Act, 2006, all imports of articles of food are subject to the provisions of the Act. It stipulates that no person shall import any article of food into India 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 articles 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. As per the test reports from the lab, the food safety aspect of the imported consignment is ensured.
- FSSAI has successfully operationalized the imported food clearance process in a phased manner since August-September 2010 through appointment of Authorized officers in terms of section 47(5) of the FSS Act, 2006 at 16 points

of entry at Delhi, Mumbai, Chennai, Kolkata and Cochin Ports (including sea, air and land).

- The data regarding the number of samples drawn & NOCs issued for the period December 2013 to October 2014 is given in the enclosed Table-1. It is informed that a total of 46,527 consignments, containing 7.087 million kilograms of imported food products have been handled by FSSAI in the year 2014 till date. In the process, 519 consignments (1.1%), weighing 4208.21 kgs of food have been issued non-conforming certificates/ rejected.
- The FSSAI is proposing to expand its presence at more sea-ports i.e. Tuticorin, Kandla, Mundra, Kakinada and Vizag during 2015-16. It is proposed to integrate FICS with Icegate (Custom Clearance System) to provide single window clearance facility to the importers. FSSAI also proposes to introduce Food Import Prioritization System (FIPS) in the near future to cut short the time taken in import clearances at ports. Strengthening of lab infrastructure has also been planned which is expected to further help in expediting the custom clearances.

Table 1: Data of Food Import Clearance for the period December 2013 to October 2014

Location	Port	Number of Consignments	Quantity (Kgs)	Number of Non-Conforming Certificates (NCC) Issued	Quantity belonging to NCC Issued (Kgs)	Number of consignments Cleared	Quantity cleared (Kgs)
Chennai	Seaport	11254	1491922	46	918 (0.06%)	12096	1491004 (99.94%)
	Airport	186	162.23	7	1.74 (1.07%)	229	160.49 (98.93%)
Mumbai	JNPT Seaport	26000	3130534	304	2193.36 (0.07%)	44440	3128341 (99.93%)
	Seaport	158	816943	15	56.52 (0.01%)	592	816886.5 (99.99%)
	Airport	2053	1760	50	24.15 (1.37%)	3690	1735.85 (98.63%)
Kolkata	Seaport	4222	1064456	6	89.24 (0.01%)	3739	1064367 (99.99%)
	Airport	30	4.532	0	0 (0%)	18	4.532 (100%)
Haldia	Seaport	400	533473	0	0 (0%)	354	533473 (100%)
Delhi	ICD	389	6425	39	243.862 (3.80%)	1125	6181.138 (96.20%)
	Airport	1006	1982.7	12	6.904 (0.35%)	3472	1975.796 (99.65%)
Cochin	Seaport	795	39652	40	923.55 (2.33%)	1241	38728.45 (97.67%)
	Airport	34	11.3	0	1.65 (14.60%)	48	9.65 (85.40%)
Total		**46527**	**7087325.762**	**519**	**4208.21 (0.06%)**	**71044**	**7083118 (99.94%)**

14.2 CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

The Central Drugs Standard Control Organization (CDSCO) headed by the Drugs Controller General (India) is the Central Authority for regulating the quality of drugs marketed in the country under the Drugs and Cosmetics Act, 1940. The regulatory control over 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. However, the manufacture, sale and distribution of drugs in the country is 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) is 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 situated at Food and Drug Bhawan, Kotla Road, New Delhi. CDSCO under its control has six Zonal offices at Mumbai, Ghaziabad, Kolkata, Chennai, Ahmadabad and Hyderabad, three Sub-Zonal offices at Bengaluru, Chandigarh and Jammu and Port Offices situated at notified port of entries 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), Bengaluru (Air Port), Goa (Sea and Air Port). Apart from these, there are seven 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.

