CHAPTER 13

Food and Drugs

13.1 FOOD SAFETY & STANDARD AUTHORITY OF INDIA (FSSAI)

Food Safety & Standards Authority of India (FSSAI) has been established under the Food Safety & Standards (FSS) 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.

13.1.1 Activities

Enforcement/Regulatory Compliance

Food Safety & Standards 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 Officers for Airports and Ports.

As on 30th September, 2017, 34,323 Central licenses have been issued by Central Licensing Authorities (CLAs). The States/UTs have granted 8,02,571 State licenses and registered 30,42,922 Food Business Operators (FBOs) under the Act. These include 2.52 lakh registrations facilitated by Common Service Centres.

Two meetings of the Central Advisory Committee were held on 16th May, 2017 and 22nd August, 2017.

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, in other States/UTs, payment towards License/ Registration fees is still being carried out through the Bank Challan mode for which the food business operator has to visit the office of State Food Safety Department. FSSAI is constantly in touch with such States/UTs to persuade them to switch over to digital mode of payment for facilitating FBOs seeking State License/Registration.

Risk Based Inspection System (RBIS): Due to limited number of food safety officials, it becomes a difficult task to inspect the premises of all the food business operators. Risk Based Inspection System (RBIS) has been developed to increase the transparency and ensure that scarce Government resources are focused on products and businesses to which greater risk is attached. The risk-based inspection system has two main components: (i) scheduling regular inspections based on a risk classification (using a risk grade) of food establishments (implemented at FSSAI and State FDA levels) and (ii) conducting inspections following a risk-based process control approach and using appropriate inspection grids (implemented by officers at local level). The Risk based classification of Licensing/Registration data has been completed. This data is classified according to Risk Grade (N). The classification data relating Central Licensing and State Licensing/Registration has been shared with States/UTs.

13.1.2 Standards & Regulations

FSSAI has constituted a Scientific Committee and 17 Scientific Panels comprising of independent scientific experts under Sections 14(1) and 13(1) of Food Safety and Standards (FSS) Act, 2006 for providing scientific opinion on various issues. FSSAI has organized several meetings of Scientific Committee and different Scientific Panels in which various scientific opinions and several food standards have been developed.

During 2017-18 (till 30.09.2017), 11 Amendment Regulations covering about 94 standards/provisions in Food Safety and Standards (Food Products Standards and Food Additive) Regulations, 2011; 5 standards/provisions in Food Safety and Standards

(Contaminants, Toxins and Residues) Regulations, 2011; 1 standard in Food Safety and Standards (Packaging and Labelling) Regulations, 2011 besides one new regulation titled Food Safety and Standards (Approval of non-specified Food and Food Ingredients) Regulations, 2017 have been finalized and notified. 75 Standards/provisions in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and two new Regulations on Food Safety and Standards (Alcoholic Beverages) Regulations, 2017 and Food Safety and Standards (Organic Foods) Regulations, 2017 have been approved by the Food Authority for final notification, and likely to be notified in final form during the reporting period.

About 268 Standards/provisions in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011; 375 Standards/ provisions in Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011; two provisions in Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011 have been approved by the Authority for draft notification to invite public comments.

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. The time frame for implementation of the Scheme is 2016-17 to 2018-19. The scheme envisages strengthening of 45 State Food Testing Labs, 12 Referral laboratories, establishing 62 Mobile Food Labs and capacity building of food testing personnel.

(i) A grant of Rs. 50 lakh each to Jammu Laboratory and Srinagar Laboratory for setting up of Microbiological Laboratory and a grant of Rs. 50 lakh each to Meghalaya, Manipur and Telangana has also been released towards the sub-component of creation/renovation of infrastructure, before procurement of lab equipment in State food laboratories. With this, upgradation of 23 States/UTs Food Testing labs has been covered under the scheme so far.

(ii) A grant of Rs. 4.25 Crore released to four referral labs viz. IICT, Hyderabad, CIFT, Kochi, IIFPT, Thanjavur and CALF, NDDB, Anand towards procurement of high end equipment.

