CHAPTER 13

Food & Drugs

13.1 FOOD SAFETY & STANDARD AUTHORITY OF INDIA (FSSAI)

Food Safety and Standards (FSS) Act, 2006 was enacted with the objective to consolidate the laws relating to food and for laying down science based standards for articles of food as well as to regulate their manufacture, storage, distribution, sale and import to ensure availability of Safe and Wholesome Food for human consumption and for matters connected therewith or incidental thereto. The Food Safety and Standards Authority of India (FSSAI) was established in the year 2008.

13.1.1 Activities

Enforcement/Regulatory Compliance

FSS Act, 2006 is being implemented by all State/UT Governments. State/UT Governments have appointed Commissioners of Food Safety, notified Adjudicating Officers, designated Officers and Food Safety Officers for respective areas to perform functions mandated under the Act. Additional Food Safety Commissioners have been notified for Railways, Airports and Ports along with Designated Offices for Airports and Ports.

There is an online process for issuance of licenses to Food Business Operators (FBOs). As on 31st March, 2019, 46,851 Central Licenses have been issued by the Central Licensing Authorities. The States/UTs have granted 10,44,992 States licenses and registered 47,97,997 FBOs. These include 10,66,645 registrations facilitated by Common Service Centres.

Four meetings of the Central Advisory Committee were held between 1.1.2018 and 31.3.2019.

At present fee for Central License is being received through online mode only. Some States have also adopted online mode for acceptance of fee for State License. However, States/UTs, where payment towards License/Registration fee is still being carried out through the Bank Challan mode are being impressed upon to switch over to digital mode.

During 1.1.2018 and 31.3.2019, FSSAI has taken several steps towards simplification and rationalization of licensing & registration processes:

- FSSAI is undertaking comprehensive review of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 which shall focus more on raising the bar for food safety compliance instead of just the documentation by means of licensing and registration.
- FSSAI is working on new software to replace the existing software application Food Licensing and Registration System (FLRS) to further simplify matters for FBOs and to make the system more transparent.
- FSSAI has completely done away with physical submission of various documents required for licensing/registration under the FSS Act.
- To avoid postal delays in getting physical signed copy of License /Registration, FSSAI has introduced issuance of system generated

License/Registration to e-mail IDs of FBOs which shall bear a Quick Response (QR) Code as a security feature to verify the License/Registration.

States have been asked to monitor the status of expired licenses on a monthly basis.

FSSAI has notified Food Safety and Standards (Food Safety Auditing) Regulations, 2018 to lay down procedure for conducting third party food safety audit of FBOs to ascertain adherence to food safety and hygiene requirements laid down in Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

FSSAI has put in place a web-based 'Food Safety Compliance through Regular Inspections and Sampling (FoSCoRIS) System' to verify compliance of food safety and hygiene standards by food businesses which replaces the manual keeping of Inspection Reports with digital records including the provision of capturing real time data viz. Images of the FBOs' premises, geo-location, date and time etc. of the inspections conducted. Three States viz. Punjab, Madhya Pradesh and Tamil Nadu have already implemented FoSCoRIS in their States.

FSSAI has launched "Clean and Safe Meat" Initiative on 11th September, 2018 with the objective to develop an ecosystem that will enable the availability of clean and safe meat and meat products to consumers. Third party audit of 40 municipal slaughter houses has already commenced and reports of 16 such slaughter houses have been received.

13.1.2 Standards and Regulations

Globally benchmarked food standards

FSSAI has constituted a Scientific Committee and 19 Scientific Panels comprising independent scientific experts under Section 14(1) and 13(1) of the FSS Act, 2006 for providing scientific opinion on various issues. During the period, FSSAI has successfully organised several meetings of Scientific Committee and all Scientific Panels in which various scientific opinions and several food standards have been developed.

So far, FSSAI has developed over 500 food product standards and reviewed and expanded standards for food additives that now has over 9000 provisos covering 350 additives and food processing aids by harmonizing the standards of food additives with Codex Standards.

FSSAI has notified some major Regulations during Jan, 2018 and March, 2019 which include Food Safety and Standards (Alcoholic Beverages) Regulations, 2018, Food Safety and Standards (Food Safety Auditing) Regulations, 2018, Food Safety and Standards (Fortification of Foods) Regulations, 2018, Food Safety and Standards (Advertisements and Claims) Regulations, 2018, Food Safety and Standards (Packaging) Regulations, 2018. Tolerance limits of antibiotics and pharmacological active substances have also been prescribed. Out of 32 areas that are listed in the Act, regulations have already been framed and notified in 28 areas.

13.1.3 Quality Assurance

Strengthening of Food Testing System in the Country: FSSAI is implementing a Central Sector Scheme for "Strengthening of Food Testing System in the Country including Provision of Mobile Food Testing Labs" (SOFTeL) with a total outlay of Rs. 481.95 crores, time frame for implementation of the scheme being 2016-17 to 2018-19. The scheme envisages strengthening of 45 State Food Testing Labs, 12 Referral Laboratories, establishing 62 Mobile Food Labs (called Food Safety on Wheels) and Capacity Building of food testing personnel. Status of implementation during the period 01.01.2018-31.03.2019 is given below-

i. A grant of Rs.144.80 crore has been sanctioned/released to 23 States/UTs for upgradation of 29 State Food Laboratories towards carrying out renovation work in

the laboratory, procurement of high-end equipment and setting up of microbiological laboratory and a total Grant-in-aid of Rs. 220.30 Crore has been sanctioned/ released to 29 States/UTs for upgradation of 37 State Food Laboratories across the country so far

ii. A grant of Rs. 13.57 crore has been released towards upgradation of seven referral laboratories towards procurement of high end equipment. With this, total Grant-in-aid of Rs. 22.735 crore has been released to 10 referral laboratories for their upgradation so far.

iii. 27 Food Safety on Wheels with a Grant-in-aid of Rs. 5 lakh per FSW towards petrol, oil, lubricants (POL) and consumables have been sanctioned to 19 States/UTs. This has raised the total number of FSWs sanctioned/ delivered from 19 to 46 to 32 States/UTs across the country.

iv. 26 training programs for laboratory personnel have been organized by FSSAI, including NABL awareness programs, Good Food Laboratory Practices (GFLP) programme and specialized training programmes viz. Training of Trainers (ToT) program on analysis of VDR including antibiotics, methods of analysis for fortificants in milk & oil etc. With this, total 49 training programs have been organised.