Other labs which are notified as Central Drugs Laboratories include the National Institute of Biologicals, Noida, for testing blood grouping reagents and certain diagnostic devices, Homeopathic Pharmacopoiea Laboratory, Ghaziabad for testing homeopathic medicines and Indian Veterinary Research Institute, Izzatnagar for testing 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 sections. 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 of CDSCO

CDSCO head-quarters:

- Grant of approval for manufacture and/or import new drugs and for conduct of clinical trials in the country;
- Approval of the licenses to manufacture certain categories of drugs as Central License Approving Authority (CLAA) for I V Fluids,

Large Volume Parenterals, Vaccine & Sera, Blood & Blood Products, r-DNA products (Biotech Products) etc.;

- Registration of foreign manufacturers of drugs and medical devices whose products are to be imported into the country and grant of licences to import drugs and medical devices;
- 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;
- Meetings of Drugs Technical Advisory Board (DTAB) to discuss matters arising of the administration of the Act and recommended amendments to the Drugs and Cosmetics Rules, 1945;
- Meetings of the Drugs Consultative Committee (DCC) to secure uniformity throughout (India) in the administration of this Act;
- Recommend banning of drugs considered harmful or sub-therapeutic under section 26A Drugs and Cosmetics Act, 1940;
- Conducting workshops and training programmes on various topics related to quality control of drugs and
- Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use.

Zonal/Sub-Zonal Offices

- The grant of test licences in Form 11 of the Drugs and Cosmetics Rules, 1945 for import of small quantities of drugs for examination, test or analysis except for clinical trials;
- Inspection of manufacturing premises jointly with State Governments for drugs covered under the CLAA Scheme 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;
- 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 and
- Launching of prosecutions in cases detected by the Zonal offices.

Airport & Seaport Offices

Monitoring of drugs, notified medical devices and cosmetics imported into the country through the scrutiny of the Bill of Entry, etc. and drawing of samples on random basis to check their quality and render advice to the concerned custom authorities. The Shipping bills of drugs exported from the country are also examined as required by the customs authorities.

Strengthening of CDSCO

In view of the wide range of the responsibilities, increased expectations of the stakeholders and above all the need to ensure availability of quality medicines in the country, CDSCO is being progressively strengthened to enable it to discharge its responsibilities effectively. The sanctioned strength of 111 posts in 2008 has been increased to 474 by 2014. At present it has 220 regular officers in

position. The vacant posts are being filled through UPSC/SSC. 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. A pharmacologist has been appointed as new drugs consultant to assist in processing of applications of new drugs and clinical trials.

Training/Workshops conducted by CDSCO with WHO support in the country

Thirty six training programmes/workshops on the following subject related to the drug control were held during the period for updating the information and sharpening of the skills of the concerned officials working in CDSCO. Some of such workshops conducted are mentioned below.

- Training courses for newly recruited Drugs Inspectors of CDSCO and States in GMP Regulatory Inspections;
- Workshop on harmonization of provisions relating to clinical trials under Schedule Y of the Drugs and Cosmetics Rules, 1945, ICMR guidelines and GCP guidelines on ethical issues;
- Workshop on "Lead Auditor Course" on Quality Management System as per IS/ISO 9001:2008;
- Training on review of Periodic Safety Updation Report (PSUR) as Post Marketing Surveillance of new drugs permitted for marketing in the country;
- Workshops on Ethical Issues during the conduct of clinical trial;
- Training On Design Review of Clinical Trial Protocol and Role of Bio-staticians;
- Workshop for GMP strengthening;
- Workshops on Review Procedure adopted for evaluation of New Drug Application, BA/BE Study and Marketing Permission and
- Workshop on Good Clinical Practices (GCP) Inspection Training.

Regulatory Activities at the CDSCO Headquarters

a) Quality Control over import of drugs

The CDSCO regulates the quality of drugs imported into 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 manufacturers 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 2014-15 (upto 31st October, 2014), the office of Drug Controller General (India) granted 152 Registration Certificates in respect of manufacturers of drugs who intend to export their products to India. During the same period, 1598 licences in Form 10 for import of such 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(I) granted 9344 test licences for the import of drugs in small quantities for test and analysis during the year 2014-15 (upto 31st October, 2014).

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 34 Registration Certificates and 28 endorsements on the existing registration certificates during the year 2014-15 (upto 31st October, 2014).

