REPORT NO.
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PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

SEVENTY NINTH REPORT

The Drugs and Cosmetics (Amendment) Bill, 2013 (Ministry of Health and Family Welfare)

(*Presented to the Rajya Sabha on* 18*th December,* 2013)
(*Laid on the Table of Lok Sabha on* 18*th December,* 2013)

Rajya Sabha Secretariat, New Delhi
December, 2013/Agrahayana, 1935 (Saka)

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CONTENTS

COMPOSITION OF THE COMMITTEE
(2013-14)

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shrimati B. Jayashree
4. Shri Mohd. Ali Khan
5. Dr. Prabhakar Kore
6. Dr. R. Lakshmanan
[&]7. Shri Rasheed Masood
8. Shri Jagat Prakash Nadda
9. Dr. Vijaylaxmi Sadho
10. Shri Arvind Kumar Singh

LOK SABHA

11. Shri Kirti Azad
12. Shri Mohd. Azharuddin
13. Shrimati Sarika Devendra Singh Baghel
14. Shri Kuvarjibhai M. Bavalia
15. Shrimati Priya Dutt
16. Dr. Sucharu Ranjan Haldar
17. Mohd. Asrarul Haque
18. Dr. Monazir Hassan
19. Dr. Sanjay Jaiswal
20. Shri Chowdhury Mohan Jatua
21. Dr. Tarun Mandal
22. Shri Mahabal Mishra
23. Shri Zafar Ali Naqvi
24. Shrimati Jayshreeben Patel
25. Shri Harin Pathak
26. Shri Ramkishun
27. Dr. Anup Kumar Saha
28. Dr. Arvind Kumar Sharma
29. Dr. Raghuvansh Prasad Singh
30. Shri P.T. Thomas
31. Vacant

[&] Vacant *vide* disqualification as a member of the Council of States (Rajya Sabha) *w.e.f.* 19th September, 2013.

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this Seventy-ninth Report of the Committee on the Drugs and Cosmetics (Amendment) Bill, 2013*.

2. In pursuance of Rule 270 of the Rules of Procedure and Conduct of Business in the Council of States relating to the Department-related Parliamentary Standing Committees, the Chairman, Rajya Sabha, referred** the Drugs and Cosmetics (Amendment) Bill, 2013 **(Annexure-I)** as introduced in the Rajya Sabha on the 29th August, 2013 to the Committee on the 9th September, 2013 for examination and report by 8th November, 2013. Subsequently, the Committee was granted extension of time till 18th December, 2013.

3. The Committee issued a Press Release inviting memoranda/views from individuals and other stakeholders (**Annexure-II)**. In response thereto 73 Memoranda from individuals and others relevant to the Bill were received. List of individuals from whom memoranda were received is at **Annexure-III**.

4. The Committee held eight sittings during the course of examination of the Bill namely 26th September, 12th November, 21st November, 22nd November, 29th November, 9th December, 16th December and 17th December, 2013. The list of witnesses heard by the Committee is at **Annexure-IV**.

5. The Committee considered the draft Report on 16th and 17th December, 2013 and adopted the same on 17th December, 2013.

6. The Committee has relied on the following documents in finalizing the Report.

(i) The Drugs and Cosmetics (Amendment) Bill, 2013;

(ii) Background Notes on the Bill received from the Department of Health and Family Welfare;

(iii) Presentation, clarifications and Oral evidence of Secretary, Department of Health and Family Welfare;

(iv) Memoranda received on the Bill from various institutes/bodies/associations/ organizations/experts and replies of the Ministry on the memoranda selected by the Committee for examination.

(v) Oral evidence and written submissions by various stakeholders/experts from various medical professions, on the Bill; and

(vi) Replies to the questions/queries raised by Members in the meeting on the Bill received from the Department of Health and Family Welfare.

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* Published in Gazette of India Extraordinary Part II Section 2, dated 29th August, 2013.
** Rajya Sabha Parliamentary Bulletin Part II, No.51252, dated 9th September, 2013.

7. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who deposed before the Committee and also those who gave their valuable suggestions to the Committee through their written submissions.

8. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

BRAJESH PATHAK
Chairman,
Department-related Parliamentary Standing Committee on Health and Family Welfare

NEW DELHI;
17th *December,* 2013
Agrahayana 26, 1935 (*Saka*)

ACRONYMS

AYUSH Drugs	–	Ayurvedic, Siddha and Unani drugs
BA and BE studies-Bio	–	Bio-Availibility and Bio-Equivalence (BE) Studies
CDA	–	Central Drugs Administration
CDA	–	Central Drugs Authority
CDSCO	–	Central Drugs Standard Control Organisation
CLA	–	Central Licensing Authority
CLAA	–	Central License Approval Authority
CSIR	–	Council of Scientific and Industrial Research
DCC	–	Drugs Consultative Committee
DCGI	–	Drug Controller General of India
DTAB	–	Drugs Technical Advisory Board
GCP	–	Good Clinical Practices
ICMR	–	Indian Council of Medical Research
MDTAB	–	Medical Devices Technical Advisory Board
SORs	–	The Statement of Objects and Reasons
SLA	–	State Licensing Authority

REPORT

1. The Drugs and Cosmetics (Amendment) Bill, 2013 (**hereinafter to be referred in the Report as 'Bill')** was introduced in the Rajya Sabha on the 29th August,2013 and referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare on the 9th September, 2013 for examination and report thereon.

2. The Statement of Objects and Reasons (SORs) appended to the Bill which *inter-alia* states that the Bill contains a revised approach to the centralized licensing in respect of seventeen categories of very critical drugs and separate regulatory provisions for Medical devices and comprehensive provisions for regulating clinical trials. The Statement is reproduced below for ready reference:–

> "*The Drugs and Cosmetics Act, 1940 is a consumer protection law, which is concerned with the standards and quality of drugs and cosmetics and regulates their import, manufacture, sale and distribution in the country.*
>
> *In January, 2003, the Central Government constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Research (CSIR) to undertake a comprehensive examination of drug regulatory issues, including the menace of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee noted that the problems in the drug regulatory system in the country are primarily due to inadequate or weak drug control infrastructure at the State and Central level and therefore, recommended centralised licensing of manufacture of drugs. The Committee further recommended for a strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organisation (CDSCO) which may be given the status of Central Drug Administration reporting directly to the Central Government.*
>
> *With a view to give effect to the recommendations of the Mashelkar Committee, the Central Government introduced the Drugs and Cosmetics (Amendment) Bill, 2007 in the Rajya Sabha on 21st August, 2007, which, inter alia, provided for centralised licensing of manufacture of drugs, regulatory provisions for clinical trials and export of drugs and cosmetics, creation of strong, well equipped, empowered, self managed and independent Central Drugs Authority in place of the existing central drugs regulatory body i.e. the CDSCO and do away with the Drugs Technical Advisory Board.*
>
> *The said Bill was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare for examination and Report. The Committee in its 30th Report made several recommendations, including for creation of a separate Chapter for regulating medical devices. The provisions relating to regulation of clinical trials and exports in the Bill also needed to be made more comprehensive and therefore, the Central Government decided to withdraw the Bill of 2007 and introduce a new Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2013 excluding the provisions relating to AYUSH drugs for which a separate Bill will be brought before Parliament.*
>
> *The new Bill contains, inter alia, a revised approach to the centralised licensing, in respect of seventeen categories of very critical drugs included in the proposed Third Schedule to the Act, a separate Chapter containing regulatory provisions for Medical Devices, more comprehensive provisions for regulating clinical trials and exports and a revised composition of the Central Drugs Authority consisting of, inter alia, Secretaries of seven Ministries and Departments of the Central Government, four State Drugs Controllers*

and four experts, with the Drugs Controller General (India) as its Member-Secretary. The Drugs Technical Advisory Board has been retained".

3. The Ministry of Health and Family Welfare in its background note made the following submissions:–

"The quality, safety and efficacy of the drugs, cosmetics and medical devices manufactured, imported and sold in the country are regulated by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 framed thereunder. The Act and Rules are enforced by both the Central and State Governments. The regulatory control over the drugs imported into the country and approval of new drugs are exercised by the Central Government through the Central Drugs Standard Control Organization (CDSCO), which is a Central Government organisation. The manufacture, sale and distribution of drugs and cosmetics are regulated by the State Drugs Control Authorities appointed by the State Governments. Medical devices are treated and regulated as drugs under the provisions of the Act. Licenses for manufacture, sale and distribution of drugs and cosmetics are issued by the State Licensing Authorities appointed by the State Governments. Licenses for manufacture of new drugs are also issued by the State Licensing Authorities but only after the CDSCO, as Central License Approval Authority (CLAA), issues its approval to the same to the State Licensing Authority. Licenses for import of drugs and cosmetics are issued only by CDSCO. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 also contain regulatory provisions for Ayurvedic, Siddha and Unani (AYUSH) drugs.

Clinical trials are the only way of establishing the quality, safety and efficacy of the drugs. However, the Act does not contain any explicit provision for regulating them. The Act also does not regulate export of drugs and cosmetics. The Act also does not contain regulatory provisions for Homoeopathy drugs.

There have been many weaknesses/deficiencies in the regulatory mechanism of drugs and cosmetics in the country. Since the subject matter is extremely sensitive and has direct bearing on the health of the people, several expert committees have examined the issue and have made recommendations in the past. One of them, the ***Mashelkar Committee****, had also made several recommendations in 2003. The Mashelkar Committee was of the view that the existing infrastructure at the Centre and States was not adequate to perform the assigned functions efficiently. The gist of the important recommendations made by the* ***Mashelkar Committee*** *are as under:*

(i) The Committee noted that the problems in the drug regulatory system in the country are primarily due to inadequate or weak drug control infrastructure at the State and Central level. Therefore, the Committee recommended that a strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organization (CDSCO) should be given the status of Central Drug Administration (CDA) reporting directly to the Ministry of Health and Family Welfare.

(ii) The Committee recommended that measures be taken to strengthen the State Drug Control Organizations with additional manpower, infrastructure, technical capability and financial resources.

(iii) The Committee observed that the issue of non uniformity of enforcement at the State level is a serious matter and needs to be addressed immediately. Therefore, the Committee recommended that the grant of manufacturing licenses should be given by Central Drug Administration (CDA) instead of the present system of grant of such licenses by the State Drug Control Authorities. However, this power should be assumed by CDA in a phased manner.

(iv) The Committee stressed the need to streamline and expedite the procedure and process of approval of applications for new drugs and clinical trials including the need to institutionalize Good Clinical Practices (GCP).

(v) The Committee recommended that the Medical Devices should be specifically defined under the Drugs and Cosmetics Act and relevant rules framed for their proper regulation with specific Medical Devices Division to be set up in the office of Central Drug Administration (CDA).

(vi) The problem of spurious and sub standard drugs was gone into in great detail by the Committee. A number of recommendations were made by the Committee in this regard that include more stringent penalties be provided by amending the Drugs and Cosmetics Act for offences relating to spurious and sub standard drugs, some of such offences be made cognizable and non-bailable, and designation of special courts for speedy trial of spurious drugs cases.

Based on the recommendations of the Mashelkar Committee, the Government had introduced two Bills in Parliament, namely, the Drugs and Cosmetics (Amendment) Bill, 2005 and the Drugs and Cosmetics (Amendment) Bill, 2007. The 2005 Bill was devoted to the problem of spurious and adulterated drugs and enhancing the penalties in the Act therefor. It has already been enacted as the Drugs and Cosmetics (Amendment) Act, 2008. Salient features of the provisions in the Drugs and Cosmetics Act, 1940 amended thereby are as follows:

(a) Maximum penalty of life imprisonment and fine of Rs. 10 lakhs or 3 times the value of the confiscated goods, whichever is more;

(b) Some of the offences made cognizable and non-bailable;

(c) Besides officers from the Drug Controller's Office, other gazetted officers also authorised to launch prosecution under the Act;

(d) Specially designated courts for trial of offences covered under the Act;

(e) Provision for compounding of minor offences.

The Drugs and Cosmetics (Amendment) Bill, 2007 was introduced in the Rajya Sabha on 21st August, 2007. The salient features of the Bill were as follows:

(a) establishment of an Central Drugs Authority;

(b) introduction of system of centralized licensing for manufacture of drugs through the Central Drugs Authority;

(c) introduction of provisions for regulating clinical trials in the country; and

(d) bringing the export of drugs, cosmetics and medical devices also within the purview of the Drugs and Cosmetics Act, 1940.

