13 Chapter

FOOD & 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 Act, 2006, as a statutory body for laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption. The Act aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multi-level, multi-departmental control to a single line of command. Various Acts and Orders that have hitherto handled food related issues in various Ministries and Departments have been integrated in the Act. Ensuring the safety and quality of food for the citizens is imperative. A comprehensive, consolidated Food Safety and Standards Act aligned with the global practices was the first step to achieve this aim. The Food Safety and Standards Authority of India is making continuous efforts for effective implementation of the FSS Act.

13.1.1 Activities of the FSSAI

1. Enforcement

Regulation of Food Safety in States: FSS Act, 2006 has been operationalized in India since 5th August, 2011. All the States/UTs have appointed Food Safety Commissioners, notified Designated Officers, Adjudicating Officers and Food Safety Officers for respective areas within the State. The State laboratories continue to act as notified laboratories under FSS Act, 2006 and Public Analysts have been re-designated as Food Analysts. 3,774 Central licenses, 1,01,687 State/UT licenses and 2,12,206 registrations have been issued by State Governments in the year 2015-16. States have also taken samples of food products and initiated both civil and criminal actions against Food Business Operators (FBOs) who were found deviating from the Act and its provisions. Till 31.03.2015, 13 Central Advisory Committee meetings have been conducted wherein States/UTs participated and discussed their issues. Some of the highlights are as follows:

- Compiling and reviewing data of the progress of enforcement activities in the States/UTs on a continuous basis;
- Established Appellate Tribunal in 21 States/UTs;
- Established Steering Committee in 27 States/UTs and
- Total 30 States/UTs have gone live till 20/11/2015 and 06 went online for Licensing/Registration (Food Licensing & Registration System) during the year 2015-16.

2. Regulation

It is the responsibility of FSSAI under the Food Safety and Standards Act, 2006 to frame standards

for food products and for food safety and to monitor their implementation in the country. Several standards have been notified and more are required to be framed. FSSAI is also in the process of harmonizing the existing standards with the Codex and other international practices. The status of notification of various standards are as given below:-

Sl. No.	Name of the Product/Commodity Standards	Status
A.	**Final Notification issued**	
1.	Maximum limit of Trans Fatty Acids up to the level of 5% in Oils and Fat Emulsions	Notified on 04.08.2015
2.	Standards for Glucose Oxidase, Kipase and Xylanase in bread	Notified on 04.11.2015
3.	Standards for Naturally Occurring Toxins (NOTS)	Notified on 04.11.2015
4.	Standards for Pullulan	Notified on 04.11.2015
5.	Standards for Chromium in Gelatin	Notified on 04.11.2015
6.	Standards for Mycotoxin	Notified on 04.11.2015
7.	Standards for Lecithin in breads	Notified on 13.11.2015
8.	Standards for Steviol Glycosides	Notified on 13.11.2015
9.	Standards for Caramel and Glazing Agents	Notified on 13.11.2015
B.	**Draft Notification issued**	
1.	Food Safety and Standards (Food Recall Procedure) Regulations	Notified on 22.04.2015
2.	Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary uses, Foods for Special Medical Purposes, Functional Foods and Novel Foods) Regulations	Notified on 30.07.2015
3.	Standards for heavy metals	Notified on 05.06.2015
4.	Standards for gluten and non-gluten foods	Notified on 28.01.2015
5.	Standards for Phytosterols	Notified on 30.07.2015
6.	Declaration of trans fat & class titles	Notified on 05.06.2015
7.	Standards for dried and salted fish	Notified on 05.06.2015
8.	Standards for melamine in milk and milk products	Notified on 05.06.2015
9.	Harmonisation of Horizontal Standards for Food Additives for use in certain food categories or individual food items	Notified on 04.08.2015
10.	Limits of Biotoxins in fish and fishery products	Notified on 12.6.2015
11.	Microbiological Standards of milk and milk products	Notified on 30.07.2015
12.	Microbiological Standards of meat & meat products	Notified on 30.07.2015
13.	Food Safety and Standards Authority of India (Procedure for Transaction of Business of Central Advisory Committee) Amendment Regulations, 2015 w.r.t. appointment of members	Notified on 04.11.2015

3. Surveillance

A new suggestive surveillance plan has been developed as per discussion with Commissioners of Food Safety held on 30th July, 2015. Copy of the surveillance plan is also distributed to States/ UTs for ensuring food safety surveillance in the States. The plan will be followed up with States/ UTs for ensuring safe and wholesome food to the consumers.