(iii) 19 Food Safety on Wheels (FSW), which are mobile food testing laboratories, have been sanctioned to 17 States and are under delivery. Each FSW has an approximate cost of Rs. 30 lakh (excluding GST). A set of booklets containing Scheme Guidelines, Operational Manual and Manuals of Simple Methods for Testing of Common adulterants in Food is also being provided in each FSW.

(iv) 11 training programs for laboratory personnel have been organized by FSSAI, including Good Food Laboratory Practices (GFLP) programme and specialized Training of Trainers Programmes on analysis of mycotoxins/ pesticide and veterinary drug residues in food.

Notification of Food Testing Laboratories during 2017-18:-

12 more laboratories have been recognized and notified under Section 43 (1) of Food Safety and Standards Act, 2006 by FSSAI. This has raised the number of notified food laboratories from 125 to 137. National Institute of Plant Health Management (NIPHM), Hyderabad and ICAR-National Centre for Research on Grapes (NRC Grapes), Pune have been recognised and are under the process of notification as Referral Laboratories under Section 43(2) of FSS Act, 2006. This will raise the total number of Referral Food Laboratories from 16 to 18.

Management of FRSL Ghaziabad on PPP Mode: Contract has been awarded to M/s Arbro Pharmaceuticals Pvt. Ltd., New Delhi for operation and management of FRSL, Ghaziabad on PPP Mode.

Booklet on DART: A revised booklet titled DART (Detect Adulteration with Rapid Test) comprising of common quick tests for detection of food adulterants at household level by citizens has been released by FSSAI on 22.08.2017.

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 (ITC-FSAN) at Export Inspection Agency's (EIA) Pilot Test House, Mumbai for imparting Classroom Trainings and Hands on Trainings to different stake holders; and to build capacity for the laboratories by training the analysts in high end instrumentation/analysis of specific food parameters like pesticides, mycotoxins, veterinary drug residues, etc. The 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 operational by the end of fiscal year 2017-18.

13.1.4 Imports

FSSAI has successfully operationalized the food import 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 for 21 points of entry at six major locations i.e. Delhi, Mumbai, Chennai, Kolkata, Tuticorin and Cochin Ports (including sea, air and land). Out of total 5500 samples, 5205 samples have been issued NOC.

During April-September, 2017, following initiatives were taken to streamline the process and reduce the time taken for Imports clearance of the food consignments:

(i) 12 new labs (increased to 137 NABL accredited labs) have been notified.

(ii) As per order dated 03.04.2017, Bangladesh Standard and Testing Institution (BSTI), Dhaka, Bangladesh has been authorized to issue test analysis certificate for a selected list of 21 imported food products.

(iii) As per Order dated 13.4.2017, if an Importer/ CHA does not turn up for visual inspection jointly with FSSAI at two occasions, Authorised Officer (AO) of FSSAI is authorized to draw the sample during visual inspection ex-parte.

(iv) As per Order dated 08.05.2017, food products may be considered for clearance separately on the basis of its compliance to Act, Rules and Regulations made thereunder, in the food consignments consisting of more than one product.

To facilitate patients with certain life threatening disease conditions, an order has been issued on 31.05.2017 for import of special food formulations for personal use by the patients.

Authorized Officers of Mumbai and Delhi were directed vide order dated 12.06.2017 to permit import of specialty foods for Inborn Error of Metabolism (IEM). A list of 72 products with their labels was also provided for facilitating the clearance of these products on the ports of Delhi and Mumbai.

As per the Food Safety and Standards (Import) Regulations, 2017, Customs, in consultation with FSSAI, has implemented Risk Management System (RMS) at Customs Single Window Interface for Facilitating Trade (SWIFT) and to optimize the functioning of RMS, FSSAI has shared relevant data with RMS team of Customs Department and further efforts are being made by the FSSAI to make the import clearance processes more efficient and effective.