The 2007 Bill was referred by the Rajya Sabha to the Department-related Parliamentary Standing Committee on the 23rd August, 2007 for examination and report. The Committee submitted its observations/recommendations in its 30th Report on the Bill on the 21st October, 2008. The report had a very large number of recommendations.

There were many developments after the receipt of the report of the Parliamentary Standing Committee. Fresh comments of State/UT Governments were sought. There was very strong opposition from the State Governments to the proposal of centralised licensing of drugs. The

issue was re-visited to evolve a mechanism which could be acceptable to all stakeholders. It was, accordingly, decided to share the responsibility of licensing of drugs with the States in a way that they would continue to issue licenses for a majority of drugs, AYUSH drugs and all cosmetics. The Bill, therefore, required very large number of amendments arising out of the recommendations of the Parliamentary Committee and the comments of the State/UT Governments. The Ministry of Law and Justice (Legislative Department), therefore, suggested withdrawal of the 2007 Bill and introduction of a new Bill in its place.

The provisions in the Drugs and Cosmetics Act, 1940 relating to Allopathic drugs and AYUSH drugs are mutually exclusive of each other with no mutual linkages. The nature of allopathic drugs and AYUSH drugs are distinctly different from each other. Accordingly the regulatory requirements are also quite different. The Bill of 2007 had provisions for amendments relating to both the Allopathic drugs and AYUSH drugs. The Government, therefore, was of the view that the two categories of drugs should be regulated through different Acts and the provisions of AYUSH drugs need to be dealt with separately. It was accordingly decided to detach the provisions relating to AYUSH drugs from the Act and not to have any amendment relating to AYUSH Drugs in the new Bill, with the ultimate aim to remove all the provisions relating to AYUSH drugs from the principal Act, i.e. the Drugs and Cosmetics Act, 1940 and to enact a new law exclusively for AYUSH drugs. It was decided that the Department of AYUSH would bring a separate Bill at an appropriate time to enact a new law for AYUSH drugs which will also take care of necessary amendments for AYUSH drugs. Further, the present Act does not contain any provision for regulating Homoeopathic drugs. The new law to be enacted by the Department of AYUSH would accordingly also contain regulatory provisions for Homoeopathic drugs.

Almost all the recommendations of the Parliamentary Standing Committee on the 2007 Bill have been accepted and incorporated in the new Bill. In accordance with the Government's decision, the 2007 Bill has been withdrawn and the new Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2013 has been introduced in its place on 29.8.2013 in the Rajya Sabha. The Drugs and Cosmetics (Amendment) Bill, 2013 contains more comprehensive provisions than the 2007 Bill.

The salient features of the Bill are as follows:

(i) New/amended definition of many terms such as drugs, medical device, new drugs, investigational new drugs, investigational medical device, clinical trials, Ethics Committee, Investigator, Protocol, Sponsor, BE and BA studies, etc.

(ii) Creation of Central Drugs Authority (CDA) with revised structure and composition, as follows:

(a) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Health and Family Welfare— Chairperson, ex-officio;

(b) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy— Member, ex-officio;

(c) Secretary, Department of AIDS Control and Director General, National AIDS Control Organisation, Ministry of Health and Family Welfare— Member, ex-officio;

(d) Secretary to the Government of India, Ministry of Commerce and Industry, Department of Commerce— Member, ex officio;

(e) Secretary to the Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals— Member, ex-officio;

(f) Secretary, Department of Health Research and Director General, Indian Council of Medical Research, Ministry of Health and Family Welfare— Member, ex-officio;

(g) Secretary to the Government of India, Ministry of Science and Technology, Department of Bio-technology— Member, ex-officio;

(h) Director General Health Services, Directorate General of Health Services, New Delhi— Member, ex-officio;

(i) Additional Secretary or Joint Secretary and Legislative Counsel in the Legislative Department, Ministry of Law and Justice in charge of the Group dealing with the work relating to the Ministry of Health and Family Welfare— Member, ex-officio;

(j) Additional Secretary or Joint Secretary in charge of the Drugs Quality Control Division in the Ministry of Health and Family Welfare— Member, ex-officio;

(k) four experts having such qualifications and experience to be nominated by the Central Government in such manner as may be prescribed— Member;

(l) four State Licensing Authorities to be nominated by the Central Government in such manner as may be prescribed— Member;

(m) Drugs Controller General of India— Member-Secretary, ex-officio.

(iii) Wide powers and functions of CDA, including the power to review/suspend/cancel licences granted by Central and State Drugs Licensing Authorities

(iv) CDA to be the Appellate Authority for decisions taken by the Central and the State Licensing Authorities

(v) Central Government to be the Appellate Authority for decisions taken by the CDA

(vi) Transfer of offices, staff and assets of the CDSCO and Central drug testing laboratories to CDA

(vii) Separate Chapter containing regulatory provisions for clinical trials, including penal provisions therefor

(viii) Taking the medical devices out of the definition and purview of the drugs and insertion of a separate Chapter containing comprehensive regulatory provisions for medical devices, including penal provisions therefor

(ix) Bringing exports within the purview of the Drugs and Cosmetics Act, 1940

(x) Reconstitution of the Drugs Technical Advisory Board (DTAB)

(xi) Establishment of a new Medical Devices Technical Advisory Board (MDTAB)

(xii) Revised composition of the Drugs Consultative Committee (DCC)

(xiii) Centralised Licensing of drugs – different from what given in the 2007 Bill – Introduction of a new Third Schedule containing the list of drugs falling within the licensing purview of the Central Licensing Authority – the Third Schedule may be amended through a Gazette Notification

[The Third Schedule would contain the following categories of drugs:

1. *Sera;*
2. *Solution of serum proteins intended for injection;*
3. *Vaccines; and includes DNA vaccines and vaccines containing living genetically engineered organisms;*
4. *Toxins;*
5. *Antigens and anti-toxins;*
6. *Anti-biotics (betalactums and cephalosporins);*
7. *Parenteral preparations meant for parenteral administration;*
8. *Hormones and preparations containing hormones;*
9. *r-DNA derived drugs;*
10. *RNA interference based products;*
11. *Monoclonal anti-bodies;*
12. *Cellular products and stem cells;*
13. *Gene therapeutic products;*
14. *Xenografts;*
15. *Cytotoxic substances (anti-Cancer drugs);*
16. *Blood products;*
17. *Modified Living Organisms.]*

(xiv) Creation of a new cadre of officers, namely, Medical Device Officers, on the lines of Drug Inspectors, for medical devices

(xv) Renaming of Drug Inspectors as Drug Control Officers

(xvi) Defining 'adulterated cosmetics' and penal provisions therefor

(xvii) Penal provisions for various offences under the Act harmonized.

4. In view of the objectives behind the proposed legislation and its impact on the regulation of drugs, cosmetics, medical devices and clinical trials and also on the diverse stakeholders including pharma manufacturers and the State Drug Regulatory Authorities, the Committee decided to acquaint itself with all shades of opinion on the Bill. The Committee accordingly gave wide publicity to the Bill through a Press Release, inviting views/suggestions from the diverse stakeholders and general public. Seventy three memoranda containing views/suggestions were received from organizations/stakeholders/experts/associations on which comments of the Ministry were sought. The Committee also held interactions with representatives of various associations as well as renowned experts/professionals. The Committee also heard the views of the Secretary, Ministry of Health and Family Welfare and his team of officers. The Committee was assisted in its deliberations by the representatives of Legislative Department and Department of Legal Affairs.

Oral Evidence of the Secretary, Department of Health and Family Welfare

5. The Secretary, Department of Health and Family Welfare, during the course of his evidence before the Committee on the 26th September, 2013, while apprising the Committee of the salient features of the Bill also acquainted it with the background of the proposed legislation.

He pointed out that India's objective of reaching universal health coverage depended critically, as the Twelfth Plan Document also says, on the principles of availability, accessibility and quality of drugs and equipments. The quality, safety and efficacy of drugs, are regulated by the Central Drugs Standard Control Organization in the Central Government and in the State Governments, by the Drug Control Departments as per the provisions the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 framed thereunder. The CDSCO and the corresponding establishments in the States also regulate the quality, safety and efficacy of medical devices, cosmetics and clinical trials. Over the decades, while the pharmaceutical industry of the country has seen unprecedented growth, there has not been a similar enhancement or improvement in the structure of the drug regulatory set-up. The Mashelkar Committee appointed by the Central Government in 2003 made many recommendations in this regard. The Secretary also made a mention of the Drugs and Cosmetics (Amendment) Bill, 2007 and this Committee's 30th Report thereon, stating further that the present Bill before the Committee is a comprehensive amendment Bill and has been brought in place of the 2007 Bill, which stands withdrawn. This Bill includes provisions for creation of a new chapter in the Act for regulation of medical devices. It includes a revised structure for a Central Drugs Authority under the effective supervision of the Central Government; it includes effective regulatory provisions for clinical trials with stringent penal provisions; it also includes a limited centralized licensing of drugs and regulatory provisions for exports. As regards the strengthening of the State Drug Control Departments, the Secretary submitted that an outlay of Rs. 1200 crores has been made in the Twelfth Plan to initiate a Centrally Sponsored Scheme for the purpose. An outlay of Rs.1800 crores for CDSCO in the Twelfth Plan has been proposed and it is hoped that the present Bill, if enacted and supported by the Government's non-legislative efforts, would change the pace of drug regulation in the country.

6. Thereafter, Shri Arun Kumar Panda, Joint Secretary, Department of Health and Family Welfare gave a power-point presentation on the said Bill covering the background of the Bill; functions of Central Drugs Standard Control Organisation (CDSCO); functions of State Licensing authorities; main recommendations of Mashelkar Committee; salient features of 2007 Bill; main recommendations of the Parliamentary Standing Committee on Health and Family Welfare; salient features of the New Bill (2013), etc. On the issue of steps taken for manpower enhancement for implementation of Drug regulatory laws, it was informed that the Drugs and Cosmetics (Amendment) Bill, 2013 envisages regulatory control over medical devices, clinical trials, exports and Central Licensing of certain categories of drugs which are not fully regulated under the present provisions of the Act apart from the existing statutory duties specified. For effective regulation of the existing and proposed provisions, manpower enhancement is essential. An ambitious outlay in the Twelfth Plan has been made in this regard for the CDSCO with Rs.1800 crore and for strengthening of the State Drug Regulatory system with Rs.1200 crore. For strengthening the Drugs Control Departments of the State/UT Governments, a new Centrally Sponsored Scheme of Strengthening of States' Drug Regulatory System has been proposed. The total financial outlay of the project, including states' share would be Rs.1550 crore. The Central share would be 75% and States' share 25%. For North-Eastern States and Special Category States, the ratio would be 90:10. Under this new scheme, it is proposed to help the States to engage personnel for their drug regulatory system. Similarly, it is proposed to help them set up new labs, for which additional personnel would be required. The Scheme would also cover States' expenses towards construction / upgradation of buildings for drug regulatory department and drug testing laboratories, purchase of testing equipments, engagement of additional manpower for the drug regulatory department and drug testing laboratories, including contractual personnel, purchase of consumables, including chemicals for the labs, computerization and IEC activities. To strengthen the CDSCO, the physical infrastructure of the existing zonal/sub-zonal/port/airport offices of CDSCO are to be up-graded. Many new offices also would have to be opened. It is proposed to create 1195 additional posts in CDSCO in various categories. A proposal for creation of 365 regular posts in the first phase

had been sent to the Department of Expenditure, out of which they have already sanctioned 165 posts. With this, the CDSCO has grown from a sanctioned strength of 111 posts in 2008 to 475 posts in 2013. In addition, contractual engagements have been done in substantial number and would also be required in future. Similarly, to strengthen the Central Drug Testing Labs, the Department of Expenditure has been requested for creation of 283 additional regular staff for various existing Central drug testing labs in the first phase. The labs are also continuously being provided new and sophisticated testing equipments. Besides strengthening the existing labs, it is also proposed to set up 56 new labs, including 8 mini labs at ports/airports and 35 mobile labs. For the new proposed labs, additional staff would be required.