4. Codex activities

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

There are 26 active Codex Committees under Codex Alimentarius Commission (CAC) working on various subjects. Each committee meets once in a year or once in 18/24 Months depending upon its nature and work load.

For each Codex Committee, a parallel Shadow Committee has been constituted by the FSSAI which develops India's position on the agenda items under consideration. The various stakeholders for each committee are representatives from different Ministries like Ministry of Health & Family Welfare, Ministry of Commerce, Ministry of Women & Child Development, Ministry of Agriculture & Farmers Welfare, Ministry of Food Processing and Department of Animal Husbandry & Dairy Fisheries, representatives from Research institutions, representatives from industry associations like Confederation of Indian Industry (CII) and Federation of Indian Chambers of Commerce and Industry (FICCI) and experts/ scientists from concerned areas.

Participation in various committee meetings and submission of comments on time

The Food Authority and the concerned Ministries/ Departments and other stakeholders have actively participated in the following Codex Committee meetings that were held during the period April 2015 to October, 2015:

Sl. No.	Codex Committee	Date
1	47th Session of Codex Committee on Pesticide Residues (CCPR)	13th to 18th April, 2015, Beijing, China
2	22nd Session of Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)	27th April to 1st May, 2015, San Jose, Costa Rica
3	38th Session of Codex Alimentarius Commission (CAC)	6th to 11th July, 2015, Geneva, Switzerland
4	2nd Session of Codex Committee on Spices and Culinary Herbs (CCSCH)	14th to 18th September, 2015, Goa, India
5	19th Session of Codex Committee on Fresh Fruits and Vegetables (CCFFV)	5th to 9th October, 2015, Ixtapa, Mexico
6	34th Session of Codex Committee on Fish and Fishery Products (CCFFP)	19th to 24th October, 2015, Norway

Submission of new work proposals

India had submitted 4 new work proposals on developing draft Codex Standards on Rosemary, Cumin, Thyme and BWG Pepper in the 1st session of Codex Committee on Spices and Culinary Herbs (CCSCH). The new work proposals were adopted by the Committee and the CAC. The draft Standard for BWG Pepper has progressed to Step 2/3 and the draft Standards for Cumin and Thyme have progressed to Step 5. India had also submitted a new work proposal on developing draft Codex Standard on Aubergines at the 18th Session of Codex Committee on Fresh Fruits and Vegetables (CCFFV) which has now progressed to Step 5/8 for final adoption by the CAC.

India also submitted 4 new work proposals on the following items in various Codex Committees this year:

- Proposal for New Work on Codex Standard for Dried and Dehydrated Ginger – 2nd Session of CCSCH;
- Proposal for New Work on Codex Standard for Dried and Dehydrated Garlic – 2nd Session of CCSCH;
- Proposal for New Work on Codex Standard for Dried or Dehydrated Chilli – 2nd Session of CCSCH and
- Proposal for New Work on Codex Standard for date palm – 19th Session of CCFFV.

Participation in EWGs

India participated in total 6 Electronic Working Groups (EWGs) set up by various Codex Committees and provided significant comments on the agenda items under consideration.

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

India has been unanimously appointed as the Regional Coordinator for Asia Region from the end of 38th Session of CAC (2015) to the end of 40th Session of CAC (2017).

13.2 REGULATORY CONTROL OVER DRUGS

The regulatory control over the import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 is exercised by Central Drugs Standard Control Organization and the State Drug Regulators. 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. The objective of the drug regulatory system is to ensure availability of safe, effective and quality drugs, cosmetics and medical devices.

13.2.1 Central Drugs Standard Control Organization (CDSCO)

The Drugs Controller General (India) is the head of Central Drugs Standard Control Organization (CDSCO).