A meeting of the experts comprising the representatives of the concerned Departments held in New Delhi on 12th June, 2017 under the chairmanship of CEO, FSSAI recommended that the ban on import of Milk and Milk products from China may be extended for a period of one year i.e. up to 23rd June, 2018 unless the safety risk assessment is undertaken based on availability of credible reports and supporting data in respect of the said products, whichever is earlier.

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 of the delegates from FSSAI and other relevant Government Departments/ Organizations participated in 07 Codex Committee meetings between 01.04.2017 and 30.09.2017.

13.1.6 Training

During April-September, 2017, three Induction Training Courses have been conducted for 137 officers and one induction training course has been conducted for 17 Designated Officers. Refresher courses have been held for Joint Food Safety Commissioners (16 participants) and One Refresher Training held for Designated Officers (16 participants).

During April-September, a total of 205 Training sessions (Training of Trainers-32 and Food Safety Supervisors Training – 173) have been held in which 4112 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 with several features, including serving as 'domain repository of experts in the field of food safety, hygiene and food nutrition; a forum for open discussion; access to wide range of E-books and E-journals and other E resources; a research project data base and facility for online submission of R&D proposals is under development.

Till 30.9.2017, FSSAI has funded 17 R&D projects 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 Management System

Revision of Schedule 4: The Schedule 4 of the FSS (Licensing & Registration of Food Businesses) Regulations, 2011 has been comprehensively reviewed in order to ensure consistent implementation of Food Safety Management System by food businesses across the food supply chain and to meet the regulatory requirements. Draft Food Safety and Standards (Licensing and Registration of Food Businesses) Amendment Regulations, 2017 has been prepared and approved by the Food Authority.

13.1.9 IEC Activities

Several initiatives have been taken to disseminate information on the latest Act, Rules and Regulations of FSSAI as well as on to promote safe and nutritious food through various IEC related activities.

World Food Day was celebrated on 16th October 2017

National Convention on Food Security, Release of Large Scale Food Fortification Guidelines by Hon'ble Union Minister State for Health & FW Shri Ashwini Kumar Choubey in the presence of Secretary (HFW) Ms. Preeti Sudan and Special Secretary & FA Ms. Vijaya Shrivastava

13.2 REGULATORY CONTROL OVER DRUGS

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 CDSCO.

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 6 Zonal offices, 6 Sub-Zonal offices, 7 Central Drugs Testing Laboratories and 9 Air Port & 14 Sea Port Offices.

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 cooper 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 States.

Apart from this there are notified Central Drugs Laboratories like National Institute of Biologicals, Noida, for testing Blood Grouping Reagents and certain diagnostic devices, Homeopathic Pharmacopoeia Laboratory, Ghaziabad for testing homeopathic medicines and Indian Veterinary Research Institute, Izzatnagar for testing veterinary medicines.

Regulatory Functions Performed at CDSCO

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

During the year 2017, till date, permissions have been granted to import New Drugs Formulations in 20 cases and New Bulk Drug Substance in 1 case; to manufacture New Drug Formulation in 18 cases and for New Bulk Drug Substance in 17 cases.

Also, for Subsequent New drugs, permissions have been granted to import Finished Formulations of New Drugs in 7 cases; to manufacture finished formulations in 22 cases and New Bulk Drug Substance in 7 cases.

2. Quality Control over Fixed Dose Combination (FDC)

During the year 2017, till date, permissions have been granted for import of Fixed Dose Combination (FDC) in 7 cases and manufacture of FDCs in 25 cases.

3. Quality Control over import of drugs

All application for Import & Registration is processed through online 'SUGAM' Portal. During the year 2017, till date, total numbers of Registration Certificate and Import Licenses issued are 586 and 3553 respectively.

4. Quality Control over import of cosmetics

Submissions has become completely online from 15.08.2017 through SUGAM portal. During the year 2017, till date, Registration Certificates issued through online portal in 515 cases and through offline mode in 85 cases.