Views of Other Stakeholders/Experts

7. Some important issues raised by some of the other experts/stakeholders are discussed briefly hereunder:–

8. During his presentation on 12th November, 2013 before the Committee, **Prof. S. K. Gupta, former Head, Department of Pharmacology**, **AIIMS** *inter-alia* delineated the following points for consideration of the Committee:-

(i) Need to delete the purview of 'Drug Control Officer' in relation to Ayurvedic, Siddha and Unani Drugs;

(ii) The term 'Medical Devices' at page 4 of the Bill should include 'sensors and electronic devices';

(ii) The term 'Investigator' at page 5 and 35 of the Bill needs to be deleted;

(iii) At page 6 of the Bill, composition of Central Drug Authority may be reworded as follows:–

(iv) there should be broad spectrum of qualification as a criteria for appointment of Drugs Controller General of India;

(v) the Ethics Committee as envisaged in the Bill may 'oversee' the Clinical Trials but should not be held responsible;

(vi) the name of Central Drugs Laboratory, should be adequately changed to include 'Medical Devices' as the term Central Drugs Laboratory may not be competent to regulate 'Medical Devices'; and

(vii) need to include a representative from the Dental Council on the Drugs, Cosmetics and Medical Devices Consultative Committee.

9. Responding to the issue regarding need to delete the purview of 'Drug Control Officer' in relation to Ayurvedic, Siddha and Unani Drugs, the representative of the Department of Health and Family Welfare submitted before the Committee, that as far as the Drugs and Cosmetics Act is concerned, it does not have anything to do with Homoeopathy. But as far as Ayurveda and the rest of the systems of medicine are concerned, they are already there in the Drugs and Cosmetics Act. However, it has been felt that there has to be a separate organization, just like the CDSCO, which will have experts, which will have a different authority, because they are completely different systems of medicine. To regulate them, the Department of AYUSH under the Ministry would come up with a separate Bill and, at that time, all those portions in this Act, which are already there in the Act, would be deleted and those parts would find place in that law which would be a separate law.

10. Further, responding to the query with regard to responsibility of the Ethics Committee for clinical trials, the representative of the Department of Health and Family Welfare submitted before

the Committee that in the present Schedule-Y, which is a part of the Drugs and Cosmetics Rules, it is the Ethics Committee that has to look into all this. The present Bill has brought in a lot of other safeguards into this Act. Primarily, all over the world, whenever there are clinical trials, it is basically the Ethics Committee that is supposed to look into these trials. That is why the registration of the Ethics Committee has been envisaged. Earlier, there was no registration. The investigator and the sponsor are also responsible, but then, all over the world, whenever clinical trials take place, the Ethics Committees are made accountable, because they are the people on the field and they are supposed to ensure that good ethical practices are adopted when clinical trials are undertaken.

11. Shri Pawan Chaudhary, Chairman, Medical Equipment Division, CII during his deposition before the Commitee on 12th November, 2013 delineated the following points for consideration of the Committee:-

(i) there is a vast difference between the terms pharmaceuticals and medical devices and the move of the Department of Health and Family Welfare to bring the control of both under the present Bill would affect not only the local and global manufacturer but would also affect the health provider namely hospitals.

(ii) the word 'Manufacture' at page 4 of the Bill should be replaced by 'Legal Manufacturers';

(iii) In Clause 7B- Chapter IIA, standards of quality of medical device have not been properly defined with respect to misbranded, adulterated and spurious forms;

(iv) Definition of 'New Medical Device' needs to be framed properly;

(v) Need to relook punitive clauses in respect to Medical Devices as the medical technology is still evolving and the knowledge in respect to such Medical Technology is still developing in the country and interpretation of the same on the basis of such nascent knowledge in this field would lead to enormous difficulties.

(vi) In section 7E *i.e.* 'Spurious Medical Device' in Chapter II A, Explanation of the term 'Spurious' may not apply to 'medical devices';

12. Shri Gautam Khanna, Chairman – FICCI, MDF and Executive Director - Healthcare, 3 M India Ltd, FICCI during his deposition before the Commitee on 12th November, 2013 delineated the following points for consideration of the Committee:–

(i) On the definition of investigational medical device, the word 'performance' should be used for medical devices instead of effectiveness:

(ii) In respect of 'Medical Devices', sufficient transition time (5 years) for implementation of the Bill as and when cleared in the Parliament must be given;

(iii) Lot of the provisions in the said Bill have been left for delegated legislation;

(iv) Size of Central Drugs Authority (CDA) is too large;

(v) Subordinate rules on compensation for clinical trials need to be updated for clarity;

(vi) Need for more guidance on operation of compensation norms;

(vii) Need to put in place a performance rating for Central Licensing Authority in the provisions of the Bill itself;

(viii) Body of Clinical Experts must be there in the Clinical Body *i.e.* the Central Drugs Authority (CDA)

(ix) There is no provision for prohibition on promotion of drugs outside label use, no prohibition on inducement to prescribe and no penalty for wrongful promotion in the Bill.

(x) There is no mandate for data integrity, reliability and variability, in the Bill;

(xi) For pharmaceutical quality, there is no bio-equivalence testing for generics outside 'new drug' definition in the Bill.

(xii) need to take into consideration the Medical Devices and Regulatory Billl which was introduced some years ago, as the said Bill has very clear aspects on regulation of medical devices.

13. Ms. Manisha Singh, ASSOCHAM during her deposition before the Commitee on 12th November, 2013 delineated the following points for consideration of the Committee:–

(i) In the definition of Medical Device the word "including the software should be restricted to built in- software" in the medical device and if the said software is outside, the same should not be considered as medical device;

(ii) need to add explanation to Clause 7(E) (e) relating to spurious medical device that the manufacture or import or sale of a medical device under a name of a third party as per the authorisation given by the owner through a licence shall not fall under the above clause;

(iii) need to exclude registered medical practitioners from the purview of Prohibition of import, manufacture and export of certain medical devices in Clause 7F(1)(vi);

(iv) need to add the following words at the beginning of Clause 4Y, "Without prejudice to the confidentiality provisions in respect of trials subjects.";

(v) need to have four different classes of members representing industry on the Medical Devices Technical Advisory Board instead of the present provision of one member at page 17, lines 29-30 of the Bill;

14. Ms. Suneela Thatte of CII Pharma Division during her deposition before the Commitee on 12th November, 2013 delineated the following points for consideration of the Committee:–

(i) In Chapter I B section 4Q, Principal Investigator/Sponsor should have primary onus in case of injury or death caused due to clinical trials;

(ii) In Chapter IB, section 4(R), the duration of medical treatment for the injury needs to be defined;

(iii) In Chapter IB, Section 4(T), there is a need for subjecting 'Ethics Committees' to an audit/inspection by regulatory authorities either from India or outside of India say USFDA, EMEA etc;

(iv) Need to delete the requirement of furnishing of 'Audit Reports by sponsors' from section 4(V) (3) of the Bill and need to make periodic review of trials by Ethics Committee by making periodic visits mandatory in Clause 4(V)(3);

(v) The Bill is silent on the fate of the clinical trials if the registration of Ethics Committee is cancelled; and

(vi) The Bill is silent regarding ongoing training and skill of regulatory officials;

(vii) discrepancy in validity of Registration of Ethics Committee in the present Bill and the Rules in force now.

15. Shri Rajiv Nath, Forum Coordinator, All India Medical Equipments Devices (AIMED) during his deposition before the Committee on 12th November, 2013 delineated the following points for consideration of the Committee:-

(i) U.S. and UK Medical Devices Regulation Laws must also be incorporated in India;

(ii) The Bill must consider the fact that Drugs and Cosmetics are different from Medical Devices and cannot be judged by the same yardstick; and

(iii) Chapter II A of the Bill which deals with 'Medical Devices' needs to bring international aspects of Medical Devices Safety and Performance, which seems to be missing in the chapter;

16. The Committee in its meeting held on the 21st November heard the views of Dr. Ranjit Roy Choudhury, National Professor of Pharmacology, and ex-Member, Board of Governors, Medical Council of India; Shri Anand Grover, Senior Advocate and Director, Lawyers Collective HIV/AIDS Unit and his team members; Shri Jagdeep Singh, President, SME Pharma Industries Confederation; and Shri P.K. Gupta, Chairman, Confederation of Indian Pharmaceutical Industries on the Bill.

17. Prof. Ranjit Roy Choudhury during the course of his deposition before the Committee submitted that Clause 4 P under Chapter 1B may be amended in such a way that it shall ensure accredition of all the three entities, engaged in clinical trials, *i.e.*, accredition of centre for clinical trials, Ethics Committee as well as the clinical Investigator. Prof. Choudhury also recommended for short training course in good clinical practice, for members of the Ethics Committee. For the purpose of making the Ethics Committee totally unbiased and sacrosanct, Prof. Choudhury suggested a panel of experts who have been accredited to be formed and Chairman and members of the Ethics Committee selected therefrom. Such a selection process would ensure selection from a pool of accredited, tested and knowledgeable people. He also suggested putting out every decision of the Ethics Committee on the Internet.

18. Shri Anand Grover during the course of his deposition *inter-alia* informed the Committee that one of the major problems was that the Drugs and Cosmetics Act, 1940 was minimal and the rules were very exhaustive and there was a need to rehaul them. He submitted that in clinical trials, the ethical considerations did not have statutory mandate whereas other issues did have it and also there was no adequate infrastructure to check the adverse events of clinical trials to the patients. Shri Grover recommended for inclusion of Phase I to IV of "Clinical Trials" (currently described under Schedule Y) in the definition of clinical trials. He also advocated inclusion of observational clinical trials, operational research, single case studies, adoptive clinical trials and add-on trial in Schedule Y. He further recommended that penalties should be imposed on both-sponsors and investigators. Shri Grover pointed out that if the permission for clinical trials is violated, it was amenable to penalties, however – nothing was provided for violation of the ethical guidelines. Talking of the Ethics Committee, Shri Grover submitted that every person, who is on the Ethics Committee, should be independently registered on a central level. He further submitted that instead of relying on the principal investigator, the Ethics Committee should go to the field and ensure that all the ethics, informed consent etc. are actually followed.

19. Shri Jagdeep Singh, President, SME Pharma Industries Confederation during the course of his deposition *inter-alia* submitted before the Committee that Schedule M of the Drugs and Cosmetics Act, was amended in 2005 whereby it was mandated that all units would be upgraded to international levels at enormous cost. The SMEs who could not upgraded were closed down, and as per an estimate, 1000 SMEs were closed down. He submitted that along with quality, availability and affordability of drugs should also be given equal consideration while effecting changes in the law. He further submitted that the centralization of drug licensing would kill the SME pharma units and further strengthen the already powerful MNCs. There was no level-playing

field and the big pharma players were making the survival of SME pharma companies difficult. In reply to a query, Shri Jagdeep Singh stated that his Confederation was in favour of strengthening the existing State and Central Drug Regulatory Framework for quality improvement but was against the idea of centralized licensing of drugs as proposed in the Bill. Shri Singh also stated that he had no objection to the CDSCO inspecting the SME pharma units for quality checks, but there should be no centralization of drug licensing, as the centralization would kill small-scale pharma industry and help the MNCs take over the market.

20. Shri P.K. Gupta, Chairman, Confederation of Indian Pharmaceutical Industry during the course of his deposition informed the Committee that the small and medium segment was the backbone of the pharmaceutical industry as it provides medicines at very competitive prices and a number of large manufacturers get their products manufactured from the small and medium industrial units. Shri Gupta submitted before the Committee that his confederation was of the view that the Drugs and Cosmetics (Amendment) Bill, 2013 would prove detrimental to the small and medium scale industry as they have limited resources at their disposal and it would not be possible for them to approach the Central Licensing Authority for every approval. If the Drugs and Cosmetics (Amendment) Bill, 2013 was implemented, it would lead to dual system of licensing for a large number of medicines and the resultant harassment to the small and medium scale pharma manufacturers. This would wipe out small and medium manufacturers from the scene. He further stated that Clause 18 D of the Bill would result in duplication of the existing system and the exports of medicines would be affected adversely. He suggested that the permission to manufacture drugs for domestic use or export should be granted by the same authority. Shri Gupta submitted that presently, 70-80 per cent work of the pharmaceutical industry was being controlled by the Central Licensing Authority and there was no justification for the DCGI to become more powerful.

