Chapter 14

Quality Control In Food & Drug Sector, Medical Stores

14.1 FOOD SAFETY & STANDARDS AUTHORITY OF INDIA (FSSAI)

The Food Safety & Standards Authority of India (FSSAI) has been established under the Food Safety & Standards Act, 2006, as a statutory body for laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption. The Food Safety and Standards Act, 2006 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 Food Safety and Standards Act, 2006.

Emphasis of the new law

- Towards high degree of consumer confidence in quality & safety of food.
- Self compliance by Food Business Operator.
- Regulations of Novel Food, Dietary Supplements, Nutraceuticals, other Health Food products and different drinks which are hitting market, frequently.
- Training and Capacity building for almost all stakeholders, especially Food handlers.
- Risk analysis, assessment, communication and management given due importance.
- Promotion of General awareness about Food safety and Food standards.

Activities

Enforcement Division: FSS Act, 2006 is being implemented by all States/UTs Government w.e.f. 5th August, 2011. States/UTs Government have appointed Food Safety Commissioners, notified Designated Officers, Adjudicating Officers and Food Safety Officers for respective areas within the State/UT.

FSSAI has empanelled Twelve Inspection/Auditing Bodies and 89 Individual for Inspection/Auditing of Food Business Operator for Food Safety Management System. FSSAI has notified 68 Nos. of Private Food Testing Laboratories which are accredited by National Accreditation Board for Testing Laboratories, New Delhi for analysis of food samples.

Media (Print and Electronic): A simple Strategy of Communication was adopted by Food Safety and Standards Authority of India (FSSAI) along with its empanelled agencies, finalized and released advertisements through Directorate of Audio Visual Publicity (DAVP) on various mediums of mass media in multilingual mode across the country. Advertisements on various topics viz licensing, misleading claims & Consumer awareness were released through Newspapers Magazines/souvenirs, Hoarding and Banners etc. Radio Jingles were broadcast on FM Gold and other channels of All India Radio.

Imports: During January-November 2012, the total quantity of food imports from the ports manned by FSSAI viz. Chennai, Delhi, Kolkata and Mumbai was 65,24,500.54 MTs & the value in INR was 30,599.88 crore.

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

International Cooperation, WTO/SPS/TBT matters: India is the signatory of Sanitary and Phytosanitary (SPS)

Agreement and Technical Barriers to Trade (TBT) Agreement of the World Trade Organization (WTO). The Food Safety and Standards Authority of India (FSSAI) is a statutory regulatory body and the draft mandatory standards prepared by FSSAI need to be notified to the WTO by giving 60 days' time before they are finally notified.

Memorandum of Understanding (MoU) with other countries: Food Safety and Standards Authority of India (FSSAI) has signed a Memorandum of Understanding with the Food and Consumer Product Safety Authority, Ministry of Economic Affairs, Agriculture and Innovation, Kingdom of the Netherlands on Cooperation in the field of Food Safety.

Quality Assurance: 15 Manuals on Method of Analysis of Food was finalized and subsequently approved by the scientific committee and further placed before the panels for finalization:-

1. Analysis of metals
2. Analysis for Food Additives
3. Beverages, Sugars and sugar products and Confectionery
4. Cereal and Cereal Products
5. Manual of Methods Spices and Condiments
6. Meat & Meat Products and Fish & Fish Products
7. Milk and Milk Products
8. Mycotoxin
9. Oils and fats
10. Pesticide Residues Analysis in Food
11. Fruits and Vegetables Products
12. Microbiological testing in foods
13. Antibiotics and Hormone Residues
14. Manual on "General Guideline on Sampling"
15. Method of Testing of Alcoholic Drinks

Product Approval: MoU has been signed on "Development of Guidelines for making available quality and safe food in schools" with the Nielson India Pvt. Ltd.

Surveillance Division

1. **Presentation from EU Delegation**: A Delegation from EU visited and held a meeting on Agri Food Trade between Europe and India on 18th July, 2012.
2. **Reward Scheme**: Food Safety and Standards Authority of India has announced a reward scheme (Rs.500/-) for information on cases of Mislabeled Food and Misleading Advertisement/ Extravagant Claim.

Training at International Level

The Food Safety and Standards Authority of India (FSSAI) conducted training programme/study tour of 14 Senior Governmental officials involved in food control in Bangladesh on functioning of the Food Authority in India during 18-23 June, 2012.

14.2 CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (CDSCO)

Introduction

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

Mission of CDSCO

The Central Drugs Standard Control Organization (CDSCO) has defined its mission as 'to safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.'

CDSCO has six zonal offices situated at Mumbai, Ghaziabad, Kolkata, Chennai, Ahmedabad and Hyderabad and three sub-zonal offices at Bangalore, Chandigarh and Jammu. Its headquarter is situated at New Delhi.

The import of the drugs, cosmetics and medical devices is permitted through the designated ports specified under

the Drugs and Cosmetics Rules, 1945. The Port Offices of CDSCO are situated at notified port of entries. These Port offices are at Mumbai (Sea and Airport), Nava Sheva (Sea Port), Kolkata (Sea and Airport), Chennai (Sea and Airport), Hyderabad (Airport), Delhi (Airport), Kochi (Sea Port) and Ahmedabad (Air Port), Bangaluru (Air Port), Goa (Sea and Air Port) and exercise control over the quality of drugs, cosmetics and medical devices imported into the country at the time of their import.