5. Quality Control over Notified Medical Devices

During the year 2017, till date, manufacturing license in 61 cases; Clinical Trial Approvals in 4 cases and Import permission in 12 cases have been granted. During the same period, Test License in 175 cases; License to import in 784 cases and Registration Certificate in 187 cases has been issued.

Hon'ble Union Minister for Health & Family Welfare Shri J.P. Nadda delivering Keynote Address at 1st World Congress on Access to Medical Products and International Laws for Trade and Health at New Delhi on 21st November, 2017

6. Grant Written Confirmation Certificates for export of APIs

During the year 2017, till date, CDSCO has issued 15 Written Confirmation Certificates and renewed 41 Written Confirmation Certificates for various Active Pharmaceutical Ingredients (API) manufactured in the country.

7. Clinical trials

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 2017, till date, permission for conduct of Global Clinical Trials in 43 cases, Clinical Trial for approval of New drugs in 34 cases and for subsequent new drugs in 12 cases has been granted.

8. Blood Banks

During the year 2017, till date, fresh grant of licenses in 67 cases; endorsements of blood components on license in 53 cases and renewal certificate in 157 cases have been issued.

9. Drugs Technical Advisory Board (DTAB)

The Drugs Technical Advisory Board is a statutory body under the Drugs and Cosmetics Act, 1940 to advice the Central Government and the State Governments on technical matters arising out of the administration of the said Act and Rules made thereunder. The Board is headed by the Director General of Health Services and DCG (I) acts as Member Secretary. Three meetings of the DTAB have been held during the year 2017.

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 in various aspects to strengthen the regulations and to facilitate ease of doing business in the country. In the year 2017, till date, a total of 14 notifications amending the rules have been finalized.

10. Drugs Consultative Committee (DCC)

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

11. 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).

12. WHO Assessment of National Regulatory Authority

WHO has assessed CDSCO from 13th to 17th February 2017 against Global Benchmarking Tool (GBT) comprising of 9 functions and 288 questions prepared by WHO for measuring the maturity of Indian National Regulatory Authority (NRA) through a stringent assessment of 5 days for various regulatory functions. Indian National Regulatory Authority has been declared "functional" with maturity level of 4, the highest level as per WHO, in five out of nine functions and 3 in the remaining functions.

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 2017-18. These include approval of a scheme for strengthening the drug regulatory structures both in the Central and also in the State at a total cost of Rs. 1,750 crores. Further SFC has recommended continuation of scheme for strengthening of States Drugs Regulatory System for a further period of two year viz, upto 2019-20 at a cost of Rs.412 crores for upgrading 31 State Labs, 38 State Drug Control Offices, Setting up of 10 New Drug Testing labs and commissioning of 20 mobile drugs testing labs. An additional component of giving incentive to States/UTs to support the functional labs/HR, based on their performance has also been included.

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. The approved schemes

also entail setting up of a National Academy for Drug Regulators.

With a view to enhance the quality, safety and efficacy of medical products in the country, three pronged strategies have 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.

Medical Devices Rules, 2017 was published vide GSR 78 (E) dated 31.01.2017 wherein requirements for import, manufacture, clinical investigation, sale and distribution of Medical Devices and In-Vitro Diagnostics have been incorporated. These Rules will be effective from 01.01.2018.

The process of implementation of e-Governance in CDSCO for online submission and processing of applications for Import and Registration of drugs, Medical Devices and Diagnostics and Cosmetics, Ethics Committee registration, permission to conduct Global Clinical Trials and Bio-equivalence studies for export purpose, test license and import permit for import of drugs for personal use has been accelerated and online licensing system through "SUGAM" portal had been developed and operationalized. CDSCO has also developed Modules for creation of database of manufacturing facilities, wholesale and retail sale licenses where data to be uploaded by the manufacturers and authenticated by the State Drugs Controllers.