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 2014-15 (upto 31st October, 2014), the office of DCG(I) granted 197 Registration Certificates to the manufacturers of the Medical Devices who intended to export their medical devices to India while 268 licences in Form 10 for import of medical devices into the country were granted during the same period. In respect of diagnostic reagents, in 19 cases registration certificates and endorsements were issued. As many as 279 approvals in Form 10 for the import of diagnostics devices 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 2014-15 (upto 31st October, 2014), the office of DCG(I) granted CLAA approval in 74 cases 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. The applications are examined in consultation with the New Drug Advisory Committees constituted for the purpose.

During the year 2014-15 (upto 31st October, 2014), approvals were granted for eight new drugs. Subsequent permissions for manufacturing and marketing in the case of recombinant DNA products were granted in eight cases and permission for import and marketing were granted in the same period in five cases.

Vaccines are considered as new drug unless certified otherwise by the DCG(I). During the year 2014-15 (upto 31st October, 2014), permission to manufacture Oral Rotavirus vaccine with new indigenous strain and Trivalent seasonal flue live attenuated vaccine was granted. Further, 11 fresh licenses and 5 endorsements on the existing manufacturing licences were also granted. India was certified as Polio free country on 27.03.2014 which reflects the continued efforts of Indian National Regulatory Authority to provide safe and efficacious Polio vaccine.

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(I).

Under the present procedure the applications for clinical trials are examined by the Technical Committee headed by the Director General of Health Services and Apex Committee headed by the Secretary, Department of Health and Family Welfare before the permission to conduct clinical trial in the country is granted. During the year 2014-15 (upto 31st October, 2014), the office of DCG (I) granted no objections for conduct of clinical trials on new drugs in 19 cases and for recombinant DNA products permissions were granted in 17 cases.

Permissions are also granted for the conduct bio-equivalence studies on drugs in chemically equivalent drug formulations to study whether they produce identical therapeutic response in patients or not.

f) Blood Banks

Licences for the Blood Banks are also granted by the office of DCG(I) as Central Licensing Approving Authority. During the year 2014-15 (upto 31st October, 2014), fresh licences were granted in 111 cases while endorsement of blood components on the existing licences were issued in 53 cases and approval of renewal certificates were issued in 75 cases.

Achievements and Initiatives taken in 2014-15

i) Strengthening of Drug Regulatory System in the country under 12th Five Year Plan

In the 12th Five Year Plan, it has been proposed that Drug Regulatory mechanism in terms of infrastructure, both physical and human resources at the Centre and the State are strengthened. Initially, it was proposed to seek sanctioned of Rs. 1800 crores for strengthening of CDSCO and Rs. 1200 crores for strengthening of State Drug Regulatory System. However, in the revised outlay the scheme has been modified and an outlay of Rs. 1058.68 crores has been proposed, which is considered absolutely essential for effective functioning of the Central Drug Regulatory System.

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.

ii) Prof. Ranjit Roy Chaudhury Expert Committee

An Expert Committee was constituted by the Ministry of Health and Family Welfare under the Chairmanship of Prof. Ranjit Roy Chaudhury to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The committee in its report has 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 include 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. Majority of the recommendations have been accepted by the Government and actions initiated. These measures will ensure that the data generated in the clinical trials is authentic while the rights of human subjects participating in the trial are well protected.

iii) Quality assurance and patient safety

In the 47th meeting of the Drugs Consultative Committee meeting held in July, 2014 it was

decided that inspections of drug manufacturing units will be exhaustive and for both Good Manufacturing Practices (GMPs) as well as Good Laboratory Practices (GLPs) to ensure quality production of Drugs in the country.

It was also decided that State Drugs Controllers should focus on patient safety and rules should be implemented in such a way that it is ensured that safe and efficacious drugs are made available to the patients. Further, in the special DCC meeting held on 27.10.2014 it has been resolved that the States/UTs Drug Regulatory Authorities will also have mission and vision adopted by the CDSCO earlier. The mission is as under:

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

iv) National Survey on to assess the prevalence of spurious substandard drugs

An All India Survey is proposed to be conducted in the country with the methodology as suggested 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 including 15 therapeutic categories of drugs as listed in National List of Essential Medicines (NLEM), 2011. 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.

v) 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 medicines 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 Secretary, HR & DG, ICMR for updating the NLEM, 2011. The committee has met three times and has prepared guidelines for revision of NLEM, 2011. Consultations are in progress for the purpose of finalization revision of NLEM.