21. Responding to some of the concerns raised by Shri Jagdeep Singh and Shri P.K. Gupta, Shri Arun Kumar Panda, Joint Secretary, Department of Health and Family Welfare, *inter-alia* informed the Committee that the Bill seeks to bring only 17 categories of the high-end, cutting-edge, high technology drugs under central licensing and these 17 categories accounted for only 10% of the pharma industry; for all the other 90%, the licensing would continue with the State licensing authorities. Responding to his observation Shri Jagdeep Singh stated that the provisions in the Bill which proposed to bring betalactums and injectibles under central licensing, were implemented, 70% of the pharmaceutical industry would have to move the CDSCO for licensing, which would prove detrimental for SME pharma units. Shri Jagdeep Singh pleaded that betalactums and injectibles should be kept outside the purview of Central licensing.

22. Dr. M. K. Bhan, Former Secretary to the Government of India, Department of Biotechnology, Ministry of Science and Technology during his deposition before the Commitee on 22nd November, 2013 submitted that there are four pillars of the process in which drugs or vaccines are produced. They are navigated through a process that not only nourishes the development but also makes sure that it is done with ethics, with competence, particularly when it reaches clinical stage where human beings are tested. Then, there are other issues which relate to making a judgment on safety, on efficacy and then policy issues related to access, pricing and other issues. However the present laws in the country fluctuate between two extremes – either too much attention to giving a free space for innovation to occur or to the opposite extreme where regulation is made so restrictive that people, whether they are public sector scientists or our companies, particularly small companies, are unable to do innovation. He submitted that what was needed was a middle path which the western world has balanced beautifully. They have found a very nice balance in their higher education, their research, their regulation, their transparent communication of safety and efficacy, and as we mature as a country, our challenge is to find that balance. He further submitted that there are two pillars of good regulation – one

is ethics and the other is competence. This Bill must guarantee two things – an ethical regulatory system and a competent regulatory system. He further highlighted certain points on the said Bill. Firstly, in the world today, the Chief Regulatory Officer of a country is appointed by the Parliament. The stature of the FDA Commissioner in the United States of America has to be cleared by the Congress. Similar is the case with the European Regulator and their status is many times, way above Secretaries of the Government. He felt that one fundamental flaw in the present Bill is that the concept of Drug Controller is all regulated and controlled by the Ministry, but less attention is paid to the stature and the process of selection of Drug Controller. He advocated giving Drug Controller, the status of special Secretary of Government of India to the Drug Regulator on the same pattern of selction that is followed for selection of the Secretaries of the Ministry of Science and Technology or the Secretary, Department of Health Research. The second issue was that of the composition of the Drug Authority, which comprises mostly of ex-officios members. He submitted that most *ex-officio* committees eventually end up sending some junior officer to represent the members who does not have time to go into the details thereby leading to setback to quality as the quality is found only in details and that is the reason to have more independent experts in the drug authority and there should be a panel for selecting those independent experts. The third issue was on the external review of any system. He was of the view that every two or three years there was a need to create a national group that reviews the Drug Regulatory Authority and whose report should come to the Parliament because these Regulatory Authorities are the foundation of future enterprise, future innovation and future protection of our people's needs. He further suggested that some external evaluation instrument must be made mandatory and the report made by these external evaluators for the Drug Regulator must be made public. He was of the view that the there was a need for Central Authority Board with sufficient external people in it and external measurement of every two years of performance and public display of that performance would lead to a much better accountability framework than what Ministry presently provides. Fourthly, there was a need to provide representation to the Department of Biotechnology in the Cosmetic and Medical Device Committee. Fifthly, he drew the attention of the Committee to one sentence in this legislation which says 'injury or death due to clinical trial' which he submitted that the wording of this sentence was creating a lot of confusion as one could suffer within a trial for two or three reasons: One is because of one's own illness; the second is because of the drug, and the third is, when one became ill and the people who were doing the trial didn't take care of the said person. He was of the view that the sentence should be framed as 'death due to a drug or due to lack of first-class medical care'.

23. Dr. B. K. Mishra of the Consumer Online Foundation during his deposition before the Commitee on 22nd November, 2013 delineated the following points for consideration of the Committee *viz.* need to educate common people on pharmacovigilance which is lacking in the Bill; adverse drug reporting must be made part of this Bill to ensure accountability; need to form a Central Body for maintaining data base of drugs; pharmaco-vigilance must be robust and time-bound but at the same time innovation should not suffer; need to have transparency in adverse drug reporting, etc.

24. The representatives of Indian Drug Manufacturers Association during their deposition before the Commitee on 22nd November, 2013 delineated the following points for consideration of the Committee *viz.* over-regulation and excessive centralization of powers must be avoided; need to reconsider keeping export of drugs outside the purview of this Bill as it would not only strain the regulatory framewok and the available resources but also delay the process of export of medicines; new provision in the Bill with respect of clinical Trials will strangle the industry as the present provisions are sufficient; need to separate Bio-regulatory study from Bio-equivalence study in respect of clinical trials; need to include more medical representation in the regulatory framework, etc.

25. The representatives of the Indian Beauty and Hygiene Association during their deposition before the Committee on 22nd November, 2013 were of the view that cosmetics should be kept out of Clinical trials as they are different from Drug trials.

26. The representatives of Federation of Pharma Entrepreneurs (FOPE) during their deposition before the Commitee on 22nd November, 2013 delineated the following points for consideration of the Committee *viz.* New regulations would increase paper work especially for small entrepreneurs as they do not have expertise for such huge paper work filing; Penal provisions have been increased enormously in the new Bill. It was suggested that there was need to include 'Mensrea or knowingly' ingredient in the penal provisions of the Bill so as to prevent its misuse; no definition of critical drugs in the 17 Drugs that are defined as critical; backdoor entry to include other drugs by notification in the critical drugs; vast powers given to Central Government to withdraw drugs approved by State Governments, etc.

27. Shri Dilip G. Shah, Secretary General, Indian Pharmaceutical Alliance during his deposition before the Committee on 29th November, 2013, delineated the following points for consideration of the Committee:

(i) the drugs meant for export should be kept outside the purview of regulatory approvals or exports should be defined in the Bill in such a way so as not to hinder exports;

(ii) Clause 6(C), which deals with the definition of 'New Drug', states that "A new drug shall continue to be a new drug for such period as may be prescribed", the timeline is not specified. Moreover, in the present Act, new drug was defined as any drug within four-years from its first approval in India. He was of the view that the new clause becomes discretionary and could be subjected to abuse in the form of data exclusivity by the western countries and therefore the existing timeline of four-year should continue as it provided transperancy and uniformity of policy.

(iii) In Chapter 1 B, Clause 4P(1) which deals with Bio-Availibility (BA)/Bio- Equivalence (BE) Studies, permission for such studies for more than four-year old drugs with proven safety and efficacy record should continue to be with Ethics Committee, instead of it being given to Central Licensing Authority as per this new Clause in the Bill since the new clause will overburden the Central Drug Authority and lead to delay in decision making thereby affecting the small drug companies.

(iv) In Chapter 1 B, Clause 4P (3), requires registration of clinical trials with the Central Drug Authority (CDA) also. As per current regulations, all clinical trials are required to be registered with Clinical Trials Registry of India maintained by Indian Council of Medical Research (ICMR). The new proviso would lead to duplication and raise transaction cost. It was submitted that registration should be given either to Central Drug Authority or ICMR.

(v) In Chapter 1 B, Clause 4P (4), Department of Scientific and Industrial Research (DSIR) approved Pharmaceutical R&D Units should be exempted from obtaining permission of Central Licensing Authority (CLA).

(vi) In Chapter 1 B, Clause 4 Q, relating to compensation for Clinical Trial injury or death, there was a need to include provisions to appoint an Appellate Authority who should give opportunity to the sponsors/subject to present their/his assessment before arriving at a final decision.

(vii) With regard to Clause 4ZA, which deals with penal provisions for penalty for clinical trials for drugs/medical device without approval, there is a minimum penalty of imprisonment of three years and a fine upto 10 lakhs, the provison of minimum imprisonment of three years is very harsh, instead it should be modified as punishment

which may range from imprisonment for minimum period of one year upto a maximum period of five years and fine upto Rs. 10 lakhs.

(viii) With regard to penal provisions in the Bill, it was submitted that the penal provisions were without adequate safeguards and prone to abuse and would discourage not only foreign investment but also domestic investment in the pharma manufacturing sector as well as research and development.

(ix) With regard to "compounding of offence", it was submitted that there should be a provision for "compounding of offence" which should be defined appropriately. This would help settle disputes effectively on the lines of other current regulations *viz.* Current Food Regulations/Legal Metrology Regulations, etc.

28. The Additional Secretary, Department of Health and Family Welfare responded to some of the concerns raised by IPA. He submitted that in respect of Compensation for Clinical Trial related to Injury or Death, the Bill had devised a unique formula for compensation based on several parameters one of which was linking the compensation to the minimum wages in case of an unskilled workers and also with health status of the patient. On the apprehension regarding abuse of penal provisions in the said Bill, he submitted that the penal provisions are an additional safeguard other than suspension of license by drug regulator in respect of the clinical trials violations in case of deliberate violation resulting in death.

29. Shri Lalit Kumar Jain, Chairman, All India SME Pharma Manufaturers Association (AISPMA), during his deposition before the Committee on 29th November, 2013, delineated the following points for consideration of the Committee *viz.* the Bill attempts to inter-mix and confuse the existing Regulatory Provisions with the gambit of approval of clinical trials and control of its conduct for which any machinery from the office of DCGI or State Drug Controller is a big misfit as Clinical Trials relate to patients being subjected to trials for measuring and monitoring safety and efficacy of the drug, whereas the Regulatory mechanism under DCGI mainly relates to control of new drug approval based on data, manufacture, distribution and sale of drugs etc. only; the Central Drugs Authority (CDA) is filled with bureaucrats which would result in delays in approvals; need to separate clinical trials of new drugs under a separate body under a Physician and allow Drug Controller General of India both at Centre and State level to be made responsible for manufacture, testing and marketing of medicines, blood products and medical devices only, etc.

CLAUSE-BY-CLAUSE EXAMINATION OF THE BILL

30. During the course of the examination of the Bill the Committee took note of concerns, suggestions and amendments as expressed by various experts/stakeholders and duly communicated them to the Ministry for its response. Committee's observations and recommendations contained in the Report reflect an extensive scrutiny of all the viewpoints put forth before it. Upon scrutiny of the replies received from the Ministry, various amendments to the said Bill have been suggested by the Committee which are discussed in the succeeding paragraphs.

Clause 2 *- In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), for the long title and first paragraph of the preamble, the following shall be substituted, namely:—*

"An Act to regulate the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto.

WHEREAS it is expedient to regulate the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto.".

Recommendation of the Committee

31. **The Committee has been informed that the exporter has to ensure that the Pharma Units whose drugs are proposed to be exported comply with the Good Manufacturing Practices (GMP) guidelines issued by the World Health Organisation (WHO). Hence no further regulation on the export of such drugs would be necessary. The Committee is of the view that if export of drugs is brought within the ambit of Drugs and Cosmetics Act/rules, it will severely affect Exports of Drugs and put domestic pharma manufacturing units/ exporters at serious disadvantage. The Committee therefore decided that the word 'export' may be omitted from this clause and consequential amendments may be made to other clauses of the Bill.**

The clause is adopted as amended.