In order to ensure efficacy of drugs, the Drugs & Cosmetics Rules, 1945 have been amended vide GSR 327 (E) dated 03.04.2017, making it the mandatory requirement of Bioavailability and Bioequivalence (BA/BE) studies for oral solid dosage forms containing Class II & IV drugs of Biopharmaceuticals Classification System (BCS), before licensing.

For continuous monitoring of quality of drugs, CDSCO has recently initiated Risk Based Inspections of Pharmaceutical manufacturing facilities based on the risk they pose with regards to the quality of drugs manufactured by them. Till date 185 risk based inspections of manufacturing facilities have been carried out in 8 phases.

Six training programmes have been conducted for newly recruited Drugs inspectors and Assistant Drugs Inspectors. The trainings have been conducted at National Institute of Biologicals, Noida and various Central Drugs testing laboratories.

The "International Conclave on Good Regulatory Practices in India", was organized on 21st and 22nd August, 2017 in Bhopal, Madhya Pradesh by the CDSCO along with Food and Drug Administration (FDA), Madhya Pradesh in collaboration with WHO Country Office. The workshop successfully built up a platform where all the state regulators could share their valuable insights with respect to their best regulatory practices in areas of Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Laboratory Practices (GLP), enforcements, prosecution, Intelligence activities and co-ordination with other states & regulatory authorities, investigation, safe disposal of medicines, control of border activities, strengthening & capacity building of laboratories of states. The open forum was a successful initiative which gave an opportunity to the states to commit to the development of a harmonized regulatory system to work together to build up a strong regulatory system in India encompassing all principles of Good Regulatory Practices (GRP).

13.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

The Indian Pharmacopoeia Commission (IPC) is a unique organization committed to set the quality specifications of drugs and pharmaceuticals in the form of Indian Pharmacopoeia (IP) and to promote rational use of medicines by bringing out National Formulary of India (NFI) and to ensure safety of medicines by running Pharmacovigilance Programme of India (PvPI) to protect health of all citizens of our country.

The major achievements of IPC during the year 2017-18 include the following:

A. Indian Pharmacopoeia (IP) - 2018

In continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines by publishing the Indian Pharmacopoeia (IP), a legal book of

Hon'ble Union Minister for Health & Family Welfare Shri J.P. Nadda releasing Guidelines at 1st World Congress on Access to Medical Products and International Laws for Trade and Health at New Delhi on 21st November, 2017

standards for monitoring the quality of Drugs and Pharmaceuticals as per the Drugs and Cosmetics Act, 1945, the Eight Edition of IP-2018 is under printing and expected to be released very soon incorporated with the following salient features:

- IP-2018 contains total 2929 monographs.
- Also incorporates 391 monographs inclusive of 82 monographs of Addendum 2015 to IP-2014; 89 monographs of Addendum 2016 to IP-2014 and 220 newly added monographs of APIs, Excipients and Dosage Forms.
- 10 New General Chapters are also included.
- 25 New Fixed Dose Combination (FDC) Monographs are first time included in this 8th edition, which are not available in any other Pharmacopoeia of the world.
- 25 New APIs and single formulations are added in IP-2018, which are not available in any other Pharmacopoeia of the world.
- Use of Chromatographic methods has been greatly extended. Classical Chemical Tests for identification of an article have been almost eliminated and more specific IR, UV Spectrophotometer and HPLC Tests have been introduced.
- For the first time Index to make user friendly is also incorporated to Volume-I of IP-2018.

B. Indian Pharmacopoeia Reference Substances (IPRS)

- 03 new Impurities were developed and information uploaded on the IPC website (www.ipc.gov.in). Thus, so far 615 IPRS including 78 Impurities are available at IPC.
- To prove the stability of already developed IPRS, retesting is performed initially after two years and then on an annual basis. A total of 158 IPRS were retested for their integrity of potency.
- 65 New Candidate Materials for Impurity Reference Standards are under validation to develop the IP Reference Substances.
- 20 IPRS issued for changing of their lot numbers due to old number of vials had out of stock or less quantity of vials remains.
- 69 new Candidate Materials have been received from Stakeholders and CDSCO and have

already been identified to develop new IP Reference Substances.