vi) Fixed Dose Combinations

There were reports that certain Fixed Dose Combinations (FDCs) of drugs were licensed by the State Licensing Authorities (SLA) without due approval of DCG(I) as required under the Drugs and Cosmetics Rules, 1945. The SLAs were requested by DCG(I) on 15.01.2013 to ask the manufacturers about such formulations to submit the data of safety and efficacy to the office of DCG(I) within 18 months. Office of DCG(I) has 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.

vii) Banning of drugs

Drugs about which reports are received that they 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) Restriction of sale of Oxytocin bulk to licensed manufacturers only and sale of vet. Oxytocin injection to veterinary hospitals only (GSR 29(E) dated 17.01.2014).

d) Analgin and all formulations containing analgin for human use to be marketed for restricted indications only (GSR 86(E) dated 13.02.2014).

viii) Prohibition of Testing of cosmetics on animals

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

ix) 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.

x) Strengthening of Central Drug Testing Laboratories

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

xi) Drugs Technical Advisory Board (DTAB)

Drugs Technical Advisory Board (DTAB) is a statutory body to advise the Central Government on technical matters arising out of the administration of the Drugs and Cosmetics Act, 1940. The term of the elected and nominated members expired on 07.04.2014 and the Board is being reconstituted.

The 67th meeting of DTAB was held on 01.04.2014 prior to the expiry of the term of elected and nominated members.

xii) Drugs Consultative Committee (DCC)

Drugs Consultative Committee (DCC) is statutory committee consisting of Central and State Drugs Controllers to discuss matters relating to uniform implementation of the Drugs and Cosmetics Act, 1940. The following two meetings of DCC had taken placed during the period.

a) 47th meeting of DCC was held on 30th & 31st July, 2014.

b) A special meeting of DCC was held on 27th October. 2014.

14.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

The Indian Pharmacopoeia Commission is mandated to publish periodically the Indian Pharmacopoeia, the official and authentic book of standards. IP Addendum-2015 to IP-2014 has been released on 28.11.2014 by Secretary, Health & Family Welfare and Chairman, India Pharmacopoeia Commission. The book will be effective from 31st March, 2015. The IP Addendum-2015 to IP-2014 is published in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of this pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines. To meet the expectations of the stakeholders, the Commission is working and the accomplishments are rolling out satisfactorily such as Addendum 2015 to IP 2014 has taken care of amendments to IP 2014 and has also incorporated 82 new monographs including 57 new chemical

monographs, 13 herbal monographs, 02 vaccines monographs and 10 radiopharmaceutical monograph. Besides these achievements, Add 2015 also includes 29 revised tests, 20 IR Spectra, 08 herbal TLC Chromatograph, 413 phyto pharmaceutical HPLC Chromatogram.

Indian Pharmacopoeia Reference Substances (IPRS)

The Indian Pharmacopoeia Commission has developed 406 IPRS including 10 Impurities upto 31/10/2014 and is poised to achieve and develop another 44 by the end of the current financial year. IPC is in the process of 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 IPC has been bestowed with the responsibility of verification of new drug molecules by CDSCO and the Commission has successfully verified 347 molecules and 100 molecules are under verification.

The Commission has successfully organized Induction Course for Drug Inspectors of CDSCO w.e.f. 15th July, 2013 to 02nd August, 2013 and 2nd September, 2013 to 20th Sept., 2013. The Commission conducted Training Programme on various Analytical instruments and Techniques for Government Drug Analyst w.e.f. 30th June, 2014 to 11th July, 2014 and 27th August, 2014 to 29th August, 2014.

National Formulary of India (NFI)

The Commission intends to bring out the 5th edition of NFI in the year 2015. The comments on pre-print version have been received and the final printing is underway.

Pharmacovigilance Programme of India (PvPI)

- India will be hosting the 'International Pharmacovigilance National Centres Meeting 2015' at New Delhi. It's expected that individuals from 130 countries to participate and discuss about the promoting global patients safety.
- An MoU was signed between Indian Pharmacopoeia Commission and National AIDS Control Organization to monitor the safety of antiretroviral medicines on 15th September 2014 at New Delhi in the presence of Additional Secretary and DG (CGHS), Ministry of Health & Family Welfare.