Notification of Food Testing Laboratories

Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018 have been notified in November, 2018. The Regulations define the eligibility, procedure, terms and conditions and obligations for recognition and notification of food laboratories and referral laboratories. Under the Regulations, notified food laboratories and referral laboratories may also be recognised as reference laboratory for the purpose of developing methods of testing, validation, proficiency testing and training. During 01.01.2018-31.03.2019:

i. 38 primary food testing labs have been recognised and notified under Section 43 (1) of Food Safety and Standards Act, 2006 by FSSAI. This has raised the number of notified primary food testing laboratories from 137 to 175.

ii. Punjab Biotechnology Incubator, Mohali and CSIR-Indian Institute of Toxicology Research, Lucknow have been notified as Referral Laboratory under Section 43(2) of FSS Act, 2006. Indian Institute of Vegetable Research, Varanasi and Indian Institute of Integrative Medicine, Jammu have been de-notified as Referral Laboratory due to lack of NABL accreditation. Now, there are total 18 Referral (Appellate) Labs of FSSAI in the country.

iii. 13 notified laboratories have been approved as reference laboratories National Reference Laboratories with the mandate to set up a country wide standard for routine procedures, reliable testing methods & validation of such standard procedure/testing methods, development of new methods and ensuring proficiency in testing across the food laboratories with special reference to the risks or food categories.

iv. One foreign laboratory namely, National Food Testing Laboratory, Thimpu, Bhutan has been recognized for analysis of food samples.

Up-gradation of FSSAIs own Referral Food Laboratories

(i) Food Research and Standardization Laboratory (FRSL), Ghaziabad has been renamed as National Food Laboratory, Ghaziabad. It has been renovated and operationalized with effect from 01.08.2018 on Public Private Partnership (PPP) mode.

(ii) Central Food Laboratory, Kolkata has also been renamed as National Food Laboratory, Kolkata. It has also been upgraded with some minor equipment and a few high end equipment.

Food Analyst Examination and Junior Analyst Examination

(i) FSSAI regularly conducts Food Analyst Examinations (FAE). During the period, 4th and 5th FAEs were conducted in which 73 and 83 candidates, respectively, were declared qualified. Now overall there are 360 qualified food analyst.

(ii) FSSAI has also started conducting Junior Analyst Examination (JAE) from 2018. During the period, 1st and 2nd JAEs were conducted in which total 184 candidates were declared as qualified Junior Analyst.

National Milk Quality Surveillance (NMQS): The Interim Report of NMQS, 2018 was released on 13.11.2018 and is available on FSSAI website. The survey was conducted through an external vendor (M/s Vimta Labs, Hyderabad). This is by far the largest systematic survey of milk both in terms of sample size (6432 samples) and numbers of parameters (4 quality parameters, 12 adulterants; and 4 contaminants). Samples that failed in the qualitative tests were quantitatively analysed. The result of the survey suggests that the milk in India is largely safe.

International Training Centre for Food Safety Analysis and Applied Nutrition (ITC-FSAN): FSSAI in collaboration with EIC and GFSP is establishing an International Training Centre for Food Safety Analysis & Applied Nutrition (ITCFSAN) at Export Inspection Agency's (EIA) Pilot Test House, ITC-FSAN is expected to become the hub for providing training programs to build capacity for the food testing laboratories in our country as well as in the neighbouring countries. The ITC-FSAN is expected to be operationalised shortly.

Addressing Micronutrient deficiencies through Food Fortification:

FSSAI is addressing micronutrient deficiencies by formulating standards for fortification of key staple viz. edible oil and milk (with Vitamin A & D), wheat flour and rice (with iron, folic acid and vitamin B12) and salt with iron (in addition to iodine) and has notified Food Safety and Standards (Fortification of Foods) Regulations, 2018 on 02.08.2018. It has also launched a logo to identify fortified food. FSSAI set up Food Fortification Resource Centre with support of Tata Trusts to promote food fortification. Voluntary fortification has begun for these staples. Availability of the fortified products in the open market has been steadily increasing. There are 70 Top and MSME brands with over 100 fortified products available in the open market across all commodities. There has been tremendous traction in the oil and milk industry, with over 30 fortified oil brands and 34 milk brands, fortified as per FSSAI standards, available in the market. In spite of a fragmented market structure, a number of wheat flour, rice and salt industry brands have begun fortifying their products. So far, 12 wheat flour brands, 2 rice brands and 12 double fortified salt brands are available in the open market.

Fortified staples (wheat flour, oil and DFS) have been introduced in Integrated Child Development Services (ICDS) and the Mid-Day Meal (MDM) Scheme and PDS Schemes.

In order to address rising incidence of Vitamin 'D' Deficiencies (VDD), particularly amongst children, Food Fortification Resource Centre (FFRC) of FSSAI launched a unique initiative, 'Project Dhoop' to highlight importance of Vitamin D through sunlight exposure.

13.1.4 Imports

As per Section 25 of the Food Safety & Standards Act, 2006, all imports of articles of food are subject to the provisions of the Act. It stipulates that no person shall import into India any article

of food in contravention of the Act or any rules and regulations made thereunder. Exercising the power of the Act, the Central Government notified the FSS (Import) Regulations, 2017 on 9th March, 2017.

FSSAI has its presence at 21 points of entry under 6 locations namely Chennai, Kolkata, Mumbai, Delhi, Cochin and Tuticorin and Food Import Clearance System (FICS) of FSSAI is linked to Customs ICE-GATE. Customs Department implements the Risk Management system (RMS), i.e. selective sampling and testing of food articles in consultation with FSSAI. FSSAI has set the parameters for RMS to be applicable on imported food items. RMS is being applied in ICEGATE before sending the consignment/bill of entry (BOE) in FICS.

During the period 01.01.2018 - 31.03.2019, out of 73,500 samples received in FICS of FSSAI through ICEGATE of Customs covering 49,17,885 Metric Tonne of food consignments for issuance of NOC, 72,689 samples covering 49,02,433 Metric Tonne of consignment were cleared.

In a meeting of experts comprising the representatives of the concerned Departments held in New Delhi on 06th December, 2018 under the Chairmanship of CEO, FSSAI, it was recommended that the ban on import of milk and milk products from China may be extended for a further period of four months i.e. upto 23rd April, 2019 or until the capacity of all notified laboratories for import testing across India have been suitably upgraded for testing melamine.