The CDSCO with its Headquarters in New Delhi, six Zonal offices situated at Mumbai, Ghaziabad, Kolkata, Chennai, Ahmadabad and Hyderabad, three Sub-Zonal offices at Bengaluru, Chandigarh and Jammu and Port Offices at notified ports of entries at Mumbai (Sea and Airport), Nava Sheva (Seaport), Kolkata (Sea and Airport), Chennai (Sea and Airport), Hyderabad (Airport), Delhi (Airport), Kochi (Seaport), Ahmedabad (Airport), Bengaluru (Airport) and Goa (Sea and Airport).

13.2.2 Central Drug Testing Laboratories

There are seven central drug testing laboratories under CDSCO. These are at Kolkata, Mumbai,

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

13.2.3 Strengthening of CDSCO

The Government has approved a scheme for strengthening of CDSCO at a cost of Rs. 900 crore to be spent during 2015-16 to 2017-18. The components of the scheme include:

- Construction of new building for 8 new offices;
- Setting up of 6 new drug testing labs for CDSCO;
- Setting up of 8 Mini Labs at Airports and Seaports;
- Up-gradation of 7 existing Central Drug Testing Labs and
- Setting up of a Training Academy.

Action has been taken to ensure implementation of above mentioned components

The Government has also started imparting training to the Officers of the regulatory structures as well as laboratory personnel both from the Central and State Governments with a view to enhance their skills. Further, the process of ISO certification of the CDSCO Offices has been initiated. The zonal offices of CDSCO at Ahmedabad, Hyderabad and sub-zonal office at Chandigarh have been certified as compliant to ISO 9001: 2008. Action has also been initiated for NABL accreditation of all laboratories. Further, training programmes and workshops are being regularly conducted by CDSCO with support of WHO and other organizations for updating the knowledge and enhancing of the skills of the concerned officials in CDSCO.

a. Quality Control over import of drugs

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

During the year 2015-16 (upto 30th November, 2015), the office of Drug Controller General (India) granted 289 registration certificates to manufacturers of drugs who intend to export their products to India. During the same period, 1924 licences in Form 10 for import of such drugs into the country were also granted.

b. Quality Control over import of cosmetics

The registration of cosmetics imported into the country was initiated from 1st April, 2013 to ensure that products imported into the country are not only of standard quality but also have been manufactured under Good Manufacturing Practices by genuine/licensed manufacturers.

This provision will ensure that only genuine and safe cosmetics are permitted to be imported in the interest of public health safety. The office of Drug Controller General (India) granted 185 registration certificates and 115 endorsements on the existing registration certificates during the year 2015-16 (upto 30th November, 2015).

c. Quality Control over Notified Medical Devices

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

During 2015-16 (upto 30th November, 2015), the office of Drug Controller General (India) issued various approvals and licences for import and clinical trial on medical devices. 294 registration certificates were granted to the manufacturers of the medical devices who intended to export their medical devices to India. 795 licences in Form 10 for import of medical devices into the country were also granted during the same period. 92 licences were granted for import of medical devices for test and analysis. In 4 cases permissions for clinical trial on medical devices were also granted.

The manufacture of the notified devices is approved by the Drug Controller General (India) as Central Licence Approving Authority (CLAA) under the Drugs and Cosmetics Rules. During the year 2015-16 (upto 30th November, 2015), the office of Drug Controller General (India) granted CLAA approval in 94 cases for manufacture of medical devices.

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

New Drugs are permitted to be marketed in the country in accordance with the permission granted by the Drugs Controller General (India) after ensuring that these are safe and efficacious and comply with the requirements of the Drugs and Cosmetics Rules. The applicants are required to provide technical data in respect of safety and efficacy before these could be permitted to be marketed in the country. The applications are examined in consultation with the New Drug Advisory Committees constituted for the purpose.

During the year 2015-16 (upto 30th November, 2015), approvals were granted for eight new drugs after due examination of their safety and efficacy. Subsequent permissions for manufacturing and marketing in the case of recombinant DNA products were granted in eight cases and permission for import and marketing were granted in the same period in five cases.

e. Clinical trials

Clinical trials of new drugs are conducted on human subjects in the country to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics) and/or adverse effects with the object of determining their safety and/or efficacy. The Drugs and Cosmetics Rules provide that clinical trials for a new drug, whether for clinical investigation or any clinical experiments are required to be conducted under and in accordance with the permission granted by the Drugs Controller General (India).