  In the first phase, 30 Antiretroviral Therapy Centres identified and training provided to them on 19th- 23rd January, 2015 which would be scaled up in a phased manner in 2015.
- NCC introduced 'ADRs reporting form for patients' (blue form) on 1st August, 2014 during the first national level meeting on 'participation of consumers in Pharmacovigilance Programme of India at IPC, Ghaziabad.
- PvPI guidance document was released on 30th July 2014 during the 47th DCC meeting by Secretary (Health), MoHFW.

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 hospital/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 grant-in-aid from the Ministry. Other institutions receiving regular annual recurring financial assistance under this programme are PGIMER, Chandigarh and NIMHANS, Bengaluru. The purpose of these centres is not only to provide de-addition 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 NATIONAL DRUG DEPENDENCE TREATMENT CENTRE (NDDTC), ALL INDIA INSTITUTE OF MEDICAL SCIENCES, GHAZIABAD

The National Drug Dependence Treatment Centre, attached to the All India Institute of Medical Sciences, functions as a national resource centre for Ministry of Health and Family Welfare, Government of India, Ministry of Social Justice and Empowerment, National AIDS Control Organization, United Nations Office on Drugs and Crime (UNODC) Regional Office for South Asia, WHO (India) and WHO SEARO. Recognizing the role and leadership that the centre enjoys nationally and internationally, the centre has been declared as the WHO Collaborating Centre on substance use disorders (WHO-IND95) in the year 2011. It has also been designated as a Regional Learning centre by UNODC and Regional Technical Training Centre by Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Round 9.

The Centre is 50 bedded and offers clinical care through out-patient, in-patient services for drug dependent persons and runs three specialty clinics- Tobacco Use Cessation, Adolescent Drug Use and Dual Diagnosis (patients having problems of Substance Use Disorder and Psychiatric Illness) clinics. These patients along with women drug users are admitted to the ward in special sections. Presently, the centre operates two community based clinics in two urban slums, Trilokpuri and SundarNagri in East Delhi.

Various treatment modalities are being used in the Centre and include medical interventions, group and individual psychotherapy sessions and family counselling. Efforts have been made to shorten hospital stay, encourage brief therapies, improve treatment adherence through supervised long-term medication distribution over flexible and extended hours. This enables the patients to remain in the treatment programme and attend to their jobs and report to the hospital without missing work. The choice of pharmacotherapy i.e. long-term medicines for free distribution has also been widened.

During the Year 2013-14, a total of 72722 patients were seen in out-patient, of whom 4299 were new and 27385 were old cases of whom 971 persons were admitted in the ward and 41038 were seen in various community clinics.

Eight Capacity building exercises for non-specialist medical doctors working in district hospitals on `Management of Substance Abuse and Dependence' were coordinated and conducted by the centre in six institutions in the country. Trainings of health professionals from Bhutan, Nepal, Bangladesh were carried out. The Centre is also conducting trainings for several categories of professionals like Medical Doctors, Nurses, Programme Managers, Counsellors, Data managers, NGO staff providing `Opioid Substitution Treatment (OST)'. Centre faculty was a resource person for conducting survey of Drug abuse in Maldives, formulation of National Policy on Alcohol under the aegis of Ministry of Social Justice & Empowerment, as well as a temporary Regional Adviser of WHO. The centre faculty acted as a resource person in various training programmes conducted by other organizations viz. National AIDS Control Organisation (NACO); Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), CHILDLINE, India etc.

The faculty were invited as speakers by various national and international organisations and presented papers in national and international Meetings/Conferences. The Faculty has 33 publications in reputed journals, 45 presentations as invited speakers at various forums, wrote 8 chapters for books and edited 17 books. Special mention may be made of the official release of 9 manuals/books in the field of substance abuse management to be used as resource material in training courses. NDDTC continued work on 14 collaborative research projects, of which 2 received international funding. The first nation-wide study of school going/out of school/street children to provide information on extent and pattern of drug use in children across 135 cities/towns in India was completed by the centre.