There are six functioning central drug testing laboratories under CDSCO, situated at Kolkata, Mumbai, Chennai, Guwahati, Chandigarh and Kasauli. One new laboratory at Hyderabad is coming up. The testing capacity of these labs is around 8,000 samples per year.

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

Regulatory Functions Performed at CDSCO

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

Functions discharged at CDSCO head quarters:

1. Grant of approval to manufacture and / or import new drugs and to conduct clinical trials with regulatory control as per provisions of the Drugs and Cosmetics Act and Rules.
2. Approval of the licenses to manufacture certain categories of drugs as Central License Approving Authority (CLAA) i.e. Blood Banks, Large Volume Parenterals, Vaccines / Sera, r-DNA derived products, in-vitro diagnostic kits for detection of HIV1 & 2, HCV & HBsag and notified medical devices and its control as per provisions of the Drugs and Cosmetics Rules.
3. 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 in the country and regulatory control over the quality of these products imported into the country.
4. Grant of Test Licences for import of drugs for the purpose of examination, test and analysis.
5. Grant of licences to import drugs by Government hospitals or Medical Institutions for the use of their patients.
6. Convening the meetings of Drugs Technical Advisory Board (DTAB) to discuss matter arising of the administration of the Act and recommended amendments to the Drugs and Cosmetics Rules.
7. Convening the meetings of the Drugs Consultative Committee (DCC) to secure uniformity throughout (India) in the administration of this Act.
8. Recommend banning of drugs considered harmful or sub-therapeutic under section 26A drugs and Cosmetics Act.
9. Conducting workshops and training programs in respect of various issues related to quality control of drugs.

Functions of the Zonal / Sub-Zonal Offices

1. Inspection of manufacturing premises jointly with State Governments for drugs covered under the CLAA Scheme i.e. I V Fluids, Large Volume Parenterals, Vaccine & Sera, Blood & Blood Products, r-DNA products (Biotech Products) etc. for the purpose of grant / renewal of licenses.
2. Inspection of private testing laboratories in coordination with the State Drug Inspectors for approval of these laboratories for carrying out tests on drugs / cosmetics on behalf of the licenses.
3. Inspection of manufacturing facilities of the firms under WHO GMP Certification Scheme.
4. Inspection of firms for capacity assessment and other provisions at the request of the Central Government.

5. Inspections to investigate complaints received from various forums.

6. Coordination with the State Drug Controllers to sort out problems involved in the investigations of drugs manufactured in one State and declared not of standards quality in another State and other such matters.

7. Launching of prosecutions in cases detected by the Zonal offices.

8. Drawing of sample of drugs for test and analysis by the Government Analysts.

Functioning of Airport & Seaport Offices

To control the import of drugs by checking documents (bill of entry) and drawing of samples on random basis to check their quality and verify shipping bills of export of drugs as requested by the customs authorities.

Manpower Strength of CDSCO

The CDSCO has presently 121 regular regular officers, namely, the Drugs Controller General (India), 14 Deputy Drugs Controllers, 13 Assistant Drugs Controllers, 65 Drug Inspectors, 13 Technical Officers, 9 Senior Technical Assistants and 6 Technical Assistants.

Recommendation for selection of 90 Drug Inspectors have already been received from the UPSC and they are expected to join shortly. The CDSCO has also engaged 234 contractual staff to assist the organization in coping with the work load at the Head quarter as well as zonal offices. 31 posts of Assistant Drug Inspectors have also been advertised by the Staff Selection Commission and their recruitment is presently under process there. Further augmenting of manpower of CDSCO is also being contemplated in view of its ever increasing workload.

Expansion of CDSCO Infrastructure

New Port offices at Bangaluru and Goa have been established to facilitate import and export of the drugs from Karnataka and Goa.

1. Training / workshops conducted with WHO support in the country

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

i. Six day workshop at CDL, Kasauli and Delhi on Advanced Good Manufacturing Practices training for Drugs Inspectors and reviewers.

ii. Two workshops on effective recall and preparation of standard operative procedures were conducted at Delhi.

iii. Workshop on design and review of clinical trial protocol, ethical oversite and role of Biostatistician in clinical studies for Drug Inspectors and reviewers.

iv. Workshop for ethical over site and monitoring of clinical trials.

v. Advanced regulatory inspections workshop using risk management approach.

vi. Observed audit of public and private manufacturers for assessment of performance of GMP inspectorate.

2. International training / workshops

CDSCO officers attended International Workshops and training programs especially in respect of Biological standardization and clinical trials to ensure that standards employed in India are world class.

CDSCO officers were also a part of observed audit conducted at Tehran under WHO.

Regulatory Activities at the Headquarter

1. Quality Control over import of drugs and cosmetics

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

During the year 2012, the office of Drug Controller General India DCG(I) granted 432 registration certificates in respect of manufacturers of the drugs who intend to export their products to India. During the same period, 3522 licences in Form 10 for import of drugs in to the country were also granted.

Permissions are also granted for import of small quantities of drugs for test and analysis in Form 11 of the Drugs and Cosmetics Rules. During the year 2012, the office of DCG(I) granted 10,300 test licences for the import of drugs in small quantities for test and analysis.

Drugs and Cosmetics Rules were amended to incorporate a system of registration of cosmetics imported into the country and the registration of cosmetics imported into the country will become mandatory from 1st April 2013.

2. 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 under the provisions of the Drugs and Cosmetics Rules. The quality control over these devices is regulated through the system of registration and import licences as applicable for drugs. The manufacture of the notified devices is approved by the DCG(I) as Central Licence Approving Authority.