Under the present procedure the applications for clinical trials are examined by the Technical Committee headed by the Director General of Health Services and the Apex Committee headed by the Secretary, Ministry of Health & Family Welfare before permission to conduct clinical trial in the country is granted. During 2015-16 (upto 30th November, 2015), the office of Drug Controller General (India) granted permission for conduct of clinical trials on new drugs in 18 cases.

In case of subsequent approvals of new drugs, manufacturing permissions were granted in 19 cases and permission to import new drugs was granted in 5 cases. The clinical trial permissions were granted in 16 cases and test licences for import of drugs for test and analysis were granted in 13 cases.

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

f. Blood Banks

The licences for the Blood Banks are approved by the office of Drug Controller General (India) as Central Licensing Approving Authority (CLAA) under the Drugs and Cosmetics Rules, 1945. During the year 2015-16 (upto 30th November, 2015), fresh licences were granted in 130 cases while endorsement on the existing licences were issued in 35 cases and approval of renewal certificates were issued in 314 cases.

13.2.4 Achievements and Initiatives taken in 2015

a. Introduction of e-Governance at CDSCO

The process of implementation of e-Governance has been initiated at CDSCO with respect to licensing system under the Drugs and Cosmetics Rules, 1945 in a phased manner to bring transparency, accountability and efficiency in the drug regulatory system.

The Minister of Health & Family Welfare inaugurated the portal www.cdscoonline.gov.in on 14.11.2015 and online licensing system "SUGAM" in respect of processing of applications for Import and Registration of drugs as well as notified medical devices and permits for import of small quantities of drugs for personal use. IT enabled software for online submission of applications for conduct of clinical trials in the country has also been initiated and made accessible to the stakeholders through the portal http://otcams.gov.in. The usual procedure of submission of applications through hard copies shall, however, continue till the system for online submission is made fully operational. The system will also receive various information on clinical trial for maintaining comprehensive data base and monitoring of clinical trials. This will help in the protection of rights, safety and well-being of trial subjects and authenticity of data generated.

b. Ease of Business at Ports

Functioning of Central Drugs Standard Control Organization (CDSCO) offices at Seaports/ Airports has been made operational on 24X7 basis. The checklist for data requirements for electronic submission of application, bill of entry and shipping bills has been integrated at a single entry point.

c. Revision of National List of Essential Medicines (NLEM), 2011

The National List of Essential Medicines (NLEM) has been revised on the basis of the recommendations of the Core Committee headed by Dr. V. M. Katoch, former Secretary, Department of Health Research & Director General, Indian Council of Medical Research.

d. Regulation of phytopharmaceutical drugs under the Drugs and Cosmetics Rules, 1945

The Drugs and Cosmetics Rules, 1945 has been amended vide G.S.R. 918 (E) dated 30.11.2015 to include phytopharmaceutical drugs i.e. plant based therapeutic products under its scope. This will ensure availability of the plant based drugs after approval of their safety and efficacy on the lines of modern drugs for specific indications and provide benefit to the patients of the traditional

therapies. This will also open up new frontiers for research and development of these products on modern lines so that these traditional drugs gain international recognition also.

13.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

The Indian Pharmacopoeia Commission is poised to publish periodically the Indian Pharmacopoeia, the official and authentic book of standards. IP Addendum-2016 to IP-2014 has been released on 14.11.2015 by Sh. Jagat Prakash Nadda, Health & Family Welfare Minister and Gen (Dr.) V. K. Singh (Retd.), Minister of State, Ministry of External Affairs, Overseas Affairs and Statistics and Programme Implementation (Independent Charge). During their visit to IPC, Ghaziabad on 14th November, 2015, the Hon'ble Ministers laid down the foundation stone for construction of Advanced Level Research Centre in the premises of IPC. The IP Addendum 2016 will be effective from 1st January, 2016. The book is published in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes to control and assurance of the quality of the medicines. The standards of this Pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines. To meet the expectations of the stakeholders, the commission is working energetically and has taken care of amendments to IP 2014 and incorporated 89 New Monographs consisting of 64 Chemical Monographs, 14 Herbal Monographs, 03 Vaccines and Immunsera for Human use, 03 Radiopharmaceuticals Monographs, 01 Blood Related Products, 04 Bio-technology Product Monographs and 02 General Chapters in this addendum. It is expected that Addendum 2016 would play a significant role in improving the quality of medicines which in turn promote public health and accelerate the growth and development of Pharma sector in the Country.