During 2018-19, several steps have been taken for further streamlining clearance of imported food consignments including:

- On the basis of certain criteria i.e. risk category of food, compliance history of importer etc. in RMS, only 5 % low risk items and 25% high risk food items are referred by Customs to FSSAI for examination and clearance;
- Simplified provision of facility of advance filing of Bill of Entry in Food Import Clearance System (FICS) to minimize the clearance time and also the demurrage charges;
- Issue of Provisional NOC (P-NOC) for imported pre-packaged retail food articles and articles requiring refrigerated storage to reduce clearance time, congestion at ports and demurrage charges on importers;
- Monthly monitoring of the performance of testing labs to ensure correct and timely report;
- Recognition of food laboratories in Bhutan and Bangladesh for issuance of test analysis certificate of imported food samples;
- List of rectifiable labelling information has been expanded to facilitate ease of doing business while ensuring the safe food imports;
- FSSAI has completed mapping of ITC-HS codes of imported food items along with risk categorisation of each ITC-HS code. With its implementation on the Customs ICEGATE in March, 2018, the food imports clearance procedures have become more efficient.

13.1.5 Codex

FSSAI, the National Codex Contact Point (NCCP), continues to be actively involved in coordinating and promoting Codex activities in India and ensuring India's effective participation in the Codex work related to the development of international food standards. Indian delegations comprising delegates from FSSAI and other relevant Government Departments /Organizations participated in 16 Codex Committee meetings between 01.01.2018 to 31,03.2019.

13.1.6 Training

FSSAI has been conducting various training courses for different categories of Regulatory

personnel. During 01.01.2018 and 31.03.2019, 9 Induction Training Courses have been conducted for 296 Food Safety Officers and 3 Induction Training Courses have been conducted for 45 Designated Officers. One Induction Training has been held for Adjudicating Officers. 3 Refresher courses have been held for 164 Food Safety Officers. Besides, 6 Special Trainings were conducted for 286 regulatory officers of different categories.

FoSTaC was started in 2017 as capacity building program to ensure Food Safety & Hygiene in Food Sector. During 01.01.2018 and 31.03.2019, a total of 4023 Training sessions (Training of Trainers -83 and Food Safety Supervisors Training -3940) have been held in which 1,08,681 persons have been trained.

13.1.7 Risk Assessment and R&D

FSSAI has established Food Safety Knowledge Assimilation Network (FSKAN), a system of network of organizations with the aim to facilitate among the scientific community co-operation through coordination of activities, exchange of information, development and implementation of joint projects within the Food Authority's responsibility. FSKAN web portal has been implemented and is available at FSSAI's website.

Till 31.03.2019, FSSAI has funded 20 R&D Projects, including 3 projects funded during the period 01.01.2018-31.03.2019, aimed at generating knowledge in areas relevant to FSSAI, where adequate research has not been undertaken so far. The findings of these projects will provide base for taking decisions in areas of food safety, standards formulation and nutrition.

13.1.8 Food Safety and Management System

Revision of Schedule 4: Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulations, 2011 lays down good hygiene practices to be followed by

Food Business Operators. FSSAI is revising this Schedule to align with international best practices It will ensure consistent implementation of Food Safety Management System by food businesses across the food supply chain and enable the FBOs to meet the regulatory requirements. Draft Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations, 2018 have been framed, inter-alia, providing for revised Schedule 4 provisions covering general requirements on hygienic and sanitary practices to be followed by all food business operators apply for license; hygiene and sanitary requirements for FBOs establishing a small slaughter house and for FBOs engaged in catering or food service operations. These Amendment Regulations have been operationalised. Revision of Schedule 4 requirements in respect of various other sectors is in progress.

With the intent to provide implementation guidance to food businesses (especially the small and medium businesses) in meeting the requirements laid down in Schedule, FSSAI has also developed sector specific guidance documents for 11 sectors. These include guidance documents for six sectors finalised during the period 01.01.2018-31.03.2019.

13.1.9 IEC Activities

Several initiatives have been taken during the period to disseminate information on the latest Act, Rules and Regulations of FSSAI as well as to promote safe and nutritious food through various IEC related activities including detailed information on website, participation in exhibitions and events, information videos on YouTube, signboards, Interactive Radio Counselling Sessions etc.

FSSAI launched on 16.10.2018, the World Food Day, *'Swasth Bharat Yatra'*, a high visibility, high impact 18000+ km relay cycle rally travelling across 6 tracks through almost every State and UT for over 100 days to propagate a powerful message - *"Eat Right India"*. Yatra culminated on 29.01.2019 at New Delhi. Engagement activities and events were held in more than 2,100 locations along the route. With more than 10 lakh participants and outreach to 2.5 crore people, the yatra made 'Eat Right India' a people's movement. Further, to engage with every section of the society, particularly the youth, *'Eat Right Creativity Challenge'* was held as a part of this movement. Over 75,000 students from more than 3600 registered schools actively participated in on-the spot poster making competition.

Eat Right Start-Up Awards were also instituted to encourage entrepreneurs in the food ecosystem. The winners were awarded in the categories of food products; food testing; food services; community outreach & engagement.

FSSAI has created one–of-its–kind Experience Zone that landscapes India's food safety ecosystem, in partnership with Tata Trust at 5th Floor, FDA Bhawan, New Delhi. Through interactive exhibits, visitors will experience the complexity of the food value chain, see the systems and processes in place and appreciate how FSSAI is nurturing partnerships between the regulator, food businesses and citizens.

International Cooperation: Apart from participation in Codex Meetings, FSSAI continued to have other bilateral engagements during 01.01.2018-31.03.2019 in the area of food safety, primarily intended for collaboration on technical and scientific areas of mutual interest and to comprehend food regulatory mechanisms of various countries, including exchange of scientific information; capacity building through visits of scientists/technicians under various projects and organizing workshops/training etc. During 01.01.2018-31.03.2019, following important activities were undertaken:

- MoU's/formal agreements for collaboration in the areas of food safety and capacity building were signed between FSSAI and respective food safety regulatory authorities/ agencies in Denmark (April, 2018), Portugal (Sept., 2018), EFSA (Sept., 2018), Japan (October, 2018) and Netherlands (March, 2019).