During the year 2012, the office of DCG(I) granted 339 registration certificates of the manufacturers of the Medical Devices who intended to export their medical devices to India. During the same period, 749 licences in Form 10 for import of medical devices to the country were also granted. Apart from this, in 117 permissions for import of Medical Devices and diagnostics devices for test and analysis were also granted.

The manufacture of the notified devices is approved by the DCG(I) as Central Licence Approving Authority under the Drugs and Cosmetics Rules. During the year 2012, the office of DCG(I) granted CLAA approval in the 99 cases in respect of grant of manufacturing licences for manufacture of medical devices.

Permissions are also granted for the conduct of clinical trial over medical devices in the country. Six Medical Devices Advisory Committees have been set up to review non-clinical as well as clinical trial data furnished by the applicants for the approval of marketing a new medical device in the country or to conduct clinical trial and give recommendation thereof. During the year 2012, the office of DCG(I) granted permission in 4 cases for clinical trials in respect of medical devices.

3. 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 Schedule Y 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 definition of the new drug also includes Fixed Dose Combinations which are required to be marketed for the first time in the country. 12 New Drug Advisory Committees have been constituted to examine the applications for approval of new drugs and clinical trials of new drug substances.

During the year 2012, permission to import finished formulations of vaccines was given in 33 cases and permissions for manufacture of vaccines as New Drugs was granted in 19 cases including recombinant and veterinary products. During the same period, in 8 cases new licences for manufacture of vaccines were also granted.

4. Clinical trials

Clinical trials of pharmaceuticals products are conducted on human subjects in the country to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics), and /or adverse effects with the object of determining their safety and /or efficacy. The Drugs and Cosmetics Rules provide that clinical trials for a new drug, whether for clinical investigation or any clinical experiments are required to be conducted under and in accordance with the permission granted by the Drugs Controller General (India). The applications for grant of permission to conduct clinical trials on new drugs in the country are examined by the office of DCG(I) for the purpose of grant of no objections for the conduct of clinical trial. During the year 2012, the office of DCG(I) granted no objections for conduct of clinical trials on new drugs in 42 cases. During the same period, no objections in 33 cases for conduct of clinical trials on vaccines were also permitted.

Office of DCG(I) also grants permissions for conducting bioequivalence studies in chemically equivalent drug formulations to study whether they produce identical therapeutic response in patients.

The office of DCG(I), during the year 2012 granted permissions in 15 cases of bioequivalence studies related to new drug approval.

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

I. Twelve New Drug Advisory Committees (NDACs) have been constituted for evaluation of clinical trial proposals of new drug substances excluding Investigation New Drugs (INDs).

II. All IND applications are evaluated by the IND committees.

III. Registration of clinical trial in ICMR registry has been made mandatory since 15.6.2009.

IV. Every approval / permission for conducting clinical trials also, inter alia, now includes a condition that in case of study related injury or death, applicant will provide complete medical care as well as compensation for the injury or death and statement to this effect should be incorporated in the informed consent form. Further in case of such injury or death the details of compensation provided should be intimated to the office of DCG (I).

V. Guidelines for conducting Clinical Trial inspection of site and sponsor /CROs have been prepared and posted on CDSCO website.

The Drugs and Cosmetics Rules are also being amended on the recommendations of DTAB to make mandatory provisions in respect of the following:

a. To incorporate a new rule for provisions for payment of compensation in case of clinical trial related injury or death

b. To incorporate New Appendix in Schedule-Y mentioning the procedures and methods of providing compensation.

c. To amend the Informed Consent Format to capture the details of address, qualification and occupation, and annual income of the subject.

d. To amend patient information sheet to mention that the applicant will provide compensation in case of trial related injury or death.

e. To expand responsibilities of Ethics Committees to ensure that committees review and recommend for compensation in Clinical Trial related injury.

f. To incorporate Rule to have authority for clinical trial inspection by CDSCO assisted by concerned state authority.

g. To incorporate Rules and Schedule Y- 2 for registration of Ethics Committees.

h. To incorporate amendment in Schedule-Y specifying that clinical trials are required to be conducted at sites which have their own Ethics Committee. However, for conduct of Bio-availability & Bio-equivalence study of drug approved in the country and/or elsewhere (for new drug approval purpose), Ethics Committee approval may be obtained from Independent Ethics Committee of same areas where the site is located.

5. Blood Banks: Licences for the Blood Banks are also granted by the office of DCG(I) as Central Licensing Approving Authority. During the year 2012, fresh licences were granted in 183 cases. Endorsement of blood components on the existing licences were issued in 180 cases during this period.

6. Amendments to the Drugs and Cosmetics Rules, 1945

Drugs and Cosmetics Rules, 1945 are amended with the recommendations of DTAB, from time to time to make it responsive to the present day needs of the society. The following amendments have been incorporated during the year 2012.

i. Amendment of rule 97 for labeling of withdrawal period on the labels of medicines for veterinary use vide GSR 28(E) dated 17.01.2012.

ii. Amendment of rule 127 to include titanium dioxide coated mica pearlescent pigments and use of colours in disinfectants vide GSR 76(E) dated 08.02.2012.

iii. Loan licensing system for drugs covered under CLAA items i.e. whole human blood and blood products, large volume parentrals, Sera and Vaccines and recombinant vide GSR 574(E) dated 17.07.2012.

iv. Inclusion of Goa port, Marmugao port in Goa and Air ports of Goa and Bangaluru as port of entry for drugs vide GSR 575(E) dated 17.07.2012.