Shri Jagat Prakash Nadda, Union Minister of Health & Family Welfare and Gen V. K. Singh (Retd.), Minister of State for External Affairs & Overseas Affairs (Independent Charge) releasing IP Addendum – 2016 to IP – 2014.

Indian Pharmacopoeia Reference Substances (IPRS)

The Indian Pharmacopoeia Commission has developed and validated 85 New IP Reference Substances. Total number of 466 IPRS are made available to the stakeholders. Indian Pharmacopoeia Commission has developed 20 new impurities by In-House Synthesis and total number of 30 New Reference Impurities have been made available to stakeholders. IPC is in the process of preparing, certifying and distributing Indian Pharmacopoeia Reference Standards which will go a long way in saving valuable foreign exchange, which the Country is forced to incur on account of import of Reference Standards of life saving drugs. IPC for the first time has come out with IPRS Impurities, which in turn will help in generating more revenue and saving foreign exchange.

During the year, the Indian Pharmacopoeia Commission was successful in coming out with additional 24 IPRS and 22 Impurities Standards. 20 new Botanical Reference Substances are under process to be developed as Botanical Reference Standards. 28 new Phytopharmaceutical Reference Standards are under process to be developed as Phyto Reference Standards. The Commission has procured high end scientific and technical instruments which are essential to cope up with international parameters of efficiency, efficacy and quality of drugs.

During this period, 35 new drugs samples were received from the office of Drugs Controller General (India) for verification and 34 new drugs samples were reported. A total of 50 port samples were received from Central Drugs Standard Control Organization (CDSCO) for analysis. Out of which reports of 40 samples were submitted to the respective CDSCO Offices. 3443 Survey samples were analysed and reported through AKS software.

The Reference Substance Division (RSD) of Indian Pharmacopoeia Laboratory has distributed/ sold 2928 IPRS vials worth Rs. 87.84 lakhs and 111 Impurities Standard worth Rs. 4.44 lakhs.

Further, 288 vials of IPRS worth Rs. 8.64 lakhs and 22 Impurities vials worth Rs. 0.88 lakhs were supplied to Government authorities free of cost.

National Formulary of India (NFI)

The Commission brought out the 5th edition of NFI in the year 2015. The book was released by the Minister of Health & Family Welfare on 14/11/2015. Several new chapters, appendices, revised chapters and revised appendix and introduction in all chapters have been included. It is expected that there will be 32 chapters and more than 450 monographs. The comments obtained on the pre-print version will be reviewed by the experts and will later be incorporated in the final print version. The Commission is working to promote the rational use of generic drugs. The 5th edition of National Formulary of India, the book of reference, is for the use of clinicians, pharmacists and nurses.

Pharmaco-vigilance Programme of India (PvPI)

The Health & Family Welfare Minister, Shri J. P. Nadda, inaugurated the "38th annual meeting of National Pharmaco-vigilance Centres participating in the WHO Programme for International Drug Monitoring" which was held in collaboration with the WHO. The meeting was jointly hosted by IPC, National Coordination Centre-Pharmaco-vigilance Programme of India, Ministry of Health & Family Welfare and the WHO Country Office. In this meeting, 150 International participants from 57 countries participated to discuss the various issues on Pharmaco-vigilance and to make appropriate recommendation to WHO.

As an important outcome of the meeting, IPC has been recognized as the first WHO Collaborating

Centre for safety of medicines and vaccines in the South-East Asia Region.

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 activities which aim at reducing the availability of illicit drugs within the country come under the purview of the Narcotics Control Bureau under the Ministry of Home Affairs and the Department of Revenue as the administrator of the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988. The demand reduction activities focus upon awareness building, treatment and rehabilitation of drug using patients. These activities are run by the Ministry of Social Justice and Empowerment as the nodal Ministry and to some extent by the Ministry of Health & Family Welfare.