- Study visits of delegation of senior officials from FSSAI and State Food Safety Commissioners and Scientists to France (Jan., 2018), UK (Feb., 2018), New Zealand (April, 2018), Singapore (May, 2018 and Jan., 2019), Europe (Netherlands, Belgium, Italy-EFSA) (Sept., 2018) and Denmark (Sept., 2018) were conducted. The visits helped in strengthening mutual collaboration while also giving exposure to the senior management from Indian food safety domain to global food regulatory ecosystems to ensure cross learnings.
- A delegation led by CEO, FSSAI attended 1st WHO/FAO Conference on Food Safety held in Ethiopia (Feb. 2019). The visit was first of its kind exposure of FSSAI with food regulatory authorities in Africa.
- In addition, FSSAI also hosted delegation from Afghanistan (Jan.-Feb.,2019) & Nepal (March, 2019) comprising officials from their food regulatory authorities and concerned Ministries/ Departments for study visit to enhance their understanding of food safety ecosystem in India.
- In October, 2018, FSSAI has been selected as an observer member of the Governing Committee of GFSP (Global Food Safety Partnership) of the World Bank for a two-year term.

National Conclave on Food Safety and Nutrition: A two-day *'National Conclave on Food Safety and Nutrition'* was organized on 8th and 9th January 2018. On 8th January, the first day, FSSAI, State Health Secretaries, Food Safety Commissioners and other stake holders reviewed at length the current status of food safety and nutrition in the country and deliberated on the way forward. On 9th Jan, 2018 a round table conference of State Health Ministers presided over by the Union Health Minister, Shri Jagat Prakash Nadda was held.

The State Health Ministers adopted a joint resolution with a seven-point charter.

This includes:

1) supporting development of robust food standards and code of practices for safe food

2) creating a positive regulatory environment

3) establishing a credible and robust national food testing system

4) addressing micronutrient deficiencies and promoting healthy dietary habits

5) bringing about large-scale social and behavioural change in citizens on safe and nutritious food

6) building a culture of self-compliance in food businesses; and

7) developing effective institutions and institutional arrangements backed with competent human resources and adequate financial resources.

13.2 REGULATORY CONTROL OVER DRUGS

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 & Rules, 1945. The manufacture, sale and distribution of drugs in the country is primarily regulated by the State Drug Control Authorities appointed by the State Governments while control over drugs imported into the country and introduced for the first time is exercised by the Central Government through Central Drugs Standard Control Organization. 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.

13.2.1 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.

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 Drugs Controller General (India) is the head of Central Drugs Standard Control Organisation (CDSCO). The CDSCO with its Headquarters in New Delhi has six Zonal offices, six Sub-Zonal offices, seven Central Drugs Testing Laboratories and nine airport & sixteen seaport offices (Including Inland Container Depots) as given below:

CDSCO (HQ) - DELHI	
ZONAL OFFICES (6) • North Zone-Ghaziabad • East Zone-Kolkata • West Zone-Mumbai • South Zone-Chennai • Zone-Hyderabad • Zone-Ahmedabad	**SUB- ZONAL OFFICES (6)** • Sub Zone-Bengaluru • Sub Zone-Jammu • Sub Zone-Goa • Sub Zone-Indore • Sub Zone-Baddi • Sub Zone-Guwahati
LABORATORIES (7) • CDL-Kolkata • CDL-Kasauli • CDTL-Mumbai • CDTL-Chennai • CDTL-Hyderabad • RDTL-Chandigarh • RDTL-Guwahati	**SEA PORTS (16)** • Mumbai • Nava Sheva • Chennai • Tuticorin • Cochin • Kolkata • Kandla • Hazira
SEA PORTS (contd..) • Goa • Vishakhapatnam • Krishnapatanam • Mundra • Kamarajar • Tughlakabad (ICD) • Patparganj (ICD) • Khodhiyar (ICD)	**AIR PORTS (9)** • Delhi • Mumbai • Chennai • Kolkata • Hyderabad • Bengaluru • Ahmedabad • Goa • Vishakhapatnam

All the seven Central Drug Testing Laboratories under CDSCO have been accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL).

The Central Drug Laboratory, Kolkata is the appellate laboratory for testing of drugs. The Central Drug Testing Laboratory, Mumbai is an appellate laboratory for Copper T-intra-uterine contraceptive devices and tubal rings. The Central Drugs Testing Laboratory, Chennai is an appellate laboratory for condoms. The Regional Drug Testing Laboratory, Chandigarh tests survey samples as well as samples sent by Drug Inspectors. The Regional Drug Testing Laboratory, Guwahati tests the samples of chemicals and biological drugs received especially from the States in the Northern Eastern Region.

Apart from this there are notified Central Drugs Laboratories like the National Institute of Biologicals, Noida, for testing Blood Grouping Reagents and certain diagnostic devices, Homeopathic Pharmacopoeia Laboratory, Ghaziabad for testing homeopathic medicines , Indian Veterinary Research Institute, Izzatnagar for testing veterinary medicines and Chaudhary Charan Singh National Institute of Animal Health, Baghpat, Uttar Pradesh for testing of Haemorrhagic Septicaemia vaccine and Ranikhet Disease vaccine.

Functions at CDSCO Headquarters

- Grant of approval for manufacture and /

or import of new drugs and for conduct of clinical trials in the country.

- Approval of the licences to manufacture certain categories of drugs as Central License Approving Authority (CLAA) such as Vaccine & Sera, Large Volume Parenteral including IV Fluids, Blood & Blood Products and r-DNA products (Biotech Products).
- 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 use by their patients.
- Conducting meetings of Drugs Technical Advisory Board (DTAB) under Section 5 of Drugs & Cosmetics Act, 1940 to discuss matter arising out of the administration of the Act and recommend amendments to the Drugs & Cosmetics Rules, 1945.
- Conducting meetings of the Drugs Consultative Committee (DCC) under Section 7 of Drugs & Cosmetics Act, 1940, with all States/UTs Drugs Controllers for uniform implementation of this Act throughout the country.
- To recommend to Central Govt. to prohibit manufacture of drugs and cosmetics considered to be harmful or sub-therapeutic in public interest under Section 26A Drugs & Cosmetics Act, 1940.
- Conducting workshops and training programs on various topics related to quality control of drugs.
- Issuance of Written Confirmation (WC) for Active Pharmaceutical Ingredients (Bulk Drugs) exported to the European Union (EU) for medicinal products for human use.

Functions at the Zonal / Sub-Zonal Offices

- The grant of test licences in Form 11 of the Drugs & 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 as well as other drugs for the purpose of grant of licenses and compliance verification.
- Inspection of approved testing laboratories in coordination with the State Drugs Control Officers 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 compliance to the provisions of Acts/Rules 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 standard quality in another State and other such matters.
- Launching of prosecutions in cases detected by the Zonal offices.

Functions at the 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 from time to time.