The Government of India also published the following notification containing draft rules inviting objections and suggestion from the public for the purpose of finalization of the draft rules for amending the Drugs and Cosmetics Rules, 1945.

i. Insertion of a new Schedule H1 containing antibiotics and certain habit forming drugs and anti-TB drugs vide GSR 228(E) dated 20.03.2012.

ii. Rules relating to permission to conduct clinical trial and inspection of clinical trial sites vide GSR 572(E) dated 17.07.2012.

iii. Rules relating to registration of Ethics Committees supervising clinical trials vide GSR 573(E) dated 17.07.2012.

iv. Rules relating to grant of manufacturing licence for single ingredient drugs in generic name only vide GSR 748(E) dated 05.10.2012.

7. Drugs Technical Advisory Board: 61st meeting of the Drugs Technical Advisory Board, a statutory body under the Drugs and Cosmetics Act, 1940 to advice the Central Government on technical matters arising out of the administration of the said Act and Rules made thereunder, were held on 24.07.2012.

8. Drugs Consultative Committee: 44th meeting of the Drugs Consultative Committee, a statutory committee 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, was held on 20.07.2012 at Delhi.

9. Banning of Drugs: The Drugs and Cosmetics Act, 1940 provides powers to Central Government to prohibit manufacture etc., of any drug or cosmetic in public interest. Drugs about which reports are received that these are likely to involve risk to human beings or animals in the present context of the knowledge are examined for their safety and rationality through the expert committees and DTAB. Manufacture and sale of the drug if considered necessary is prohibited by Central Government in public interest through a gazette notification. During the year 2012 the Government of India has prohibited the 'serodiagnostic test kits for diagnosis of tuberculosis' through notification vide GSR 432 (E) 07.06.2012 and GSR 433(E) dated 07.06.2012 under Section 26A of the Drugs and Cosmetics Act.

10. Statutory Directions under section 33P of Drugs & Cosmetics Act, 1940

The issue of cancellation of licenses by the State Licensing Authorities for manufacture of drug formulations falling under the purview of the new drugs especially in respect of fixed dose combinations. In the light of the observations made by the Department Related Parliamentary Standing Committee in its 59th Report on the functioning of CDSCO was discussed in the Drugs Consultative Committee in the meeting held on 20th July, 2012. It has been reiterated in the meeting that such license for new drugs for unapproved FDCs must not be granted by any State Licensing Authorities. The State drug licensing authorities had also been issuing licenses of drug formulations along with the brand names which was not in line with the spirit of the provisions of the Drugs & Cosmetics Rules. Hence, the Ministry issued statutory directions under section 33P to the State Governments on 1.10.2012 on the following issues:

- Not to grant licenses for manufacture for sale or for distribution or for export of new drugs, except in accordance with the procedure laid down under the said rules i.e. without prior approval of the Drugs Controller General (India).
- To grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only.

11. Overseas Inspections: To ensure that the foreign manufacturers exporting drugs to India conform to Good Manufacturing Practices, it was decided to conduct overseas inspections of the manufacturing sites wherever considered necessary. During the year 2012, in February, 2012, four firms in China were inspected. Three firms were manufacturing bulk drugs and one was manufacturing diagnostics kits.

12. Pharmacovigilance Programme: A Pharmacovigilance Programme of India (PVPI) was launched on 14.07.2010 to capture Adverse Drug Reactions data in Indian populations in a systematic way. The programme is being coordinated by the Indian Pharmacopeia Commission, Ghaziabad. The main objective of the programme is to monitor Adverse Drug Reactions (ADRs) in Indian population. Currently 60 medical colleges are functioning as Adverse Drug Reaction (ADR) centers under the programme. More than 20,000 ADRs have been collected so far under this programme.

13. National Regulatory Authority (NRA) assessment by WHO

India has a Rs. 19,000 crore worth vaccine industry which is exporting two third of the vaccines manufactured in the country while one third is domestically consumed. The major international procurement agencies for vaccines are WHO, UNICEF, Gates Foundation, Clinton Foundation etc. which purchase vaccines for use across

the world. These agencies procure vaccines on the basis of assurance by the WHO that these are of high quality and safe and efficacious for use.

During the year 2012-13, the CDSCO has successfully crossed a landmark in the quality control when a 16 member International team headed by Mr. Lahouari Belgharbi of WHO, after conducting an extensive four day audit from 10-14 December, 2012 in respect of the vaccine clearance procedures adopted by the National Regulatory Authority (NRA) i.e. office of the Drugs Controller General India, was satisfied that the procedures adopted by the NRA are stringent enough and the international community can be assured that the vaccines permitted for manufacture by the said authority are of high quality, safe and efficacious. The team had regulatory officials from USA, France, Sweden, Switzerland, China, Indonesia, Thailand and Iran. The major parameters for assessment were related to Institutional Development Plan, Quality System, independence of regulatory authorities, recall systems etc. This has brought recognition that Central Drug Regulatory System of India is at par with International standards. The prior technical support provided by WHO as a part of their technical support to the Indian Regulatory System had provided trainings to the Indian Regulatory officials, which helped in a big way in strengthening and bringing the Indian drug regulatory system at par with the International Standards.

The De-briefing meeting of WHO officials with the Ministry of Health & Family Welfare held on 13.12.2012.