The centre provided inputs for the national policy being framed by the Ministry of Social Justice and Empowerment. Further, inputs were provided to the Ministry of Finance for modifications in the NDPS policy. The Faculty have contributed on important policy planning issues as members of Expert Committee to develop national drug de-addiction services, National Master Plan for drug abuse control, National working group on building technical capacity etc. The faculty also contributed as experts in the Technical Resource Group on Injecting Drug Users (IDU) of NACO and Expert committee formed by National Commission for Protection of Child Rights (NCPCR) on Drug use in Children.

NDDTC continues to conduct the Drug abuse Monitoring System (DAMS) exercise under which data on pattern and profile of new treatment seekers at 122 De-addiction centres is collected and collated.

The Ministry of Health and Family Welfare has embarked, under the aegis of DDAP, strengthening of the De-addiction Centres (DAC) across the country. There are a total of such 122 centres, however, many of them are not functioning to the desired level. It has been proposed to increase the budget of the 3 regional centres, including NDDTC, so that with the enhanced budget, pilot project could be started to strengthen 45 DACs up to 2016-17 and make them functional in a way that these are able to provide comprehensive care to the people affected by the substance and drug use disorders.

14.6 DRUG DE-ADDICTION AND TREATMENT CENTRE, DEPARTMENT OF PSYCHIATRY, PGIMER, CHANDIGARH

Drug De-Addiction and Treatment Centre (DDTC), PGIMER, Chandigarh was established in 1988. At present it has a 20 bedded inpatient section, outpatient Department and a community clinic at Kharar, Punjab. In 2014, an Urban Outreach Clinic was also started in Manimajra, U.T. Chandigarh. In DDTC, during 2014-15, nearly 12000 new and follow up patients were seen in the outpatient

Service and 300 patients admitted to the ward. Counselling sessions were held with nearly 13000 patients. Laboratory services were provided to 4000 patients. A total of 350 yoga sessions and 319 art of living sessions had also been provided to patients. In community services around 30 camps were conducted and a total of 500 patients were seen. Various training programmes have also been initiated to 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. About 20 research publications have come out from research conducted at DDTC and published in reputed national and international scientific journals. Postdoctoral course i.e. DM in Addiction Psychiatry has also been approved. It will be first such course in the country to create a new cadre of de-addiction specialists.

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

The Centre for Addiction Medicine (CAM) at NIMHANS, Bengaluru, has expanded itself in the current year with adding 5 more rooms [2 deluxe + 3 single rooms] to the existing 57 bedded male ward and has also started its women's addiction ward from August 2014. The CAM has registered 2712 new patients, 10292 patients in out-patient follow up and 6074 phone calls follow up made during the period April 2014 to January 2015. 891 patients were admitted to the CAM in-patient ward during the above period for inpatient treatment. There is a comprehensive inpatient treatment 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.

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.

- The 20 bedded inpatient facilities for substance-using women, was inaugurated on 16th August 2014;
- The drug-toxicology laboratory which tests 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;
- The CAM conducted several research studies on behavioural 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;
- 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. They have conducted awareness programmesat PHCs and Anganwadi Centers throughout Bengaluru. Awareness programmes on alcohol and substance use for youth and also for family members of patients were carried out.
- The Centre for Addiction Medicine, TCC staff from NIMHANS conducted several awareness programme in collaboration with the Central Board of Workers Education, on tobacco related problems, behavioural counselling and treatment.

Treatment

There is a comprehensive inpatient programme consisting of individual therapy, group counseling, family counseling and aftercare. The Centre is actively carrying out a buprenorphine maintenance programme which is in the process of evaluation.

Training

As done in the previous years, post-graduate trainees in psychiatry, psychology, psychiatric social work, psychiatric nursing etc. from the National Institute of Mental Health and Neuro Sciences, Bengaluru received hands-on training in management of persons with addiction. A Training Workshop on national capacity building training of doctors on substance use disorders in South Zone was held in March 2014, at NIMHANS, Bengaluru. This programme was funded by Department of Revenue, Ministry of Finance, Government of India under National Fund for Control of Drug Abuse (NFCDA). Fourteen doctors from Andhra Pradesh, Tamil Nadu, Kerala and Goa participated for this two weeks intensive training workshop.