32. ***Clause 6, sub-clause (iii)****- after clause (aa), the following clauses shall be inserted, namely:—*

'(ab) "Central Drugs Authority" means the Central Drugs Authority of India constituted under sub-section (1) of section 4A;

(ac) "Central Drugs Laboratory" means a drug testing laboratory established by the Central Government, by whatever name, for carrying out the functions assigned to it under this Act and rules made thereunder;

(ad) "Central Licensing Authority" means the Drugs Controller General of India designated as such under sub-section (2) of section 4J;

(ae) "Chairperson" means the Chairperson of the Central Drugs Authority;

(af) "clinical trial" means—

(i) in respect of drugs, any systematic study of new drug, investigational new drug or bioavailability or bioequivalence study of any drug in human subjects to generate data for discovering or verifyingits clinical, pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug;

(ii) in respect of cosmetics, the systematic study, including dermatological study, of a cosmetic including a new cosmetic on human subjects to generate data for discovering or verifying its adverse effects with the objective of determining safety, efficacy or tolerance of the cosmetic;

*(iii) in respect of medical devices, the systematic clinical investigation or study of a medical device, investigational medical device or a new medical device, in, or on human subjects to assess the safety or performanc*e of the medical device;'

Recommendation of the Committee

33. **The Committee decided that in the definition of clinical trial provided in (af) (i) the words "any drug" should be substituted by "any new drug", since generally Bioavailability/ Bioequivalence studies of approved Drugs are conducted in Healthy Volunteers with recommended doses. The use of most of such approved drugs at recommended doses are generally considered safe for use even in healthy volunteers except certain categories of toxic drugs like Cytotoxic Anti-Cancer Drugs, therefore, regulation of BA/BE studies of approved Drugs may not be required. In any case such BA/BE Studies are conducted with the approval of respective Ethics Committees.**

34. **As regards the definition of clinical trial in respect of cosmetics provided in (af) (ii) the words "of a cosmetic including a new cosmetic" should be substituted by the words "of any new cosmetic" as the cosmetics containing approved ingredients are generally considered safe. The Committee, therefore, recommends that clinical trials of all cosmetics may not be required to be regulated. Clinical Trials of only cosmetics having new ingredients (new Cosmetics) should be regulated.**

35. **In the definition of clinical trial in respect of Medical Device provided in (af) (iii) line 2, after the words "study of a" the words "medical device" should be omitted as the Medical Devices are approved in the country after ensuring their safety and effectiveness. Clinical trials of all Medical Devices may not be required to be regulated. Therefore, Committee recommends that Clinical Trials of only new Medical Devices should be regulated. In line 4, the words "safety or performance" should be substituted by the words "safety and performance or effectiveness", since the term "effectiveness" in Medical Device regulation is generally used to mean the efficacy which has been confirmed through Non-Clinical as well as Clinical studies. However, the term "performance" generally means the capability of the Device to give desired result. In case of High-risk Medical Device, it may be appropriate to use the term "Effectiveness". However, in case of Low-risk Medical Device, the term "Performance" may be appropriate.**

Clause 6, sub-clause (vi)–

36. *after clause (b), the following clauses shall be inserted, namely:—*

'(ba) "Drugs Control Officer" means—

(i) in relation to Ayurvedic, Siddha or Unani drug, a Drugs Control Officer appointed by the Central Government or a State Government under section 33G;

(ii) in relation to any other drug or cosmetic, a Drugs Control Officer appointed by the Central Drugs Authority or a State Government under section 21;

(iii) in relation to any medical device, the Medical Device Officer appointed by the Central Drugs Authority under section 7H;

Recommendation of the Committee

37. **The Department of Health and Family Welfare had informed that the Department AYUSH would be bringing a separate enactment for regulation of ASU&H Drugs. The Committee therefore, recommends that the Department of AYUSH should bring the proposed Bill for regulation of ASU&H Drugs within one year and consequential changes may be made in the above said Clause, subsequent to enactment of an Act to regulate ASU&H drugs.**

38. *Clause 6 (x)- for clause (f), the following clause shall be substituted, namely:–*

'(f) "Manufacture" means—

(i) in relation to any drug (except human blood and its components, or any cosmetic) includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adapting any drug or cosmetic with a view to its sale, export, stocking or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business;

(ii) in relation to human blood and its components includes any process or part of a process of collection, processing, storage, packing, labeling and testing for its use, sale, export or distribution for transfusion in human beings;

(iii) in relation to any medical device, includes any process or part of process for making, assembling, altering, ornamenting, finishing, packing, labelling, or adapting any medical device with a view to its sale or stock or export or distribution but does not include assembling or adapting a device already on the market for an individual patient;'

Recommendation of the Committee

39. **As regards the definition of manufacture in relation to human blood in (f) (ii) line 3 the words "… sale, export" should be omitted as sale and export of whole human blood is not generally permitted. Therefore, the word "Sale and Export" in respect of Human Blood is not appropriate.**

40. **As regards definition of Clinical Trials, concerns have been expressed that it fails to classify phase I, II, III and IV clinical trials and other types of clinical trials. The Committee, therefore, recommends that the Department should address the above concerns while framing the rules concerning Clinical Trials to ensure effective regulation of all kinds of Clinical Trials.**

41. **The term "New Medical Device" has not been defined in this Clause. The Committee therefore recommends that the Department should also include and define the term "New Medical Devices" in this Clause itself.**

Clause 7

42. After Chapter I of the principal Act, the following Chapters shall be inserted, namely:—

'CHAPTER IA
CENTRAL DRUGS AUTHORITY

4A. (1) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority to exercise the powers conferred on, and perform the functions assigned to it by or under this Act.

(2) The Central Drugs Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal, with power to acquire, hold and dispose of property, both movable and immovable, and to contract, and shall, by the said name, sue or be sued.

(3) The head office of the Central Drugs Authority shall be in the National Capital Region.

(4) The Central Drugs Authority may, with the prior approval of the Central Government, by notification in the Official Gazette, establish its offices at such other places in India as it considers necessary.

4B. (1) The Central Drugs Authority shall consist of the following, namely:—

(a) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Health and Family Welfare— Chairperson, ex-officio;

(b) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy— Member, ex-officio;

(c) Secretary, Department of AIDS Control and Director General, National AIDS Control Organisation, Ministry of Health and Family Welfare— Member, ex-officio;

(d) Secretary to the Government of India, Ministry of Commerce and Industry, Department of Commerce— Member, ex-officio;

(e) Secretary to the Government of India, Ministry of Chemicals and Fertilisers, Department of Pharmaceuticals— Member, ex-officio;

(f) Secretary, Department of Health Research and Director General, Indian Council of Medical Research, Ministry of Health and Family Welfare— Member, ex-officio;

(g) Secretary to the Government of India, Ministry of Science and Technology, Department of Bio-technology— Member, ex-officio;

(h) Director General Health Services, Directorate General of Health Services, New Delhi— Member, ex-officio;

(i) Additional Secretary or Joint Secretary and Legislative Counsel in the Legislative Department, Ministry of Law and Justice in charge of the Group dealing with the work relating to the Ministry of Health and Family Welfare— Member, ex-officio;

(j) Additional Secretary or Joint Secretary in charge of the Drugs Quality Control Division in the Ministry of Health and Family Welfare— Member, ex-officio;

(k) four experts having such qualifications and experience to be nominated by the Central Government in such manner as may be prescribed— Member;

(l) four State Licensing Authorities to be nominated by the Central Government in such manner as may be prescribed— Member;

(m) Drugs Controller General of India— Member-Secretary, ex-officio.

(2) The Members appointed under clause (k) of sub-section (1) shall hold office for a period of three years from the date of their nomination, and shall be eligible for re-nomination;

(3) The Central Drugs Authority shall meet at such time and place and shall observe such rules of procedure in regard to the transaction of business at its meeting and allowances payable to a Member for attending such meetings as may be specified by regulations.

4C. (1) On and from the date of constitution of the Central Drugs Authority,—

(a) any reference to the Central Drugs Standards Control Organisation in any law other than this Act or in any contract or other instruction shall be deemed as a reference to the Central Drugs Authority;

(b) all properties and assets, movable and immovable, of, or belonging to, the Central Drugs Standards Control Organisation, shall vest in the Central Drugs Authority;

(c) all rights and liabilities of the Central Drugs Standards Control Organisation shall be transferred to, and be the rights and liabilities of, the Central Drugs Authority;

(d) without prejudice to the provisions of clause (c), all debts, obligations and liabilities incurred, all contracts entered into and all matters and things engaged to be done by, with or for, the Central Drugs Standards Control Organisation immediately before the said date, for or in connection with the purpose of the said Central Drugs Standards Control Organisation shall be deemed to have incurred, entered into or engaged to be done by, with or for, the Central Drugs Authority;

(e) all sums of money due to the Central Drugs Standards Control Organisation immediately before that date shall be deemed to be due to the Central Drugs Authority;

(f) all suits and other legal proceedings instituted or which could have been instituted by or against the Central Drugs Standards Control Organisation immediately before that date may be continued or may be instituted by or against the Central Drugs Authority;

(g) every employee of the Central Drugs Standards Control Organisation holding any office under the Central Drugs Standards Control Organisation immediately before that date shall hold his office in the Central Drugs Authority by the same tenure and upon the same terms and conditions of service as respects remuneration, leave, provident fund, retirement and other terminal benefits as he would have held such office if the Central Drugs Authority had not been constituted and shall continue to do so as an employee of the Central Drugs Authority or until the expiry of the period of six months from that date if such employee opts not to be the employee of the Central Drugs Authority within such period:

Provided that the salaries, allowances and other conditions of service of such employees shall not be varied to their disadvantage on exercise of their option to become the employee of the Central Drugs Authority.

(2) Notwithstanding anything in the Industrial Dispute Act, 1947 or in any other law for the time being in force, absorption of any employee by the Central Drugs Authority in its regular service under this section shall not entitle such employee to any compensation under that Act or any other law and no such claim shall be entertained by any court, tribunal or other authority.

4D. Any Member having any direct or indirect interest, whether pecuniary or otherwise, in any matter coming up for consideration at a meeting of the Central Drugs Authority, shall, as soon as possible after the relevant circumstances have come to his knowledge, disclose the nature of his interest at such meeting and such disclosure shall be recorded in the proceedings of the Authority, and the Member shall not take any part in any deliberation or decision of the Authority with respect to that matter.

4E. No act or proceeding of the Central Drugs Authority shall be invalidated merely by reason of––

(a) any vacancy in, or any defect in the constitution of, the Central Drugs Authority; or

(b) any defect in the nomination of a person as a Member of the Central Drugs Authority; or

(c) any irregularity in the procedure of the Authority not affecting the merits of the case.

4F. A Member of the Central Drugs Authority nominated under clause (k) of sub-section (1) of section 4B may, by notice in writing under his hand addressed to the Central Government, resign his office:

Provided that the Member shall, unless he is permitted by the Central Government to relinquish his office sooner, continue to hold office until the expiry of three months from the date of receipt of such notice or until a person duly appointed as his successor enters upon office or until the expiry of his term of office, whichever is the earliest.

4G. *(1) The Central Government shall appoint the Drugs Controller General of India or other person having such specialised qualifications and experience as may be prescribed to perform the functions and discharge the duties assigned to the Drugs Controller General of India by or under this Act.*

(2) The salaries, allowances and pensions payable to the Drugs Controller General of India, appointed under sub-section (1) shall be such as may be determined by the Central Government.

4H. *(1) The Central Government may, in consultation with the Central Drugs Authority create, such number of posts as it considers necessary for the efficient discharge of the functions and exercise of the powers by the Central Drugs Authority under this Act.*

(2) The manner of appointment of officers and employees of the Central Drugs Authority, their salaries, allowances and pension and other conditions of service shall be such as may be determined by the Central Drugs Authority by regulations with the approval of the Central Government.

4I. *The Central Drugs Authority shall—*

(a) specify, by regulations, the guidelines, norms, structures and requirements for effective functioning of the Central Licensing Authority and the State Licensing Authorities;

(b) assess periodically the functioning of the Central Licensing Authority and the State Licensing Authorities;

(c) have power to issue directions to the Central Licensing Authority and the State Licensing Authorities to ensure compliance with the guidelines, norms, structures and requirements specified by it under clause (a);

(d) review, suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or the State Licensing Authorities;

(e) specify, by regulations, the fees or charges for issue or renewal of licences, certificates, approvals and permissions by the Central Licensing Authority and the State Licensing authorities;

(f) coordinate, mediate and decide upon the disputes arising out of the implementation of the provisions of the Act and rules and regulations made thereunder between two or more States Licensing Authorities;

(g) constitute such committees or sub-committees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act;

(h) recommend to the Central Government the measures as regards the standards of drugs, cosmetics and medical devices for effective implementation of the provisions of this Act;

(i) perform such other functions as may be prescribed by the Central Government.