14.3 INDIAN PHARMACOPOEIA COMMISSION (IPC)

The year in consideration is of great challenges and expectations for the Indian Pharmacopoeia Commission. In order to fulfill its main objectives, the Commission has to focus on its priority works with limited resources. By accepting these challenges, after successfully publishing the Addendum 2012 to Indian Pharmacopoeia 2010, the book of standards for drugs, one of the important works to be accomplished was to publish IP 2014. The work on the book is expected to be completed by the end of March, 2013.

The 4th edition of National Formulary of India (NFI), the book of reference for the use of clinicians, pharmacists and nurses, was published in 2011 after a gap of three decades. The Apex Body and Core Committees for NFI have been constituted for bringing out the 5th edition of NFI. The work of publishing of the 5th edition of NFI is currently under way in IP Commission.

During the year, the Indian Pharmacopoeia Commission was successful in achieving the target of coming out with 178 Indian Pharmacopoeia Reference Substances (IPRS) by 31.12.2012 and is on way to achieve the target of 250 IPRS by 31/03/2013. The Commission is striving vigorously for preparing, certifying and distributing Indian Pharmacopoeia Reference Standards which will go a long way to save valuable foreign currency which the Country is forced to incur on account of import of Reference Standards of life saving drugs.

Under the Pharmacovigilance Programme of India, which was recast and entrusted for implementation to the Indian Pharmacopoeia Commission, approximately 40,500 Adverse Drug Reactions (ADR) have been collected till 31/12/2012. Out of these 30,000 ADRs have been committed to Uppsala Monitoring Centre, Sweden. During the year under this programme, the Commission has enhanced the number of Adverse Drug Reaction Monitoring Centres from 60 to 90.

The Commission is briskly analysing and validating the Certificate of Analysis (COA) of new Drugs. The number of samples of new drugs tested has gone upto 172 by the end of December, 2012. During the year, the Commission has procured high end scientific and technical instruments which are very essential to cope up with international parameters of efficiency, efficacy and quality of drugs.

14.4 DRUG DE-ADDICTION PROGRAMME (DDAP)

The Constitution of India under Article 47 enjoins that the state shall endeavor to bring about prohibition of the consumption of intoxication drinks and drugs, which are injurious to health. The activities to reduce the drug use related problems in the country could broadly be divided into two arms - supply reduction and demand reduction. The supply reduction activities which aim at reducing the availability of illicit drugs within the country come under the purview of the Narcotics Control Bureau under the Ministry of Home Affairs and the Department of Revenue as the administrator of the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988. The demand reduction activities focus upon awareness building, treatment and rehabilitation of drug using patients. These activities are run by the Ministry of Social Justice and Empowerment as the nodal Ministry and to some extent by the Ministry of Health and Family Welfare. The Ministry of Health & Family Welfare operates a limited Drug De-addiction Programme by providing financial grants for augmenting post abuse treatment facilities in select Central Government hospitals / institutions and the Government hospitals / institutions in North-East States. Under this programme, a national nodal centre, the "National Drug Dependence Treatment Centre (NDDTC), Ghaziabad (U.P.)", has been established under the All India Institute of Medical Sciences (AIIMS), New Delhi. The NDDTC receives regular annual recurring grants-in-aid from the Ministry. Other institutions receiving regular annual recurring financial assistance under this programme are Dr. Ram Manohar Lohia Hospital, New Delhi, Sucheta Kriplani Hospital, New Delhi, PGIMER, Chandigarh, JIPMER, Puducherry and NIMHANS, Bangalore. The purpose of these centres is not only to provide de-addiction and rehabilitation services to the patients but also to conduct research and provide training to medical doctors in the area of drug de-addiction.

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

Drug De-addiction & Treatment Centre (DDTC), Department of Psychiatry, PGIMER, Chandigarh was established during 1988-89. Currently, it has a 20-bedded in patient section, Out Patient Department (OPD) and a Community Clinic at Kharar, Punjab. Till date more than 9000 new patients have been registered and more than 60,000 follow up visits of old patients have been registered at the DDTC OPD. Nearly 5000 patients have been treated as in patients. On 24th March 1998, DDTC extended its service directly at the community level by starting its Community Clinic at the Civil Hospital, Kharar (Punjab). Patients are examined and treated then and there, with the provision for referral for the more sick patients to the DDTC inpatient section. During the year under review (1st April, 2012 till 30th September 2012), the Centre treated 186 subjects as inpatients and registered 462 subjects as new cases in the DDTC OPD. The total number of subjects seen at the Walk-in-Clinic is 1098 and 3142 follow-up visits were registered in the DDTC OPD in 2012. The institute is running a social assessment and rehabilitation service for the inpatients and outpatients. This includes psychosocial assessment and therapy sessions at the Institute and in the community and efforts at social-occupational rehabilitation in the community also. The centre conducted weekly clinic at the Kharar Civil Hospital and launched monthly De-addiction camps in the villages. The larger aim of these camps is to spread awareness among the masses about the problem of substance use and the sources of help and treatment available in the community. In 2012, DDTC held 3 such camps and 21 other similar extramural activities. The Centre has conducted training in various aspects of drug abuse for many categories of staff and personnel from both within and outside the Institute. The Centre has also developed material for healthy education and training. Besides, the Centre is undertaking original research in issues related to substance use disorders.