Extra-Mural Training

The following workshops and training activities were conducted at the CAM during the calendar year 2014:

- Virtual Knowledge Network Addiction CME on Alcohol and Tabacco use Disorders was held from 25th March to 15th April 2014 for psychiatrists and other health professionals across India. It was a video conference based CME and each session had case discussions followed by didactics. There were four weekly sessions. The NIMHANS academic team conducted this virtual CME video with participants who had logged in from different parts of India. The participants accessed as well as interacted online with the experts from NIMHANS from their work place. There were around 40 to 70 participants for each session. The participants received 4 CME credit points from Karnataka Medical Council.
- **Virtual Knowledge Network Addiction training programme on Opioid use Disorders and Management: July and August 2014:** This weekly live ONLINE interactive training programme was held every Tuesday in the month of July and August 2014. Apart from live case discussion and didactic, there was an e-learning module for the participants. Around 60 participants from various part of the Country actively participated in the LIVE video conference based training and 40 successfully completed the e-learning module and receive the e-certificate.
- Virtual Knowledge Network Addiction training programme on Addiction and Comorbidity: September, 2014.
- **Training Workshop for healthcare professionals on Buprenorphine Oral Substitution Treatment (OST):** This was held from 6th to 10th January 2014 at Bengaluru. Doctors, nurses, counsellors from these OST centres newly established by NACO and State AIDS Control Society participated in this workshop. This was funded by Global Fund for TB, HIV and AIDS (GFTAM round 9) in collaboration with NACO.
- **Training Workshopson Co-morbidity:** This was held from 18th to 21st March 2014 at Bengaluru. This four day training workshop was participated by doctors and nurses who are working in Opioid Substitution Treatment centres (OST) funded by NACO. This was funded by Globe; fund for TB, HIV and AIDS (GFTAM round 9) in collaboration for NACO.

- *Training workshop*: National capacity building training of doctors on substance use disorders in south Zone was held in March 2014, at NIMHANS, Bengaluru. This programme was funded by Department of Revenue, Ministry of Finance and Government of India under National fund for Control of Drug Abuse (NFCDA). Fourteen doctors from Andhra Pradesh, Tamil Nadu, Kerala and Goa participated for this two weeks' intensive training workshop.
- Workshop in Addressing Risk Factors for Non-Communicable Diseases, organized on behalf of the World Health Organization Country Office, India, NIMHANS, Bengaluru, 6-7 February 2014.
- Workshop on Forensic Psychiatry training, NIMRPSYCON, 7 Mach 2014.
- NCD manual reviewmeeting of Experts Group, WHO country office and Ministry of Health and Family Welfare, Govt. of India, New Delhi, 26 August 2014.

Contribution to the PM's Office (PMO) on Man Ki Baat on Addiction

The CAM prepared a video and sent a contribution on the importance of training experts in drug abuse treatment and cessation to the PMO in response to the announcement from the PMO prior to the Honourable PM's address on addiction in the Man ki Baat programme.

14.8 MEDICAL STORE ORGANIZATION (MSO)

Medical Stores Organization under the Directorate General of Health Services is a century old Organization. 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 functions of Medical Store Organization is to procure store and supply of quality medicine to its about 1800 indenters at a competitive price through its seven GMSDs located at various places.

During 2014-15, MSO has operated rate contract for 514 branded drugs and 157 generic drugs. The process of submission of indents and procurement of all Proprietary & Generic drugs was done online through MSO website application programme developed by NIC. An exhaustive new formulary consisting of 1447 Generic drugs has been finalized.

The Medical Stores Depot had arranged immediate medical relief supply of essential life-saving medicines for flood affected areas of the States of Jammu & Kashmir and Cyclone affected area of Odisha, Telengana during 2014-15. The medical store depots also arranged to supply the Quadrivalent Meningococcal Meningitis Vaccine (QMMV), Seasonal Influenza Vaccine (SIV) for Haj Pilgrims, Rapid Diagnostic Kits, Miltefosine Capsules for eradication of malaria during 2014-15.

GMSD, Karnal, Mumbai, Chennai and Kolkata are having cold chain facilities and handling storage & distribution of vaccines. The GMSDs are also storing and distributing the material for national programme like TB Programme, Family Welfare Programme, Anti Leprosy drugs, NVBDCP, NLFP and PPE Kits for Ebola etc.