- 104 New Drugs samples were received from the Office of Drugs Controller General (India) for verification and reports generated were submitted to the CDSCO, FDA Bhawan, New Delhi.
- 142 port samples received from CDSCO, IGI Cargo Complex, New Delhi were analyzed and reports generated were submitted to the respective CDSCO Offices in New Delhi.

C. Accreditation and Certification

- IPC has been assessed and accredited in accordance with the standard ISO Guide 34:2009 "General Requirements for the Competence of Reference Material Producers" as Reference Material Producer (RMP) by National Accreditation Board for Testing and Calibration Laboratories (NABL).
- IPC has been assessed and accredited in accordance with the standard ISO/IEC 17025:2005 "General Requirement for the Competence of Testing & Calibration Laboratories" in the discipline of Chemical and Biological Testing by National Accreditation Board for Testing and Calibration Laboratories (NABL).
- IPC has been assessed and accredited in accordance with the standard ISO/IEC 17043:2010 as Proficiency Testing (PT) Provider in the field of Chemical by National Accreditation Board for Testing and Calibration Laboratories (NABL).

D. Synthesis of Impurities

New molecules are being introduced in the global market regularly. The impurity profile is one of the most important issues in modern pharmaceutical analysis in the process of technology development for the production of high-purity substances. The new monographs are introduced in IP which become official standards in India and may be adopted globally.

In order to achieve the goal of providing maximum safety of drugs to the public, the work of Impurity Synthesis is also being carried out at IPC in collaboration with Indian Institute of Chemical Technology (IICT), Hyderabad.

E. Pharmacovigilance Programme of India (PvPI)

Indian Pharmacopoeia Commission (IPC) as a National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) performs the following activities during the period:

- **WHO-Collaborating Centre for Pharmacovigilance**

Based on quantity, quality of the work carried out by the NCC-PvPI and its significant contribution to WHO-UMC, now IPC is recognized as one of the sixth WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services.

- **Initiated Intensive Drug Monitoring (IDM) under PvPI**
  - Initiated IDM for the drugs like SGLT-2 Inhibitors, Sofosbuvir & Pioglitazone.
  - Identified total 16 sites for the IDM study for above mentioned drugs.
- **Coordination activities with National Health Programs**

National ToT for expansion of Bedaquiline Shorter MDR-TB regimen with updated Guidelines for PMDT in India was organized by Central TB Division & WHO-Country Office at New Delhi from 18th to 20th April, 2017.

13.4 DRUG DE-ADDICTION PROGRAMME (DDAP)

The Constitution of India, under Article 47, enjoins that the State shall endeavor to bring about prohibition of 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 & 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. 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, Bengaluru. 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)

National Drug Dependence Treatment Centre (NDDTC) is a state of the art facility for providing treatment services to the patients with substance use disorders. It is also a WHO collaborating centre on substance use. 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.

Among educational and academic initiatives, NDDTC has started the AIIMS Video Clinic (AVC) at the Telemedicine facility, AIIMS. The centre organised the "Capacity Building for Tobacco Cessation" workshop on the occasion of "World No Tobacco Day" on 30th May, 2017 and a national Continuing Medical Education (CME) on "Emerging issues in substance use disorders" on 22nd July, 2017 (in collaboration with the National Academy of Medical Sciences). An important upcoming initiative is the First Annual Conference on Addiction Psychiatry 2017, to be held from 27-29 November 2017 at AIIMS, New Delhi. The faculty of the centre regularly acts as a resource person in various training programmes on Opioid Substitution Therapy (OST), training of counsellors by State Council for Education Research and Training (SCERT), orientation programmes for various service providers including law enforcement agencies, and induction training programmes for Drug Treatment Clinics Scheme (DTCS). Many faculty members are renowned technical experts and hold key positions in national and international professional expert and advisory bodies.