4J. *(1) The Drugs Controller General of India shall exercise the powers conferred upon him under this Act or the rules made thereunder.*

(2) The Drugs Controller General of India shall act as the Central Licensing Authority and shall have powers to—

(a) issue, renew, suspend or cancel licences or certificates or permission, as the case may be, for import, export or manufacture of drugs, cosmetics or medical devices or permission for conducting clinical trials;

(b) recall or direct to recall any drug, cosmetic or medical device;

(c) collect the fees or charges for issue or renewal of licences, certificates, approvals and permissions issued by the Central Licensing Authority under this Act;

(d) discharge any other functions as may be assigned to him by the Central Drugs Authority;

(3) The Drugs Controller General of India may, with the prior approval of the Central Drugs Authority, delegate such of his powers to the officers of the Central Drugs Authority as may be considered necessary.

(4) The Drugs Controller General of India shall be the legal representative of the Central Drugs Authority, and shall be responsible for day-to-day administration of the Central Drugs Authority.

(5) The Drugs Controller General of India shall have administrative control over the officers and employees of the Central Drugs Authority.

4K. The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Central Drugs Authority grants of such sums of money as are required by it.

4L. (1) The Central Drugs Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor- General of India.

(2) The accounts of the Central Drugs Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Central Drugs Authority to the Comptroller and Auditor-General.

(3) The Comptroller and Auditor-General of India and any other person appointed by him in connection with the audit of the accounts of the Central Drugs Authority shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has, in connection with the audit of the Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Central Drugs Authority.

(4) The accounts of the Central Drugs Authority as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon, shall be forwarded annually to the Central Government and that Government shall cause the same to be laid, as soon as may be after it is received, before each House of Parliament.

4M. (1) The Central Drugs Authority shall prepare every year an annual report in such form and manner and at such time as may be prescribed by the Central Government, giving summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government.

(2) A copy of the report forwarded under sub-section (1) shall be laid, as soon as may be after it is received, before each House of Parliament.

4N. (1) The Central Government may, after consultation with or on the recommendation of the Central Drugs Authority and subject to previous publication, by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.

(2) Without prejudice to the generality of the foregoing powers, such rules may provide for all or any of the following matters, namely:—

(a) the form and manner in which the accounts of the Central Drugs Authority shall be maintained under sub-section (1) of section 4L;

(b) the form and manner in which and the time within which annual report is to be prepared under sub-section (1) of section 4M.

4O. (1) The Central Drugs Authority may, with the approval of the Central Government, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder.

(2) In particular, and without prejudice to the generality of the foregoing powers, such regulations may provide for all or any of the following matters, namely:—

(a) the allowances payable to a Member for attending the meetings of the Central Drugs Authority under sub-section (3) of section 4B;

(b) the manner of appointment of the officers and employees of the Central Drugs Authority, their salaries, allowances and pension and other conditions of service under sub-section (2) of section 4H;

(c) the matters specified under clauses (a) and (e) of section 4I;

(d) the functions of the Central Drugs Laboratory and the functions of the Director of the Central Drugs Laboratory under the proviso to sub-section (1) of section 6.

Recommendation of the Committee

43. **The sections mentioned above suggest constitution of a Central Drugs Authority and its composition. Neither the Mashelkar Committee Report nor the Committee on Health and Family Welfare in its 30th Report on the Drugs and Cosmetics (Amendment) Bill, 2007 presented to the House on the 21st October, 2008 recommended for constitution of a Central Drugs Authority (CDA) as proposed in the Bill. Instead, both the Reports recommended for strengthening of the existing Drugs Regulatory Body *i.e.* CDSCO and a strong Central Drug Administration. The proposed CDA is studded with bureaucratic heads of seven Central Ministries and four Secretary and Additional Secretary/Joint Secretary level bureaucrats as *ex-officio* members of the CDA with Health Secretary as its Chairperson. The proposed CDA and its composition is unprecedented as no other Regulatory Body in the country or outside the country has such composition and it is not acceptable to the Committee.**

44. **As regards the Central Drugs Administration (CDA), the Committee feels that there is a need for effective discharge of the enforcement activities and it requires a strong, professionally managed administration as enforcement activities require actions against unscrupulous manufacturing companies and coordination with various State Regulatory Authorities. The Central Drug Administration should be headed by a Chief Drug Controller General of India of the rank of Secretary/Special Secretary having requisite technical and**

professional qualifications and expertise/experience pertaining to various aspects of drugs, medical devices and clinical trials. Besides, there should be three separate divisions-one each for the drugs, medical devices and conduct of clinical trials headed by their respective Drugs/Medical Devices/Clinical Trials Controllers having requisite technical and professional qualifications and expertise/experience in their respective fields and duly supported by well-trained technical/professional officers and staff. The proposed administration should be given adequate autonomy to discharge its functions enumerated under the Act. The Committee therefore, recommends that the words "Central Drugs Authority" may be replaced by "Central Drugs Administration". It is proposed that Central Drugs Administration will be answerable to the Ministry of Health and Family Welfare. The Chief Controller General of India will be selected through Search-cum-selection Committee headed by the Cabinet Secretary and a process similar to appointment of Secretary, Department of Biotechnology may be considered. Accordingly, Section 4A to 4I and 4K to 4O should be amended suitably. The Committee further recommends that there should be a provision for review of functioning of CDA by a panel of independent experts in the act itself. The Committee also recommends that consequential changes in the Act may also be made.

*45. **Section 4P-** (1) No person shall initiate or conduct any clinical trial in respect of a new drug or investigational new drug or medical device or investigational medical device or cosmetic or bioavailability or bioequivalence study of any drug in human subjects except under, and in accordance with, the permission granted by the Central Licensing Authority in such manner as may be prescribed.*

(2) No person shall initiate or conduct any clinical trial unless it is approved by the Ethics Committee constituted under section 4T, in such manner as may be prescribed.

(3) No person shall initiate or conduct any clinical trial before it is registered with the Central Drugs Authority in such manner as may be prescribed.

(4) No permission from the Central Licensing Authority under this Chapter shall be required to initiate or conduct any bioequivalence or bioavailability studies of approved drugs by the Government Institutes, Hospitals, autonomous medical or Pharmacy institutions for academic or research purposes.

*46. **Section 4Q-** In case of injury or death of a person in course of a clinical trial, whether such injury or death has been caused due to the clinical trial, shall be decided by the Drugs Controller General of India or such authority in such manner as may be prescribed.*

*47. **Section 4R(2)-** In case injury or death of a person occurs due to the clinical trial, the person conducting such clinical trial shall give him, or as the case may be, his legal heir, such compensation as may be decided by the Drugs Controller General of India or such authority, in such manner as may be prescribed.*

*48. **Section 4U(2)-** The Ethics Committee shall appoint, from amongst its members, a Chairperson (who is from outside the institution), and a member-convenor.*

*49. **Section 4V(2)**- The Ethics Committee shall be responsible to safeguard the rights, safety and well being of all trial participants enrolled in the clinical trial.*

Recommendation of the Committee

50. **In the proposed section 4P (1) line 2 and 3, the Committee recommends that the words "medical device", "cosmetic" and "any drug", may be substituted by "new medical device", "new cosmetic" and "new drug" respectively, as the medical devices are approved**

in the country after ensuring their safety and effectiveness. Therefore, clinical trials of all medical devices may not be required to be regulated. Clinical Trials of only new Medical Devices should be regulated. Similarly, the Cosmetics containing approved ingredients are generally considered safe. Therefore clinical trials of all cosmetics may not be required to be regulated. Clinical Trials of only cosmetics having new ingredient (new Cosmetics) should be regulated. Further generally Bioavailability/Bioequivalence studies of approved Drugs are conducted in Healthy Volunteers with recommended doses. The use of most of such approved Drugs at recommended doses are generally considered safe for use even in healthy volunteers except certain categories of toxic Drugs like Cytotoxic Anti-Cancer Drugs. Therefore regulation of BA/BE studies of approved Drugs may not be required. In any case such BA/BE Studies are conducted with the approval of respected Ethics Committtee. The Committee further recommends that the definitions of "New Medical Device" and "New Cosmetics" may be included in the Bill.

51. **Since BA/BE Studies of approved Drugs are proposed to be kept out of the purview of regulation, therefore, such exemptions proposed in Section 4P(4) for Government Institutions are not necessary. The Committee accordingly recommends that the sub-section (4) of the proposed section 4P should be omitted.**

52. **As regards compensation for injury or death due to clinical trial (Chapter 1B, 4Q), the Committee recommends that Principal Investigator appointed by the Chief Drug Controller of India (as recommended by Committee) and the Ethics Committee should be given responsibility for determining the cause of injury or death. The Chief Drug Controller of India should act as Appellate Authority for both, the "Subject" and the "Sponsor". The Chief Drug Controller of India should refer such appeal to the Serious Adverse Event Panel of Experts which will give the final decision.**

53. **As regards Medical Treatment and compensation for injury due to Clinical Trial, under the proposed Section 4 R(2), the word "person" in line 1 should be substituted by "Sponsor or his representative whosoever has obtained the permission from Central Licensing Authority for".**

54. **As regards Composition of Ethics Committee under the proposed Section 4 U(2) which states that "The Ethics Committee shall appoint, from amongst its members, a Chairperson (who is from outside the institution), and a member-convenor.", the expression "member-convenor" should be substituted with "Member-Secretary" as the "Member Secretary" is the most commonly used term.**

55. **As regards functions and responsibilities of Ethics Committees proposed under Section 4 V(2), after the words "….be responsible to" the words "oversee the conduct of clinical trial" should be inserted. This is because, responsibility to safeguard the rights, safety and well-being of all trial participants enrolled in the clinical trial not only lies with the Ethics Committee but with all the Stakeholders *viz.* Investigators, Sponsors and Regulatory Authorities.**

Clause 10

56. After section 5 of the principal Act, the following section shall be inserted, namely:—

"5A. (1) The Central Government shall, by notification in the Official Gazette, constitute, a Medical Devices Technical Advisory Board to advise the Central Government, the Central Drugs Authority and State Governments on technical matters pertaining to medical devices, arising out of the administration of this Act and to carry out other functions assigned to it by or under this Act.

(2) The Board shall consist of the following members, namely:—

(a) the Director General, Indian Council of Medical Research, who shall be the Chairperson, ex-officio;

(b) the Drugs Controller General of India, ex-officio;

(c) one expert each from the following, having qualifications and experience in the field of medical devices, to be nominated by—

(i) the Department of Science and Technology;

(ii) the Department of Atomic Energy;

(iii) the Department of Electronic and Information Technology;

(iv) the Central Government from the Government testing laboratories connected with the testing of medical devices;

(v) the Indian Council of Medical Research;

(vi) the Bureau of Indian Standard;

(vii) the Defence Research and Development Organisation;

(d) one expert from the field of biomedical technology from recognized technical educational institutions, to be nominated by the Central Government;

(e) one expert from the field of biomaterial or polymer technology from recognised technical educational institutions, to be nominated by the Central Government;

(f) one person representing recognised consumer associations to be nominated by the Ministry of Consumer Affairs;

(g) one pharmacologist to be nominated by the Central Government from recognised medical or research institute in the field of medical devices;

(h) one expert to be nominated by the Central Government from recognized medical or research institute from amongst persons involved in conduct of clinical trials;

(i) one person to be nominated by the Central Government from the medical device industry.

Recommendation of the Committee

57. **After Section 5A(2)(i), the following item should be inserted:- "(j) Two State Licensing authorities to be nominated by the Central Government.", as it would be appropriate to have representation from State Regulatory Authorities.**

58. **Clause 13**

7F (*1*) No person shall himself or by any other person on his behalf,—

(*a*) import, or manufacture for sale or for export, or export—

(*i*) any medical device which is not of standard quality;

(*ii*) any misbranded medical device;

(*iii*) any adulterated medical device;

(*iv*) any spurious medical device;

(*v*) any software or part or component or instrument or the list of the software or part or ingredient or instrument contained in it, unless displayed in the prescribed manner on the label or container thereof;

(*vi*) any medical device which by means of any statement, design or accessory accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect;

Recommendation of the Committee

59. **The proposed Section 7F provides for Prohibition of Import, Manufacture and Export of certain medical devices. Section 7F(1) (vi), provides an open-ended interpretation. The Committee recommends that after the words "any such other effects" the words "as may be prescribed" may be inserted.**

Clause 24

60. *After section 18C of the principal Act, the following sections shall be inserted, namely:–*

"18D. No drug or cosmetic or medical device shall be exported except in accordance with the conditions of a permission or licence or certificate, as the case may be, issued by the Central Licensing Authority, in such manner, as may be prescribed.