ISO Certification of CDSCO Offices

In order to have transparency and accountability, CDSCO(HQ) and its Zonal offices at Ahmedabad, Hyderabad, Ghaziabad and Kolkataand sub-zonal office at Chandigarh are QMS (ISO 9001: 2008) certified.

REGULATORY FUNCTIONS OF CDSCO

1. Grant of permission/approvals for new drugs and subsequent new drugs in the country

New Drugs and Subsequent 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, 1945. The applicants are required to provide technical data in respect of safety and efficacy before these can be permitted to be marketed in the country. The applications are examined in consultation with the Subject Expert Committees constituted for the purpose.

During the year 2018-19, till date, permissions have been granted to import New Drug formulations in 15 cases and New Bulk Drug Substance in 1 case; Similarly permission to manufacture New Drug formulation in 36 cases and New Bulk Drug Substance in 30 cases has been granted.

Also, for Subsequent New Drugs, permissions have been granted to import finished formulations in 21 cases and to manufacture finished formulations in 68 cases and New Bulk Drug Substance in 45 cases.

2. Quality Control over Fixed Dose Combination (FDC)

These Fixed dose combinations which are required to be marketed for the first time in the country are permitted to be marketed in the country by the Drugs Controller General (India) after ensuring that these are safe and efficacious and comply with the requirements of Drugs and Cosmetics Rules 1945.

During the year 2018, permissions have been granted for import of FDCs in 21 cases; manufacture of FDCs in 28 cases; clinical trial permission in 14 cases and BE (Bio-equivalence) permission in 24 cases.

3. Quality Control over import of drugs

The import of drugs 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 Drugs & Cosmetics Rules, 1945. The quality of imported drugs is further monitored at the port offices when the drugs are actually imported.

All applications for import & registration are processed through online 'SUGAM' portal. During the year 2018-19, total number of Registration Certificates and Import Licenses issued are 437 and 2867, respectively.

4. Quality Control over import of cosmetics

Submission of applications has become completely online from 15.08.2017 through SUGAM portal. During the year 2018, Registration Certificates have been issued through online portal in 1324 cases.

5. Quality Control over import of Biological products

During the year 2018, Registration Certificates have been issued in 48 cases and Import Licenses in 76 cases for vaccines and r-DNA products, similarly for plasma derived blood products, Registration Certificates have been issued in 25 cases and Import Licenses in 28 cases.

6. Quality Control over Notified Medical Devices

Medical Devices notified by the Government of India under the Drugs & Cosmetics Act, 1940 are regulated by CDSCO as 'drugs' under the provisions of the Drugs and Cosmetics Rules, 1945. The quality control over these devices is regulated through the system of registration and import licences.

During the year 2018, manufacturing license in 71 cases; loan licenses in 2 cases; Clinical Trial approvals in 4 cases and import permission in 197 cases have been granted. During the same period, Test Licenses in 207 cases and licence to import in 568 cases have been issued.

7. Grant of Written Confirmation Certificates for export of APIs

The European Union Directive, which became effective from 2nd July, 2013, requires that every consignment of Active Pharmaceutical Ingredients (APIs) from non-EU / non-listed countries must be supported by 'Written Confirmation Certificate' issued by the competent authority of the country. CDSCO was nominated as competent authority for the issue of such certificates.

During the year 2018, CDSCO has issued 136 Written Confirmation Certificates for export of Active Pharmaceutical Ingredients (APIs) manufactured in the country to European Union.

8. Bio Availability/ Bio Equivalence

During the year 2018, applications for conduct of BA/BE studies in 3173 online cases have been processed and approved.

CDSCO has also issued 21 BA/BE study center/ Bio-analytical Laboratories approvals for centres/ laboratories involved in conduct of BA/BE studies in human subjects for domestic as well as export purpose.

9. 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 objective of determining their safety and 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).

During the year 2018, permission for conduct of Global Clinical Trials in 104 cases and Clinical Trial for approval of new drugs in 50 cases for subsequent new drugs in 21 cases and for biological in 61cases has been granted.

10. Blood Banks

The licenses for the Blood Banks are approved by the office of DCG (I) as Central License Approving Authority (CLAA) under the Drugs & Cosmetics Rules, 1945. During the year 2017, fresh grant of licenses in 277 cases, endorsement of blood components on license in 115 cases and renewal certificates in 469 cases have been issued.

11. Drugs Technical Advisory Board (DTAB)

The Drugs Technical Advisory Board is a statutory body under the Drugs and Cosmetics Act, 1940 to advise 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 have been held during the year 2018.

- 78th Meeting of DTAB was held on 12th February, 2018.
- 79th Meeting of DTAB was held on 16th May, 2018.
- 80th Meeting of DTAB was held on 25th July, 2018.

- 81st Meeting of DTAB was held on 29th November, 2018.

The DTAB considered various proposals relating to streamlining of regulatory control over the drugs in the country. The Drugs and Cosmetics Rules have been amended from time to time to strengthen the regulations and to facilitate ease of doing business in the country. In the year 2018, a total of 454 notifications have been finalized.

12. Drugs Consultative Committee (DCC)

The Drugs Consultative Committee is also a statutory committee under the Act, consisting of Central and State Drug Controllers to advise the Government on matters relating to uniform implementation of the Drugs and Cosmetics Act and Rules made thereunder. Three meetings of the Drugs Consultative Committee have been held as under:

- 53rd Meeting of DCC was held on 9th April, 2018.
- 54th Meeting of DCC was held on 30th July, 2018.
- 55th Meeting of DCC was held on 31st January, 2019 & 1st February, 2019.

13. Quality Assurance

QA division has been established and functional in CDSCO since 2012 in CDSCO (HQ) and quality management system is fully implemented which is certified by Bureau of Indian Standards (BIS).

13.2.2 Strengthening of CDSCO

The Government has, with a view to improve the quality, safety and efficacy of medical products taken a series of measures during 2015-16 to 2018-19. These include approval of a scheme for strengthening the drug regulatory structures both at the Central and the State levels at a total cost of Rs. 1,750 crores. Further continuation of scheme for strengthening of State Drugs Regulatory System for a further period of two years upto 2019-20 at a cost of Rs. 412 crores has been approved.

The Scheme for strengthening includes setting up of 7 new drugs/ medical devices/cosmetics testing Central labs and 8 Mini labs at Airports and Seaports for assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

With a view to enhancing the quality, safety and efficacy of medical products in the country, three pronged strategy has been adopted viz (i) Product quality through testing of larger samples; (ii) Process quality through GMP and GLP inspections; and (iii) Comprehensive training of regulatory and laboratory personnel.