The Ministry of Health & Family Welfare operates a limited Drug De-addiction Programme by providing financial grants for augmenting post abuse treatment facilities in select Central Government hospitals/institutions and the Government hospital/institutions in North-East States. Under this programme, a National Nodal Centre, the "National Drug Dependence Treatment Centre (NDDTC), Ghaziabad (U.P.)", has been established under the All India Institute of Medical Sciences (AIIMS), New Delhi. The NDDTC receives regular annual recurring grant-in-aid from the Ministry. Other institutions receiving regular annual recurring financial assistance under this programme are PGIMER, Chandigarh and NIMHANS, Bengaluru. The purpose of these centres is not only to provide de-addition and rehabilitation services to the patients but also to conduct research and provide training to medical doctors in the area of drug de-addiction.

13.5 NATIONAL DRUG DEPENDENCE TREATMENT CENTRE (NDDTC), ALL INDIA INSTITUTE OF MEDICAL SCIENCE, NEW DELHI

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

The Centre is 50 bedded and offers clinical care through out-patient and in-patient services for drug dependent persons and runs three Specialty Clinics - Tobacco Use Cessation, Adolescent Drug Use, and Dual Diagnosis (patients having problems of Substance Use Disorder and Psychiatric Illness). Presently, the Centre operates two community based clinics in two urban slums, Trilokpuri and Sundar Nagri in East Delhi.

Various treatment modalities are being used in the Centre viz. medical interventions, group and individual psychotherapy sessions and family counselling. Efforts have been made to shorten hospital stay, encourage brief therapies, improve

treatment adherence through supervised long-term medication distribution over flexible and extended hours. This enables the patients to remain in the treatment programme and attend to their jobs and report to the hospital without missing work. The choice of pharmacotherapy i.e. long-term medicines for free distribution has also been widened.

During the period from 1.4.2015 to 31.12.2015, a total of 75,297 patients were seen in OPD, of whom 4,945 were new cases and 70,352 were old cases of whom 775 persons were admitted in the ward.

Nine Capacity building exercises for 104 non specialist medical doctors working in district hospitals on `Management of Substance Abuse and Dependence' were coordinated and conducted by the Centre in six institutions in the country through funding by the Ministry of Finance. Trainings of health professionals from Bhutan, Nepal, and Bangladesh were carried out. The Centre is also conducting trainings for several categories of professionals like Medical Doctors, Nurses, Programme Managers, Counsellors, Data managers, NGO staff providing 'Opioid Substitution Treatment (OST)'. Centre's faculty acted as a resource person in various survey and training programmes conducted by other countries as well as government of India organisations viz. National AIDS Control Organisation (NACO); CHILDLINE, India etc. The Centre contributed significantly for developing curriculum for training for Child Drug Addiction Treatment.

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

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

The National Drug Dependence Treatment Centre has taken further stride in clinical services, teaching and research areas by starting a new specialized course in "DM-Addiction Psychiatry", from 1st January, 2016. The recruitment for the first batch has already been done through rigorous system as is done for other academic courses, at AIIMS.

The clinical services, related to new OPD registration, follow up visits in OPD, admission and discharges of patients is now carried out through fully computerized facility and further expansion to serve day to day need is in process. Telemedicine unit is underway and will soon start its operation. A website is also soon going to start for teaching and training purposes for health personnel in various aspects of mental health and drug abuse and dependence.

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 in-patient section, out-patient department and a community clinic at Kharar, Boothgarh and Ropar in the State of Punjab. In 2015, an Urban Outreach Clinic was started in District Hospital, Ropar in

Punjab. In DDTC, nearly 12059 new and follow up patients were seen in the out-patient service and 251 patients admitted to the ward. Counseling sessions were held with nearly 14244 patients. Laboratory services were provided to 4294 patients. A total of 325 yoga sessions and 350 art of living sessions were also provided to patients. In community services, 15 camps were conducted and a total of 885 patients were seen. Various training programmes have been initiated for health professionals. A number of original research were carried out in areas relevant to alcohol, drug abuse and dependence. About 25 research publications have come out from research conducted at DDTC and published in reputed national and international scientific journals. Post-doctoral course i.e. DM in Addiction Psychiatry has been running since January, 2014. This is the first such course in the country which will create a new cadre of de-addiction specialists.