Recommendation of the Committee

61. **The Committee recommends that for the Section 18D, the following should be substituted: "The manner of regulation of exports of drugs, cosmetics and medical devices shall be as prescribed in the Rules", as at present manufacturers of Drugs for exports are regulated by the State Regulatory Authority. The provisions for Regulation of exports of all Drugs, Medical Device and Cosmetics as proposed in the Section 18 (D), may create hurdles to the exporters which may affect the export.**

Clause 29

62. *For section 23 of the principal Act, the following section shall be substituted, namely:–*

"23. The Drugs Control Officer or the Medical Device Officer shall take sample of drugs or cosmetics or medical devices, as the case may be, for test and examination under Chapter IIA or Chapter IV, as the case may be, in such manner as may be prescribed.".

Recommendation of the Committee

63. **As regards substitution of new Section for Section 23, line 2, the Committee recommends that the words "as the case may be" after the words "Medical Device" should be omitted as these words are superfluous.**

Clause 47

64. *After section 33P of the principal Act, the following sections shall be inserted, namely:–*

"33Q. The Central Drugs Authority may suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or the State Licensing Authority, in the

public interest and for the reasons to be recorded in writing or if the permission, licence or certificate, as the case may be, is found not to have been issued in accordance with the provisions of this Act and the rules and regulations made thereunder, in the manner as may be prescribed.

33R. (1) Any person aggrieved by any action or decision of any State Licensing Authority or the Central Licensing Authority, may prefer an appeal to the Central Drugs Authority within such period and in such manner as may be prescribed.

(2) Any person aggrieved by any action or decision of the Central Drugs Authority, may prefer an appeal to the Central Government within such period and in such manner as may be prescribed."

Recommendation of the Committee

65. **Section 33Q deals with the power of CDA to suspend or cancel permission… issued by SLA or CLA. The Committee recommends that the words "Central Drugs Authority" should be substituted by the words "Central Government" as the Committee is not in favour of setting up of CDA.**

66**. The Committee feels that the appellate authority for the actions taken by the SLA should be with the State Government. The Committee therefore recommends that the proposed Section 33R(2) may be reworded as follows:**

"Any person aggrieved by any action or decision of any State Licensing Authority may prefer an appeal to the State Government. Any person aggrieved by any action or decision of Central Licensing Authority may prefer an appeal to the Central Government."

*67***. Clause 53.—***This clause seeks to insert a new Schedule, namely, "THE THIRD SCHEDULE", in the Act relating to Categories of drugs which the Central Licensing Authority is empowered to issue license containing seventeen categories of drugs.*

Clause 53 (Third Schedule)

After the Second Schedule to the principal Act, the following Schedule shall be inserted, namely:–

"THE THIRD SCHEDULE

[See section 18(3)]

CATEGORIES OF DRUGS WHICH THE CENTRAL LICENSING AUTHORITY IS EMPOWERED TO ISSUE LICENCE:

1. Sera;
2. Solution of serum proteins intended for injection;
3. Vaccines; and includes DNA vaccines and vaccines containing living genetically engineered organisms;
4. Toxins;
5. Antigens and anti-toxins;
6. Anti-biotics (betalactums and cephalosporins);
7. Parenteral preparations meant for parenteral administration;

8. Hormones and preparations containing hormones;
9. r-DNA derived drugs;
10. RNA interference based products;
11. Monoclonal anti-bodies;
12. Cellular products and stem cells;
13. Gene therapeutic products;
14. Xenografts;
15. Cytotoxic substances (anti-Cancer drugs);
16. Blood products;
17. Modified Living Organisms.".

Recommendation of the Committee

68. **During the course of oral evidence before the Committee strong objections have been raised on Central Licensing of 17 Categories of Drugs as mentioned in the proposed III[rd] Schedule in General and especially 2 categories of Drugs namely Betalactums and Cephalosporins Antibiotics and Parenteral Preparations. The Committee recommends that in view of the concerns received from various stakeholders on the centralized licensing of Betalactums and Cephalosporins Antibiotics and Parenteral Preparations, they may be reconsidered.**

Penal Provisions

69. Concerns have been expressed before the Committee by some stakeholders that some penal provisions provided in the Bill are very stringent for even minor offences. The Committee will deal with penal provisions in the following paragraphs.

70. ***Section 4ZE.*** *Whoever, himself or by any other person on his behalf, conducts clinical trials with any drug or investigational new drug or medical device or investigational medical device or cosmetic in contravention of conditions of permission issued under section 4P and rules made thereunder shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than five lakh rupees:*

Recommendation of the Committee

71. **The Committee recommends that the punishment provided in the proposed section 4ZE may be reworded as follows:-**

"imprisonment for a term which may extend to 3 years or fine which may extend to five lakh rupees or both"

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

72 ***Section 18D****. No drug or cosmetic or medical device shall be exported except in accordance with the conditions of a permission or licence or certificate, as the case may be, issued by the Central Licensing Authority, in such manner, as may be prescribed.*

73. ***Section 18E****. Whoever, himself or by any other person on his behalf, exports any drug, cosmetic or medical device in contravention of the provisions of section 18D shall be punishable*

with imprisonment for a term which shall not be less than one year and shall also be liable to fine which shall not be less than two lakh rupees or three times value of the drug, cosmetic or medical device exported or confiscated, whichever is more.

74. ***Section 18F.*** *Whoever having been convicted of an offence under section 18E is again convicted of an offence under that section, shall be punishable with imprisonment for a term which shall not be less than two years and with fine which shall not be less than five lakh rupees or three times value of the drug, cosmetic or medical device exported or confiscated, whichever is more."*

Recommendation of the Committee

75. **The Committee recommends that the proposed section 18D, 18E and 18F may be deleted.**

76. ***Section 22 sub-section 3.*** *If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1), he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.*

Recommendation of the Committee

77. **The Committee recommends that the words "which may extend to three years or with fine or with both" may be substituted by the following:**

"for a term which may extend to 3 years or fine which may extend to rupees fifty thousand or both"

78. ***Section 28A.*** *Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than twenty thousand rupees or with both.*

Recommendation of the Committee

79. **The Committee recommends that the provision for imprisonment and fine as proposed in section 28A may be reworded as follows:**

"may extend to 3 years or fine which may extend to rupees three lakh or both"

80. **The Committee adopts the remaining clauses of the Bill without any changes. The Committee recommends that the Bill may be passed incorporating the suggestions made by it.**

General Recommendations

81. **The Committee feels that excessive delegation of Legislative powers to the Government have been provided in the Bill. Even basics have not been provided in certain provisions. Everything has been left to subordinate legislation. Similarly composition of Ethics Committee too has been left to subordinate legislation. The Committee recommends that the Department should avoid excessive regulation by means of subordinate legislation. All such provisions may be relooked and atleast basics may be provided in the Act.**

82. **The Committee recommends that the Rules to be framed after amendment of the said Bill may be notified within six months of the passing of the said Bill.**

83. **It has been brought to the notice of the Committee that the market is flooded with a number of food supplements claiming medicinal and curable properties. These food supplements are prescribed by the doctors of the Government/Private Hospitals/Institutions all over the country. Presently, the existing CDSCO has no control over manufacturing, import, sale, distribution, efficacy, quality standards and pricing of such products. It is also not known whether any clinical trial is conducted to find out efficacy and effectiveness of these products. The Committee, therefore, recommends that if any of such food supplements claim to have medicinal properties, efficacy and effectiveness in curing the diseases/illnesses, they should also be brought under the purview of the proposed Central Drug Administration for the purpose of their import, manufacturing, sale and distribution, etc.**

84. **The Committee noted very valid concerns (placed at Annexure V) raised by the Department of Commerce, an executive organ of the Government of India regarding exports, new drug and medical devices which is indicative of the fact that the Ministry of Health and Family Welfare has not done due diligence and in-depth study of all the issues involved therein. Wider consultations were not held before formulating the Bill. The Committee, therefore, recommends that before enactment of the Bill, the Ministry of Health and Family Welfare should hold intensive and meaningful consultations with the Department of Commerce with specific reference to the concerns expressed by that Department and address them in a mutually satisfactory manner.**

RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE

1. **The Committee has been informed that the exporter has to ensure that the Pharma Units whose drugs are proposed to be exported comply with the Good Manufacturing Practices (GMP) guidelines issued by the World Health Organisation (WHO). Hence no further regulation on the export of such drugs would be necessary. The Committee is of the view that if export of drugs is brought within the ambit of Drugs and Cosmetics Act/rules, it will severely affect Exports of Drugs and put domestic pharma manufacturing units/ exporters at serious disadvantage. The Committee therefore decided that the word 'export' may be omitted from this clause and consequential amendments may be made to other clauses of the Bill.** (Para 31)

2. **The Committee decided that in the definition of clinical trial provided in (af) (i) the words "any drug" should be substituted by "any new drug", since generally Bioavailability/ Bioequivalence studies of approved Drugs are conducted in Healthy Volunteers with recommended doses. The use of most of such approved drugs at recommended doses are generally considered safe for use even in healthy volunteers except certain categories of toxic drugs like Cytotoxic Anti-Cancer Drugs, therefore, regulation of BA/BE studies of approved Drugs may not be required. In any case such BA/BE Studies are conducted with the approval of respective Ethics Committees.** (Para 33)

3. **As regards the definition of clinical trial in respect of cosmetics provided in (af) (ii) the words "of a cosmetic including a new cosmetic" should be substituted by the words "of any new cosmetic" as the cosmetics containing approved ingredients are generally considered safe. The Committee, therefore, recommends that clinical trials of all cosmetics may not be required to be regulated. Clinical Trials of only cosmetics having new ingredients (new Cosmetics) should be regulated.** (Para 34)

4. **In the definition of clinical trial in respect of Medical Device provided in (af) (iii) line 2, after the words "study of a" the words "medical device" should be omitted as the Medical Devices are approved in the country after ensuring their safety and effectiveness. Clinical trials of all Medical Devices may not be required to be regulated. Therefore, Committee recommends that Clinical Trials of only new Medical Devices should be regulated. In line 4, the words "safety or performance" should be substituted by the words "safety and performance or effectiveness", since the term "effectiveness" in Medical Device regulation is generally used to mean the efficacy which has been confirmed through Non-Clinical as well as Clinical studies. However, the term "performance" generally means the capability of the Device to give desired result. In case of High-risk Medical Device, it may be appropriate to use the term "Effectiveness". However, in case of Low-risk Medical Device, the term "Performance" may be appropriate.** (Para 35)

5. **The Department of Health and Family Welfare had informed that the Department AYUSH would be bringing a separate enactment for regulation of ASU&H Drugs. The Committee therefore, recommends that the Department of AYUSH should bring the proposed Bill for regulation of ASU&H Drugs within one year and consequential changes may be made in the above said Clause, subsequent to enactment of an Act to regulate ASU&H drugs.** (Para 37)

6. **As regards the definition of manufacture in relation to human blood in (f) (ii) line 3 the words "… sale, export" should be omitted as sale and export of whole human blood is not generally permitted. Therefore, the word "Sale and Export" in respect of Human Blood is not appropriate.** (Para 39)

7. **As regards definition of Clinical Trials, concerns have been expressed that it fails to classify phase I, II, III and IV clinical trials and other types of clinical trials. The Committee, therefore, recommends that the Department should address the above concerns while framing the rules concerning Clinical Trials to ensure effective regulation of all kinds of Clinical Trials.** (Para 40)

8. **The term "New Medical Device" has not been defined in this Clause. The Committee therefore recommends that the Department should also include and define the term "New Medical Devices" in this Clause itself.** (Para 41)