Actual Data of Drug De-Addiction & Treatment Centre, PGIMER, Chandigarh

	1st April- Projected 30th Sept. 2012 upto 31st March 2013	
A. 1. Total no. of patients in Walk-in-Clinic	1098	2196
2. Total no. of patients worked up (evaluated in detail)	462	924
3. Total no. of patients for follow-up visits	3142	6284
B. No. of patients admitted in Drug De-addiction Ward.	186	372
C. Drug De-addiction Laboratory		
1. No.of renal and liver function test	174	348
2. No. of TLC (Thin Layer Chromatography)	133	266
D. Social Work		
1. Intake evaluation in OPD	1098	2196
2. Psychosocial work up with admitted patients	14	28
3. Group sessions	16	32
4. Intervention – home, office, telephonic	420	840
5. Outpatient Interventions	45	90
E. Yoga Sessions	150	300
F. Art of Living sessions	122	244
G. Extension service and extra-mural activities		
1. Kharar De-addiction Clinic		
No. of new patients	66	132
No. of old patients	200	400
2. De-addiction camps	3	6
Other community awareness programs	21	42

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

The National Drug Dependence Treatment Centre (NDDTC), AIIMS which was established during the year 1987-88 and functioning at Deen Dayal Upadhyay Hospital, Hari Nagar later shifted in its own building constructed at CGO complex, Kamla Nehru Nagar, Ghaziabad started indoor facilities. Community Clinic of this centre at Trilokpuri has been functioning from August, 2003 and a mobile clinic in an urban slum area of Delhi w.e.f. March, 2007. Apart from rendering patient-care services, the centre, engaged in a number of research projects has a well equipped laboratory for both clinic and pre- clinical research and CME activities.

A. Number of patients treated

Clinical Statistics: OPD new cases -4136, OPD old cases -50086, Total no of Patients- 54222 and Total Admission- 709.

B. Laboratory Investigations for Patient Care

a) Total Number of Drugs of Abuse Screened in urine Samples: 17654

Drugs Nos.: Morphine 2207, Codeine 748, uprenorphine 2237, Detropropoxyphene 2246, Pentazocine 22, Naltrexone 24, Naloxone 219, Pheniramine (Avil)1748, Nitrazepam 2216, Diazepam 2216, Chlordiazepoxide 2216, Cannabis 337 and Cotinine 218.

b) Health Damage: Biochemical Investigations 19083, Hematological Investigations 5238, Total HIV Screened 267, HIV Positive 43 and HIV negative 224.

C. Research Projects (Ongoing)

Funded

Methadone Maintenance Treatment in India: A multi-site feasibility and effectiveness study. Anju Dhawan, Rajat Ray, Atul Ambekar, Raka Jain, Deepak Yadav, Anita Chopra. Project supported by the UNODC ROSA (2011 – ongoing). Fund: Rs. 39.0 lakhs

An assessment of pattern, profile and correlates of drug use among adolescents in India. Anju Dhawan, Ramandeep Pattanayak, Anita Chopra. Funded by National Commission for Protection of Child Rights (NCPCR) (November, 2012– March, 2013). Fund: Rs. 16.54 lakhs

Efficacy of Varenicline for smokeless tobacco use. Raka Jain, Sonali Jhanjee, Veena Jain, R Schnoll (University of Pennsylvania). Funded by National Institute of Drug Abuse (NIDA), NIH, US Government, USA (March, 2011- March, 2014). Fund: Rs.64 lakhs.

Feasibility of Transporting Urine Samples of Drug Users on Filter Paper for Screening Drugs of Abuse: A Pilot Exploratory Study. Raka Jain, Atul Ambekar, Rizwana Quraishi. Funded by ICMR (March, 2012- March, 2014). Funds: Rs. 12.5 lakhs.

Effect of Nalbuphine on Opiate Withdrawal in Rats: Behavioural, Biochemical and Molecular study. Raka Jain, TS Roy, Anju Dhawan, Funded by ICMR (March, 2012-March, 2015). Funds: Rs.46 lakhs.

Development of a web-Portal on problem of alcohol use in India. Rajat Ray, Atul Ambekar, Sanjay Gupta. Funded by World Health Organization (Geneva) (2010 – 2013). Funds: 4 lakhs

National Drug Use Survey, Maldives. Idaho Fahumy, Yaseer Wasim, Atul Ambekar, R. M. Pandey. Project of UNODC ROSA (2011-ongoing).

Global Fund Round 9 IDU-HIV Project for capacity building of cadre working towards prevention of HIV among IDUs under NACO Programme. Funded by Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) (2012- October, 2015 - Ongoing)

Non Funded

Rapid Situation Assessment of Drug and Alcohol Use at Digboi, Assam. Rajat Ray, Atul Ambekar, Rakesh Lal, Deepak Yadav. Funded by India Oil Corporation Ltd, AOD, Digboi (2010- Ongoing). All expenditure borne by Indian Oil Corp, Digboi, Assam.

Study to explore transition to injecting drug use by opioid users in North India. Atul Ambekar, Anita Chopra, Hem Sethi. Project supported by SPYM, Regional Resource and Training Centre, North, MSJE, Govt of India (2012 – ongoing).

A Pilot Study of Feasibility and Efficacy of Brief Intervention compared with Simple Advice when linked to the Brief ASSIST for Substance Use Disorders in Primary Health Care and Community Setting. Atul Ambekar, Deepak Yadav. Funded by University of Adelaide-WHO Collaborating Centre (2011-ongoing).