During the period under report, a total of 8060 new cases were registered (NDDTC-7513, Trilokpuri-252, Sunder Nagri-295). The old cases comprised of 1,05,134 patients (NDDTC-41,378; Trilokpuri-17,309; Sunder Nagri-46,447). Statistics for the speciality clinics are: NEW - Adolescents (87), Dual Diagnosis (91), Tobacco Cessation (39), Women Clinic (18) and Family Empowerment Clinics (4); and OLD - Adolescents (325), Dual Diagnosis (365), Tobacco Cessation (421), Women Clinic (100). A total of 894 patients were hospitalized.

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

The 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 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.

13.7 CENTRE FOR ADDICTION MEDICINE, NATINAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES, BENGALURU

Centre for Addiction Medicine (CAM) completed its 25 years of service in the month of June 2017. The Centre has an 80 bed inpatient centre for both men and women.

Since inception the Centre has provided training to hundreds of post-graduate students from mental health medical and non-medical disciplines, who in turn, carry out several community and clinical related interventions for addiction prevention and treatment. The Centre has trained medical officers from different States. Each November, for the last 20 years, the Centre has been conducting a one month orientation in substance use disorder management for medical and non-medical.

13.8 MEDICAL STORES ORGANIZATION

Medical Store Organization (MSO) established in 1942, a subordinate wing of Directorate General of Health Services under Ministry of Health & Family Welfare, Government of India has been functioning for finalization of rate contract and procurement & supply of medicines at the right time with right quantity and right quality to the various Health Care Institutions of the country including Para–Military forces and CGHS units through its seven sub offices called Government Medical Store Depots (GMSDs) located at New Delhi, Mumbai, Kolkata, Karnal, Guwahati, Chennai & Hyderabad. There are approx. 1500 indenters under them.

The MSO also handles the storage and distribution of medical stores worth Rs. 750 crore per year (approx.) under National & International Health Programmes of MoHFW, Govt. of India such as NVBDCP, RCH, Family Welfare, Anti TB, Anti Leprosy and various immunization programmes over and above the procurement part.

Apart from accomplishing this onerous responsibility which is a continuous activity, it also undertakes the need based procurement and supply of medicines in natural calamities like Flood, Earthquake and other disasters.

The MSO has arranged the procurement & supply of the quadrivalent meningococcal meningitis vaccine (QMMV); influenza vaccine (SIV) for Haj Pilgrims; Yellow Fever Vaccine for CRI, Kasauli and provisioned for emergency Supply to Cuba and Procurement of Anti-Malaria Medicines or Kits for CRPF Battalions during the Year 2017-18. The MSO also procured and arranged supplies of H1N1 drugs to different states in India.

The MSO through the GMSDs, accepts drugs from various registered manufacturers, duly inspects each & every batch and gets these drugs tested from two different Government approved Laboratories by sending Coded Samples.

There is a provision to deregister manufacturing units & contract holding firms in the events of failure of drugs supplied by them.

The MSO developed/established its own website and web application software (mso@gov.in) for carrying out various activities through this application software such as “Indenting by the indenters”,

“Compilation of demands”, “Processing of LPPs and Sanctions”, “Placement of Supply Orders”, “Inspection & receipt of the stores”.

During the year 2017-18 till 31st August 2017, total online procurement & supply of generic & proprietary medicines has been initiated through above application (in value) as under:

(Figures in Crore)

1.	Generic Medicines	Rs. 51.18
2.	Proprietary Medicines	Rs. 190.41
3.	Patent Medicines	Rs. 01.05

In addition to above MSO has initiated & finalized the following: -

i) The rates of 152 Generic Drugs have been finalized for conclusion of Rate contract for two years.

ii) The MSO/CGHS & Central Govt. Hospitals have an existing Generic Drug formulary containing more than 2000 formulations on the basis of which generic tenders are invited by the MSO/GMSDs.