During 2018-19, Ministry of Health and Family Welfare and CDSCO have also taken several regulatory measures for streamlining the regulatory system in the country. Details are as under:

E-Governance

- CDSCO has embarked on a comprehensive e-Governance program. As part of the e-Governance, CDSCO has launched a portal www.cdscomdonline.gov.in exclusively for filing of applications of medical devices, their processing and tracking, both for Central and State Governments.
- CDSCO had earlier launched a portal SUGAM which has been developed in phases. In 2018, online submission and processing of applications for grant of permissions for marketing of New Drugs, Fixed Dose Combination New Drugs, Subsequent New Drugs, Vaccines, Recombinant Drugs, etc. have been developed.
- A module for creation of database for all the manufacturing facilities in the country and the products approved for marketing has been developed and launched under SUGAM portal. This will provide a comprehensive data base of all the manufacturing facilities approved in the country along with the products permitted to be marketed by them.
- CDSCO has developed a new website

www.cdsco.gov.in with latest features and complying with GIGW Guidelines for India Government Websites issued by the Government of India. The website provides easy browsing, search facility, improved user experience, etc.

- CDSCO has seven laboratories under it which are engaged in test/analysis of drugs, cosmetics, medical devices and vaccines. A portal digitizing various functionalities of the laboratories has been developed which is known as SUGAMLABS. The portal will enable timely testing of drugs and maintain integrity and traceability of samples.

Clinical Trial

- New Drug and Clinical Trial Rules, 2019 have been notified vide G.S.R. 227(E) dated 19.03.2019, to have comprehensive rules for approval of Clinical Trials and New Drugs. These rules contain various provisions for improving transparency and accountability and also to facilitate research and development of new drugs.

Upgradation of Schedule M

- A draft amendment to the Rules vide GSR 999 (E) dated 5th October, 2018 has been issued to make Schedule M more comprehensive and at par with the WHO-GMP guidelines.

Prohibition of Irrational FDCs:

- Central Government has prohibited 328 FDCs and restricted 6 FDCs on 07.09.2018. However, these notifications have been challenged before courts of law. Further, on 11.01.2019, 80 FDCs have been prohibited.

Intelligence cell:

- Intelligence cell at CDSCO HQ was set-up on 26.03.2018 with an aim to collect and collate the information on suspected illegal activities and conduct intelligence activities in coordination with State and other regulatory bodies.

Based on the information collected, total 141 raids were conducted across the country which include 8 raids in the area of FDCs, 4 raids in the area of New Drugs, 32 raids in the area of Cosmetics, 45 raids in the area of Medical Devices. Action as appropriate under the law, is taken against the concerned persons.

Ease of Doing Business

- **Increasing the validity of WHO COPP:** CDSCO has issued instructions to extend the validity of Certificate of Pharmaceutical Product (COPP) under the WHO GMP Certification Scheme from 2 years to 3 years subject to the condition that the GMP status of the manufacturing facility is monitored as per WHO guidelines through periodic inspections.

- **Waiver of NOC for export purpose:** CDSCO has issued a notice to remove the requirement of No Objection Certificate (NOC) with respect to shipping bills from the port offices of CDSCO for the export consignments to any country if such shipping bills are filed by the manufacturer, having valid licence under Drugs and Cosmetics Act.

- **Delegation of powers to the States:** CDSCO has delegated powers to all States/ UTs Drug Controllers for issuance of No Objection Certificate (NOC) with respect to unapproved / banned drugs for export purpose only.

- **Public relation office:** A Public relation office was set-up at CDSCO (HQ) in March, 2018. It will act as a single window for disposal of grievances of stakeholders and also provide information to the innovators regarding regulatory requirement for commercialization of their product further it will guide, assist and handhold investors in various phases of business life cycle as

per existing focus on "Invest India/Make in India". A public notice was issued regarding promotion of innovation & start up business in India in pharmaceutical sector to provide a direct video-conferencing facility at DCG(I), office to entrepreneurs, researchers and innovators. CDSCO has also provided Toll free No. 1800111454 and Email startupinnov@cdsco.nic.in to support and guide stakeholders.

Quality

- **Stability of drugs and safety of excipients:** G.S.R. 360 (E), dated 10.04.2018 has been published making it mandatory for the applicants to submit evidence of stability, safety of excipients, etc. to the State Licensing Authority before grant of product manufacturing license.
- **Central Medical Device Testing Laboratory:** S.O. 2237 (E), dated 1st June, 2018 has been published designating the laboratories having facilities for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory for the purposes of testing and evaluation, functioning as an appellate laboratory and carrying out any other function as may be specifically assigned to it by the Central Government in relation to the medical devices.
- **Performance evaluation report:** GSR 889(E), dated 1st August, 2018 has been published requiring submission of performance evaluation report by the manufacturer in case of in-vitro diagnostic medical devices.
- **Inclusion of 14 steroids for external use under Schedule H:** GSR 277 (E), dated 23rd March, 2018 has been published for including 14 steroids for external use under Schedule H for preventing their abuse/ misuse.

E-Pharmacy

- **Regulation of sale of drugs over internet:** Draft Rules vide GSR 817 (E), dated 28th August, 2018 have been published for inserting PART VIB in the Drugs Cosmetics Rules 1945 for regulation of sale of drugs over internet (e-pharmacy).

Import

- G.S.R. 1193(E) dated 12.12.2018 has been published enhancing fees for import registration/permission and import license of drugs.

Regulation of Cosmetics

- Draft notification vide G.S.R. 1153(E) dated 29.11.2018 has been issued for separate set of comprehensive rules for cosmetics.

Regulation of Blood banks

- Draft notifications vide G.S.R. 1152(E) dated 29.11.2018 has been issued for amendment of Rules for Blood Banks.

Training and Skill development

- Training program has been conducted for newly recruited Assistant Drugs Controllers and Drugs Inspectors. The training has been conducted at National Institute of Biologicals, Noida.
- CDSCO has conducted second Annual Regulators Conclave for Central and State Regulatory Authorities in India in collaboration with World Health Organization during 23.08.2018 to 24.08.2018 at Kasauli, Himachal Pradesh. The workshop successfully built up a platform where the regulators from Centre and States, international experts from WHO and industry representatives shared their valuable insights for adoption of best practices for strengthening of regulatory systems in India. The event was live web-streamed across the country.