Training courses /Seminars/Workshops – hosted

Training Course for Medical professionals, Bhutan from 23.7.12 to 4.8.12 funded by the Department of Revenue, Ministry of Finance, Govt of India.

Training Course for Medical professionals, Bangladesh from 24th September – 6th October, 2012 funded by the Ministry of External Affairs, Govt of India.

Training programme at NIMHANS – October, 2012 under the activity "National Capacity Building of Medical Professionals on Treatment of Substance Use Disorders." Funded by National Fund For Control of Drug Abuse (NFCDA), Department of Revenue, Ministry of Finance, Govt of India.

Review-cum-refresher training workshop held from 19 – 21 November, 2012 under the project entitled "Methadone Maintenance Treatment in India: A multi-site Feasibility and Effectiveness Study."

Two Day Training of Research Investigators at four sites - Aizawl- 1-2 May, 2012; Pune - 26 & 27 November, 2012; Kerala - 13 & 14 December, 2012.

Two trainings in April and December, 2012, Delhi, under the project entitled "An assessment of pattern, profile and correlates of drug use among adolescents in India". Funded by National Commission for Protection of Child Rights (NCPCR) under the GFATM project seven Training courses for Medical Doctors and Nurses, Programme Managers, Counsellors, Data managers, NGO staff were conducted to support capacity building of medical staff as well as those providing Opioid Substitution Treatment (OST). 25-29th June; 9-13th July; 6-10th August; 30th October- 4 November; 26th -30th November; 17-21 December; 18-22 December, 2012.

Others

Faculty acted as resource persons in training programmes conducted by other organizations like OST trainings by NACO and GFATM, training of counsellors by SCERT, training of staff of NGOs by CHILDLINE, India. Clinical practice guidelines on Opioid dependence and inhalant use for Indian Psychiatric Society have been developed.

Sensitisation and orientation meetings of targeted intervention sites (NGOs) at four sites- Mumbai, Imphal, Kapurthala and Bhatinda. Monitoring visits have been made to these sites in April, 2012

Clinical practice guidelines on Opioid dependence and inhalant use for Indian Psychiatric Society have been developed.

14.7 NATIONAL INSTITUTE OF MENTAL HEALTH AND NEURO SCIENCES, BANGALURU

Centre for Addiction Medicine

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

Clinical services

The Centre for Addiction Medicine has provided comprehensive substance use cessation treatment to 1862 new patients and followed up 7170 patients during the year period April, 2012 to December, 2012. 838 patients were given inpatient treatment during the above period.

Training and training programmes

During the year Institute has conducted the following workshops:

1. During this year, there was a request from the NRHM, Govt of Himachal Pradesh to train their medical officers in drug abuse prevention and management. Faculty from the Centre of Addiction Medicine went in two batches to conduct a Workshop for medical officers of Himachal Pradesh in Shimla. Following this sensitization, it was proposed to conduct 4 training programmes for the medical officers from Himachal Pradesh to train around 50 medical officers at NIMHANS, for 15 days for each batch. Institute has already completed 3 such training programmes during the last year and trained around 32 medical officers.
2. Institute also trained medical Officers in the Southern zone "National capacity building" – Training of doctors on substance use disorders twice in the last year at NIMHANS, Bangalore.

Routine training is provided to post-graduates of psychiatry, psychiatric social work, clinical psychology and nursing from the institute. It was trained around 64 medical officers, 62 psychiatric social workers, 11 clinical psychologists and around 1022 nursing staff.

Community awareness: A community assessment of alcohol, tobacco and other drugs is being carried out in 3 urban communities. The CAM provides counseling twice a week at the Urban Mental Health Centre of NIMHANS in BTM layout. Several training programmes have been carried out for substance use management including motivation enhancement, relapse prevention, assertiveness training and the use of yoga in addiction. Pamphlets have been designed for distribution to the local community in the local languages.

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

The newly constructed women's ward is almost complete and will be ready to commence from April 2013. Institute has also initiated and sought permission for construction of two more floors to house the office and other patient related activities along with a research facility. The current office space is proposed to be extended for housing more male patients.

The toxicology lab has conducted more than 4900 tests during this period. An additional headspace was obtained for the GC-MS this year.

The CAM has also expanded its community outreach by offering services to an urban community through the NIMHANS Centre for Well-being. A lot of awareness activity is being conducted to reach out to the general public, educational institutions and workplaces in order to carry out prevention activities in drug abuse. The CAM has integrated tobacco cessation activities along with drug de-addiction activities. Several doctors and dentists have been trained through this activity. The TCC team has also conducted several programmes for students and the general public to create awareness on use of tobacco and other related products.

A clinical cohort has been set up and a cohort manager has been appointed. PDF programme have been started and three residents are doing their PDF under addiction medicine.

Research: Areas of research undertaken during the current year include a WHO multicentred study on patterns and consequence of alcohol misuse in India, ICMR study on genetics in alcohol dependence, ICMR – DHR study on intervention for partners of men with alcohol dependence. A cohort study YIMAGINE (Youth mental disorders Imaging Genetics and Interventions Network) has been proposed. Many dissertations are being carried out in the area of addiction related to imaging, toxicology, gender and community interventions.

Manual: A manual on in-depth counselling of families for alcohol dependence is under print.

14.8 JAWAHARLAL INSTITUTE OF POSTGRADUATE EDUCATION & RESEARCH (JIPMER), PUDUCHERRY

Regional De-Addiction Centre- JIPMER

Drug de-addiction services were started under the Department of Psychiatry at JIPMER in 1962. It was upgraded and designated as Regional De-addiction Centre in 1991 by Ministry of Health and Family Welfare, Government of India. Currently it functions as one of the six regional centers for de-addiction under the Ministry.