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

13.7.1 The Centre for Addiction Medicine (CAM) has a comprehensive clinical service with 3 days of out-patient services per week and 24X7 in-patient and emergency services. CAM provides a comprehensive treatment programme consisting of individual and family assessment, individually tailored treatment which includes pharmacological treatment of withdrawal and craving, long term prevention of relapse, individual & group counseling, family counseling and intensive aftercare.

The CAM has registered 2086 new patients and 8643 patients in out-patient follow up over the period of 8 months from April to November, 2015. 739 patients were admitted to the CAM in-patient ward during the above period for in-patient treatment.

The toxicology lab at the Centre for Addiction Medicine has conducted 8539 tests during the above period which includes testing for all substances of abuse and other drug related tests.

A multi-disciplinary team consisting of Psychiatrists, Psychiatric Social Workers, Psychologists, Follow-up Counselors, Community Social workers, Yoga Therapist, Occupational Therapist, Tobacco Cessation Clinic and a toxicology lab has been formed in NIMHANS, Bengaluru. Given below is the summary of workshops, training programmes and other activities conducted by the team.

13.7.2 Follow-Up/Aftercare Counsellors team

The team of Follow up Counsellors besides attending to OPD, make phone calls, send SMS as reminder for patients for follow up consultation and also make home visits to meet patients who have not come for follow-up for more than 3 months. The total no. of 9307 phone calls and around 15745 SMS were made to patients during the above period. The counselors have made 205 home visits during the above period. There is an increase of around 11% of patients coming for follow up and the status of 40% of patients is known after the follow up counselors have started calling them and sending SMS.

13.7.3 Virtual Learning Center, NIMHANS

The mission of VKN NIMHANS ECHO is to build workforce and provide coordinated quality care in the area of addiction and mental health by linking through a cost-effective modern technology. Through this weekly tele-health session, community healthcare professionals get connected to the multi-disciplinary team of Centre for Addiction Medicine.

The ongoing weekly NIMHANS ECHO tele Health sessions, conducted through multi-point videoconferencing, consist of component of both

case based learning i.e. case presentations by community practitioner or "spokes" combined with guided practice by multi-disciplinary expert team at the "hub (NIMHANS) and didactic sessions by hub experts. The doctors also present clinical cases and seek clarification regarding standard management from the multi-disciplinary team as well as peers who have logged in simultaneously. The guided practice of case management strengthens the confidence and enhance the skills of the practitioner. Patients also get the best treatment in their own community without travelling to a distant Specialty Centre situated in big cities. The live (synchronous) session is integrated with an e-learning (asynchronous) module certification for the participating practitioner.

Over the last six months 500 health professionals form India and neighboring countries, participated for 30 online LIVE tele-Health sessions. On average, 30 speakers participated in each session. There were about 2000 man hours of participation for this weekly session. Fifty complex health disorders are being co-managed with the spokes from various region of India. There is significant increase in ability to diagnose, decide evidence based treatment and handling complications among the participants. More than 100 participants received the e-certificate for completing the online modules. The recorded expert didactic videos available on the website have been watched by 2556 viewers with 10000 minutes of watch time.

13.8 MEDICAL STORE ORGANIZATION (MSO)

Medical Store Organization is a century old organization which consists of seven Medical Store Depots located at Mumbai, Kolkata, Chennai, Karnal, New Delhi, Hyderabad and Guwahati under the Directorate General of Health Services.

The main function of Medical Store Organization is to procure, store and supply medicines to about 1800 indenters through its seven GMSDs. The MSO is also storing and distributing the medicines of Cold Chain Vaccines for National Programmes like T. B., Family Welfare Programme, Anti Leprosy drugs, NVBDCP, NLEP, preparedness of Pandemic (Influenza A H1N1) and PPE Kits for Ebola etc.

The MSO has also arranged for procurement and immediate medical relief supply of essential life-saving medicines for earth quake of Nepal; Quadrivalent Meningococcal Meningitis Vaccine (QMMV); Swine Influenza Vaccine (SIV) for Haj Pilgrims; Yellow Fever Vaccine for CRI, Kasauli; and ACT-AL & Miltefosine Capsules for NVBDCP during 2015-16.

The new combined Generic Drug formulary of 1165 Molecules for MSO/CGHS & Chennai Government Hospitals containing 2000 formulation has been finalized.


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