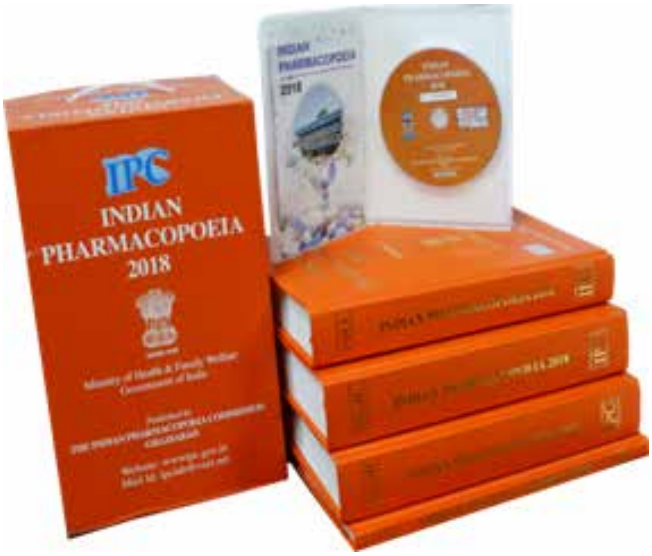
13.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

Major achievements

A. Indian Pharmacopoeia (IP)

IP is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Ministry of Health & Family Welfare, Government of India in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules 1945 thereunder. IP is recognized as the official book of standards for the drugs being manufactured and/or marketed in India. The standards of the IP are authoritative in nature and are enforced by the regulatory authorities for ensuring the quality of drugs in India. As per the criteria to be adhered to : the interpretation of a monograph must be in accordance with all the general requirements, testing methods, texts and notices pertaining to it, in the IP. A product is not of standard quality unless it complies with all the requirements of the monograph.

FEATURES OF IP 2018

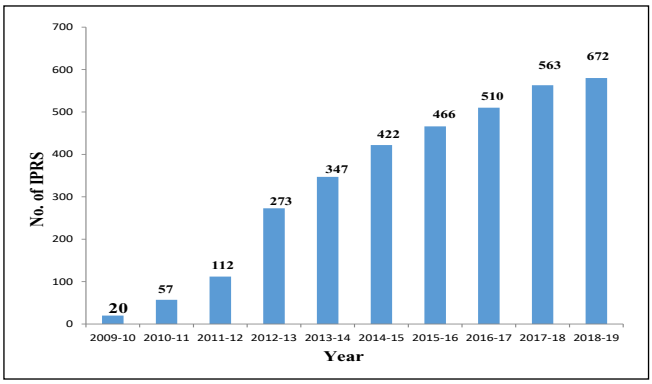


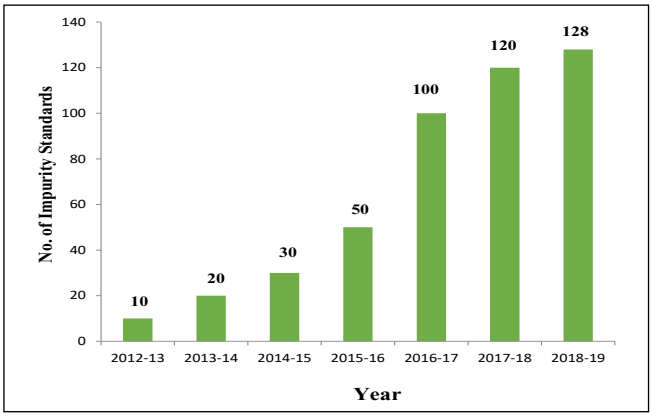
- **220 new monographs**
  - 49 API
  - 64 Formulations
  - 53 Fixed dose formulations
  - 02 Excipients
  - 02 Antibiotics
- 170 Chemical Monographs
- 02 Vaccines & Immunosera for Human use
- 06 Biotechnology derived therapeutic products
- 10 Blood and blood related products
- 15 Herbs and herbal products
- 03 Radiopharmaceutical
- 14 veterinary non-biological monographs

B. Indian Pharmacopoeia Reference Substances (IPRS)

Indian Pharmacopoeia Reference Substances (IPRS) are highly characterized substances that are used in the official methods prescribed in IP for the purpose of comparison to ensure the identity, purity, strength and quality of drug substances and drug products. They are used by the stakeholders to qualify the working standards used for routine analysis in the laboratories such as for quantitative (e.g. assay and impurity) and qualitative (e.g., identification) analysis. IPRS characterization involves collaboration processes and additional procedures other than those used in routine testing to produce Reference Substances of the highest quality and make them readily available to the public.

Thus, so far 672 IPRS including 120 Impurities are available at IPC.





C. Pharmacovigilance Programme of India (PvPI)

The milestone-marking the formal launch of Pharma-covigilance Programme of India (PvPI), Indian Pharmacopeia Commission (IPC) as the World Health Organization (WHO)-Collaborating Centre for Pharma-covigilance in Public Health Programmes and Regulatory Services was laid at IPC in Ghaziabad on 30th October, 2017. PvPI as a WHO-CC will provide scientific support to countries in Asia for Pharmacovigilance in public health programmes such as those concerning tuberculosis, neglected tropical diseases, vector-borne diseases and HIV-AIDS and also for Adverse Event Following Immunization (AEFI) and regulatory issues.

Trainings/Skill Development Programme

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), successfully conducted nearly 550 induction-cum-training/advance-level training/ skill development programme and CMEs during the index period and trained 33,080 healthcare professionals.

13.4 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 intoxicating 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 categories- supply reduction and demand reduction. The supply reduction which aims at reducing the availability of illicit drugs within the country come under the purview of the NCB under the MHA 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 (NDPS) 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 Drug De-addiction Programme (DDAP) by providing financial grants for augmenting post abuse treatment facilities in selected 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 other DDTCs receiving regular annual recurring financial assistance under this programme are PGIMER, Chandigarh and NIMHANS, Bangalore. The purpose of these centres is not only to provide de-addiction services and rehabilitation services to the patients but also to conduct research and provide training to medical doctors in the area of drug de-addiction.

13.5 NATIONAL DRUG DEPENDENCE TREATMENT CENTRE (NDDTC), GHAZIABAD

National Drug Dependence Treatment Centre (NDDTC) is a state of the art facility for providing treatment services to the patients with substance use disorders. The Centre is in forefront of clinical care, teaching, research, community outreach programme, and assisting in policy making in the field of substance use disorders. NDDTC has state of the art, well-equipped laboratories to detect various drugs in body fluids and biochemical investigations. The Centre provides outpatient and inpatient services, and outreach services in undeserved area of the city. It is presently a 50 bedded treatment facility with expansion plan for future. The Centre has also been designated as a Regional Learning Centre by UNODC (ROSA) and WHO (SEARO) and continues to be the WHO Collaborating Centre on Substance Abuse since 2012.