The drug de-addiction clinic is conducted every Saturday (forenoon) which registers new cases and does regular follow up of old cases. Clinic offers comprehensive psychosocial assessment and management of substance abuse disorders. Various psychological interventions like motivation enhancement therapy, group psychoeducation sessions, and relapse prevention sessions are regularly conducted for outpatient and inpatient cases. Tobacco cessation services are also made available in this clinic.

Services and facilities available at the centre include

- **Clinical services:** Outpatient based, inpatient based, community care in urban and rural area through community health camps.
- **Teaching/training:** MBBS interns, MD-Psychiatry residents, General Duty Medical Officers from various states, Nursing staff and students of Masters in Social Work and Psychology.
- **Laboratory services:** Biochemical, haematological tests and screening for HIV, Hepatitis B and C as part of assessment of health, and referral services to other specialities for investigation and management of medical complications related to substance abuse.
- **Information and Library:** for substance abuse related health education various pamphlets, videos are available in local language

Role of centre in this region

1. Providing health care services to patients through hospital and community based approaches,
2. Health education- talks on radio and talks to youth on substance use disorders delivered by faculty,
3. Manpower development in the field of de-addiction and mental health services- trains various categories of students and staff,
4. Documentation and creation of database to facilitate research in this area,
5. Assessment of substance abuse among rural elderly in collaboration with preventive social medicine.

Education

1) **Undergraduates:** During their clinical posting in the Department of Psychiatry, MBBS students are taught to identify alcohol dependence, alcohol withdrawal and on managing it. They are exposed to functioning of de-addiction clinic at the centre.

2) Other paramedical students from Psychology, Social work and Nursing branches are part of

psychiatry orientation. They are introduced to the topic substance use disorders and their prevalence.

3) **Postgradutes:** Residents doing MD (Psychiatry) are posted for 6 months during their entire course duration. They are trained on history taking for substance abuse and treating substance abuse related emergencies and managing comorbid psychiatric illnesses. They also undertake seminars, journal clubs and make case conferences. Many of them are pursuing post-doctoral thesis with research project in the de-addiction field.

4) M.Sc nursing students are also trained in field de-addiction and they are taking projects related to this field.

Continuing Medical Education

- Our faculty regularly attends conferences, workshops, seminars and training courses related to the field.
- Faculty is involved in regional networking of de-addiction services
- Lectures are delivered by faculty to nursing students from different medical colleges
- Public awareness through media is done regularly by our faculty
- as part of commitment to NDPS act, centre is planning to upgrade its services

1. Performance for the year (2012-13) [Jan 2012 to Dec 2012]

Patient Care

General Information			
1.	Total No. of beds	:	07
2.	OPD Attendance	:	1857
3.	Admission in ward	:	72
4.	Discharges	:	76

	New cases	Old cases	Total
OPD attendance:	697	1160	1857
Admitted patients:	72	-	72
Total	**769**	**1160**	**1929**

14.9 MEDICAL STORE ORGANIZATION (MSO)

Medical Stores Organization under the Directorate General of Health Services is a century old Organization. Originally, it was created primarily to meet the need of Medical Stores of the troops and Military based Hospital and to hold reserves in the event of hostilities with other countries. In 1942, the Army authorities established their own Depot and MSO came under civil administration of the Central Government. The Medical Stores consist of seven Medical Stores Depot located at Mumbai, Kolkata, Chennai, Hyderabad, Guwahati, Karnal & New Delhi. The main function of Medical Stores Organization is to procure and supply of quality medicines to its indenters at a competitive price through its seven GMSDs located at various places.

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

The MSO procures medicines as per the two formularies, one for proprietary/branded drugs (622 drugs) and other for generic drugs (1128 drugs). During 2011-12 rate contract for 611 Proprietary/ branded drugs and 127 generic drugs was available. Accordingly procurement actions were taken against the indents received from the indenters which includes CGHS Units, Central Govt. Hospitals under administrative control of DGHS, DHS Port Blair, and various Para Military Forces etc.

The Medical Stores Organization had arranged immediate medical relief supply of PPE Kits, Triple Layer Masks, N-95 Masks, Swine Flu Medicines whenever instructions received from Directorate of EMR. The Medical Store Organization had also procured and supplied Quadrivalent meningococcal meningitis vaccine and influenza vaccine for Haj Pilgrims during 2011-12.

To bring transparency and accountability in the working of MSO has entered into e-governance mode. All the indents from indenters along with the information relating to the dispatch of store have been placed on line.

As the guiding manual of MSO was very old and had lost its significance in present scenario a revised and upgraded Procurement and Operational manual for Medical Store Organization and Government Medical Store Depots was implemented with effect from 18-05-2011.

The immunization Programme is getting more complex due to addition of new vaccines in the Universal national Immunization Programme. It has been decided to improve and modernize cold chain facilities in all existing seven GMSDs so that the storage and distribution of vaccine can be undertaken more effectively. The proposal has already been approved by the Ministry and HLL was appointed for project implementation.

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

As per Inspection Report of 2008-09 of Internal Audit Wing of Ministry of Health & Family Welfare, out of the 41 Audit Para's, 16 Para's have been settled subject to verification by the next audit party and efforts to settle remaining 25 Para's is under progress.