In this year, the NDDTC has released the First report of survey - Magnitude of Substance Use in India, funded by the Ministry of Social Justice and Empowerment, Government of India. Among other important national-level initiatives, the centre has embarked upon a multicentric study on detection of New Psychotropic Substances(NPS) among substance use treatment seekers in India, as well as Developing and Implementing Training Mechanism for use of Essential Narcotic Drugs (ENDs) for treatment of Opioid Dependence – both initiatives supported by the Department of Revenue, Ministry of Finance. The Centre has also initiated and carried out the WHO Biennium activities.

The NDDTC has also carried forth the Strengthening the Drug De-addiction Programme: Establishment of DTCs (DTC Scheme). A web portal (www.dtc-sheme.in) has been developed to (a) enhance the visibility of DTC activity, (b) educate the potential patient, as well as for (c) smoother coordination and information management for all the DTCs and the coordinating agencies.

During the period of 1st April, 2018 to 31st March, 2019, a total of 2,21,947 patients visits occurred and 10,681 new patients were registered. Services were provided through regular Outpatient Department, 3 Community clinics and 5 Specialty clinics. A total of 1341 patients were admitted to the ward. Investigations carried out were: screening for drugs of abuse (14 addictive drugs) (29,285), biochemistry (43,128), haematology (17,758), and HIV screening (313).

13.6 DRUG DE-ADDICTION AND TREATMENT CENTRE (DDTC), PGIMER, CHANDIGARH

The Drug De-Addiction and Treatment Centre (DDTC), PGIMER, Chandigarh was established in 1988. At present it has a 30 bedded (only 20 functional) inpatient section, outpatient department and community clinics at Kharar and Boothgarh in the state of Punjab. In 2016, an Urban Outreach Clinic has been started at Civil Hospital Naraingarh in the state of Haryana. At the DDTC, it is planned to expand the bed strength from 20 beds to 50 beds. DDTC, PGIMER, Chandigarh has received National Award for Outstanding Services in the field of prevention of alcoholism and substance (Drug) Abuse, under the Category- Best Research or Innovation, including a prize of Rs. 5.00 Lakh,

the award was presented by Hon'ble President of India on 26th June, 2018.

During the period of 1st January, 2018 to 30th March, 2019, a total of 4979 patients visited in Walk-in-Clinic and total 18352 patients for follow-up visits. A total 392 patients were admitted to the ward.

13.7 CENTRE FOR ADDICTION MEDICINE (CAM), NATIONAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES, BENGALURU

The Centre comprises of 80 bed inpatient facility, 60 for men and 20 for women. Since inception, the Centre has provided training to hundreds of post-graduate students from mental health medical and non-medical disciplines, which in turn carry out several community and clinical related interventions for addiction prevention and treatment. The Centre has also trained medical officers from Karnataka and other southern states, doctors from Himachal Pradesh, Bihar, Chhattisgarh and presently Orissa. Each November, for the last 20 years, the Centre conducts a one-month orientation in substance use disorder management for medical and non-medical professionals.

The Centre has developed a digital evaluation and prescription programme for outpatient assessment and are now expanding this to the inpatient and emergency services. In addition to clinical services and research, there is a lot of emphasis given to research in the area of substance use and addiction, both through post-graduate work and funded projects.

The CAM has registered 4198 new patients, 19380 patients in out-patient follow up and 14552 telephonic follow up were made during the above period. 1453 patients were admitted to the CAM in-patient ward during the above period for inpatient treatment. There is a comprehensive inpatient program consisting of individual and family assessment, individually tailored treatments which involve pharmacological treatments for withdrawal and long term prevention of relapse, individual and group counselling, family counselling and intensive aftercare.

The drug-toxicology laboratory which tested around 27126 samples for drugs and alcohol in urine and blood has had to add one more 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.

13.8 MEDICAL STORES ORGANIZATION

The Medical Store Organization (MSO) was set up in 1942 as a subordinate wing of the Directorate General of Health Services under the Ministry of Health and Family Welfare, Medical Store Organization has 7 Government Medical Store Depots (GMSD), in New Delhi, Mumbai, Kolkata, Chennai, Hyderabad, Karnal & Guwahati. These 7 GMSD's not only store and stock essential drugs and vaccines but also provide last mile logistic support and deliver stocks to healthcare units in the country. The GMSD's provide storage and logistic support to important National programs such as National Immunization Programme. MSO finalizes rate contracts(RC) for drugs which are used by the various Health Care Institutions in the country, Para-military forces and CGHS units in the country also use RCs and GMSDs for uninterrupted drug supply. About 1500 Government agencies utilize the supplies from GMSDs.

MSO website has now been refurbished with three level security audit and SSL security certification. Data base and web application of MSO has been shifted to NIC Cloud. Drug & Vaccine Delivery Management System (DVDMS) is being implemented by CDAC. Registration of indenters on the new website has begun and the initial web portal is visible at url: http:/uatdvdmsmsodelhi.dcservices.in. Lease line connections have been provided at all divisions of MSO and E-office has been implemented. At GMSD Delhi, and Kolkata, E-office has been implemented.

MSO has created identities and roles for senior officers at each GMSD at the Central Procurement Portal (CPP) portal. MSO has started E-tendering for procurement of about 1500 Generic drugs for the first time through the CPP for greater accountability & openness in the process of tendering. Rate Contract for 525 Generic Drugs being carried out by GMSD, Delhi is in advanced stage. Rate Contract for 503 Generic Drugs being carried out by GMSD, Hyderabad also is in advanced stage. Rate Contract for 23+8, patented drugs have been finalized and orders have been placed through various GMSD's on behalf of indenters and regular supplies are being received at all GMSD's. Procurement and timely distribution of QMM Vaccine & SI Vaccine for Haj Pilgrims was carried out for Session 2018 by 7 GMSDs. Tender for session 2019 has been floated through the NIC e-portal Procurement of Anti-Malarial Medicines and Kits for CRPF Battalions during the Year 2018-19 was finalized. Finalization of Rate contract for a period of 1 year for H1N1 Drugs has been approved by the Competent Authority. MSO/GMSDs procured various generic and patented drugs worth Rs. 143 Crores during Financial year 2018-19.MSO/ GMSDs also handled program stores worth Rs. 1310 Crores.