9. **The sections mentioned above suggest constitution of a Central Drugs Authority and its composition. Neither the Mashelkar Committee Report nor the Committee on Health and Family Welfare in its 30th Report on the Drugs and Cosmetics (Amendment) Bill, 2007 presented to the House on the 21st October, 2008 recommended for constitution of a Central Drugs Authority (CDA) as proposed in the Bill. Instead, both the Reports recommended for strengthening of the existing Drugs Regulatory Body *i.e.* CDSCO and a strong Central Drug Administration. The proposed CDA is studded with bureaucratic heads of seven Central Ministries and four Secretary and Additional Secretary/Joint Secretary level bureaucrats as ex-officio members of the CDA with Health Secretary as its Chairperson. The proposed CDA and its composition is unprecedented as no other Regulatory Body in the country or outside the country has such composition and it is not acceptable to the Committee.** (Para 43)

10. **As regards the Central Drugs Administration (CDA), the Committee feels that there is a need for effective discharge of the enforcement activities and it requires a strong, professionally managed administration as enforcement activities require actions against unscrupulous manufacturing companies and coordination with various State Regulatory Authorities. The Central Drug Administration should be headed by a Chief Drug Controller General of India of the rank of Secretary/Special Secretary having requisite technical and professional qualifications and expertise/experience pertaining to various aspects of drugs, medical devices and clinical trials. Besides, there should be three separate divisions-one each for the drugs, medical devices and conduct of clinical trials headed by their respective Drugs/Medical Devices/Clinical Trials Controllers having requisite technical and professional qualifications and expertise/experience in their respective fields and duly supported by well-trained technical/professional officers and staff. The proposed administration should be given adequate autonomy to discharge its functions enumerated under the Act. The Committee therefore, recommends that the words "Central Drugs Authority" may be replaced by "Central Drugs Administration". It is proposed that Central Drugs Administration will be answerable to the Ministry of Health and Family Welfare. The Chief Controller General of India will be selected through Search-cum-selection Committee headed by the Cabinet Secretary and a process similar to appointment of Secretary, Department of Biotechnology may be considered. Accordingly, Section 4A to 4I and 4K to 4O should be amended suitably. The Committee further recommends that there should be a provision for review of functioning of CDA by a panel of independent experts in the act itself. The Committee also recommends that consequential changes in the Act may also be made.** (Para 44)

11. **In the proposed section 4P (1) line 2 and 3, the Committee recommends that the words "medical device", "cosmetic" and "any drug", may be substituted by "new medical**

device", "new cosmetic" and "new drug" respectively, as the medical devices are approved in the country after ensuring their safety and effectiveness. Therefore, clinical trials of all medical devices may not be required to be regulated. Clinical Trials of only new Medical Devices should be regulated. Similarly, the Cosmetics containing approved ingredients are generally considered safe. Therefore clinical trials of all cosmetics may not be required to be regulated. Clinical Trials of only cosmetics having new ingredient (new Cosmetics) should be regulated. Further generally Bioavailability/Bioequivalence studies of approved Drugs are conducted in Healthy Volunteers with recommended doses. The use of most of such approved Drugs at recommended doses are generally considered safe for use even in healthy volunteers except certain categories of toxic Drugs like Cytotoxic Anti-Cancer Drugs. Therefore regulation of BA/BE studies of approved Drugs may not be required. In any case such BA/BE Studies are conducted with the approval of respected Ethics Committee. The Committee further recommends that the definitions of "New Medical Device" and "New Cosmetics" may be included in the Bill. (Para 50)

12. **Since BA/BE Studies of approved Drugs are proposed to be kept out of the purview of regulation, therefore, such exemptions proposed in Section 4P(4) for Government Institutions are not necessary. The Committee accordingly recommends that the sub-section (4) of the proposed section 4P should be omitted.** (Para 51)

13. **As regards compensation for injury or death due to clinical trial (Chapter 1B, 4Q), the Committee recommends that Principal Investigator appointed by the Chief Drug Controller of India (as recommended by Committee) and the Ethics Committee should be given responsibility for determining the cause of injury or death. The Chief Drug Controller of India should act as Appellate Authority for both, the "Subject" and the "Sponsor". The Chief Drug Controller of India should refer such appeal to the Serious Adverse Event Panel of Experts which will give the final decision.** (Para 52)

14. **As regards Medical Treatment and compensation for injury due to Clinical Trial, under the proposed Section 4 R(2), the word "person" in line 1 should be substituted by "Sponsor or his representative whosoever has obtained the permission from Central Licensing Authority for".** (Para 53)

15. **As regards Composition of Ethics Committee under the proposed Section 4 U(2) which states that "The Ethics Committee shall appoint, from amongst its members, a Chairperson (who is from outside the institution), and a member-convenor.", the expression "member-convenor" should be substituted with "Member-Secretary" as the "Member Secretary" is the most commonly used term.** (Para 54)

16. **As regards functions and responsibilities of Ethics Committees proposed under Section 4 V (2), after the words "…be responsible to" the words "oversee the conduct of clinical trial" should be inserted. This is because, responsibility to safeguard the rights, safety and well-being of all trial participants enrolled in the clinical trial not only lies with the Ethics Committee but with all the Stakeholders *viz.* Investigators, Sponsors and Regulatory Authorities.** (Para 55)

17. **After Section 5A(2)(i), the following item should be inserted:- "(j) Two State Licensing authorities to be nominated by the Central Government.", as it would be appropriate to have representation from State Regulatory Authorities.** (Para 57)

18. **The proposed Section 7F provides for Prohibition of Import, Manufacture and Export of certain medical devices. Section 7F(1) (vi), provides an open-ended interpretation. The Committee recommends that after the words "any such other effects" the words "as may be prescribed" may be inserted.** (Para 59)

19. **The Committee recommends that for the Section 18D, the following should be substituted: "The manner of regulation of exports of drugs, cosmetics and medical devices shall be as prescribed in the Rules", as at present manufacturers of Drugs for exports are regulated by the State Regulatory Authority. The provisions for Regulation of exports of all Drugs, Medical Device and Cosmetics as proposed in the Section 18 (D), may create hurdles to the exporters which may affect the export.** (Para 61)

20. **As regards substitution of new Section for Section 23, line 2, the Committee recommends that the words "as the case may be" after the words "Medical Device" should be omitted as these words are superfluous.** (Para 63)

21. **Section 33Q deals with the power of CDA to suspend or cancel permission… issued by SLA or CLA. The Committee recommends that the words "Central Drugs Authority" should be substituted by the words "Central Government" as the Committee is not in favour of setting up of CDA.** (Para 65)

22. **The Committee feels that the appellate authority for the actions taken by the SLA should be with the State Government. The Committee therefore recommends that the proposed Section 33R(2) may be reworded as follows:**

> ***"Any person aggrieved by any action or decision of any State Licensing Authority may prefer an appeal to the State Government. Any person aggrieved by any action or decision of Central Licensing Authority may prefer an appeal to the Central Government."*** (Para 66)

23. **During the course of oral evidence before the Committee strong objections have been raised on Central Licensing of 17 Categories of Drugs as mentioned in the proposed IIIrd Schedule in General and especially 2 categories of Drugs namely Betalactums and Cephalosporins Antibiotics and Parenteral Preparations. The Committee recommends that in view of the concerns received from various stakeholders on the centralized licensing of Betalactums and Cephalosporins Antibiotics and Parenteral Preparations, they may be reconsidered.** (Para 68)

24. **The Committee recommends that the punishment provided in the proposed section 4ZE may be reworded as follows:–**

> ***"imprisonment for a term which may extend to 3 years or fine which may extend to five lakh rupees or both".*** (Para 71)

25. **The Committee recommend that the proposed section 18D, 18E and 18F may be deleted.** (Para 75)

26. **The Committee recommends that the words "which may extend to three years or with fine or with both" may be substituted by the following:**

> ***"for a term which may extend to 3 years or fine which may extend to rupees fifty thousand or both"***. (Para 77)

27. **The Committee recommends that the provision for imprisonment and fine as proposed in section 28A may be reworded as follows:**

> ***"may extend to 3 years or fine which may extend to rupees three lakh or both".*** (Para 79)

28. **The Committee adopts the remaining clauses of the Bill without any changes. The Committee recommends that the Bill may be passed incorporating the suggestions made by it.** (Para 80)

General Recommendations

29. **The Committee feels that excessive delegation of Legislative powers to the Government have been provided in the Bill. Even basics have not been provided in certain provisions. Everything has been left to subordinate legislation. Similarly composition of Ethics Committee too has been left to subordinate legislation. The Committee recommends that the Department should avoid excessive regulation by means of subordinate legislation. All such provisions may be relooked and atleast basics may be provided in the Act.** (Para 81)

30. **The Committee recommends that the Rules to be framed after amendment of the said Bill may be notified within six months of the passing of the said Bill.** (Para 82)

31. **It has been brought to the notice of the Committee that the market is flooded with a number of food supplements claiming medicinal and curable properties. These food supplements are prescribed by the doctors of the Government/Private Hospitals/Institutions all over the country. Presently, the existing CDSCO has no control over manufacturing, import, sale, distribution, efficacy, quality standards and pricing of such products. It is also not known whether any clinical trial is conducted to find out efficacy and effectiveness of these products. The Committee, therefore, recommends that if any of such food supplements claim to have medicinal properties, efficacy and effectiveness in curing the diseases/illnesses, they should also be brought under the purview of the proposed Central Drug Administration for the purpose of their import, manufacturing, sale and distribution, etc.** (Para 83)

32. **The Committee noted very valid concerns (placed at Annexure V) raised by the Department of Commerce, an executive organ of the Government of India regarding exports, new drug and medical devices which is indicative of the fact that the Ministry of Health and Family Welfare has not done due diligence and in-depth study of all the issues involved therein. Wider consultations were not held before formulating the Bill. The Committee, therefore, recommends that before enactment of the Bill, the Ministry of Health and Family Welfare should hold intensive and meaningful consultations with the Department of Commerce with specific reference to the concerns expressed by that Department and address them in a mutually satisfactory manner.** (Para 84)

MINUTES

III

THIRD MEETING

(2013-14)

The Committee met at 2.00 P.M. on Thursday, the 26th September, 2013 in Committee Room 'D', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shri Mohd. Ali Khan
4. Dr. Prabhakar Kore
5. Dr. R. Lakshmanan
6. Shri Jagat Prakash Nadda
7. Dr. Vijaylaxmi Sadho
8. Shri Arvind Kumar Singh

LOK SABHA

9. Shrimati Sarika Devendra Singh Baghel
10. Shri Kuvarjibhai M. Bavalia
11. Mohd. Asrarul Haque
12. Dr. Sanjay Jaiswal
13. Dr. Tarun Mandal
14. Shri Mahabal Mishra
15. Shrimati Jayshreeben Patel
16. Shri Harin Pathak
17. Shri Ramkishun
18. Dr. Anup Kumar Saha
19. Shri P. T. Thomas

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shri R.B. Gupta, *Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

WITNESSES

I. Department of Health and Family Welfare (Ministry of Health and Family Welfare)

1. Shri Keshav Desiraju, Secretary

2. Shri R.K. Jain, Additional, Secretary and Director General (CGHS)
3. Shri C.K. Mishra, Additional Secretary

II. * * *

III. Legislative Department (Ministry of Law and Justice)

Dr. Sanjay Singh, Additional Secretary

I. Opening Remarks

2. At the outset, the Chairman welcomed Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, to hear views of the Secretary, Department of Health and Family Welfare on two Bills, namely (i) the Drugs and Cosmetics (Amendment) Bill, 2013 and * * *.

II. Oral evidence on the Drugs and Cosmetics (Amendment) Bill, 2013

3. Before hearing the views of Shri Keshav Desiraju, Secretary, Department of Health and Family Welfare, the Chairman brought to the notice of the Committee the fact that the Director General of Health Services, who was invited through Health Secretary, to appear before the Committee directly sent a letter to Chairman seeking his exemption from appearance before the Committee, bypassing the Secretary, Department of Health and Family Welfare which amount to violation of proper protocol. The Secretary apologized on behalf of Dr. Jagdish Prasad, Director General of Health Services for this lapse. The Committee accepted the apology and directed that such incident should not be allowed to recur in future. The Committee then heard the views of the Secretary, on the Drugs and Cosmetics (Amendment) Bill, 2013. The Secretary gave a brief of the circumstances necessitating introduction of the said amendment Bill. Thereafter, Shri Arun Kumar Panda, Joint Secretary, Department of Health and Family Welfare gave a power-point presentation on the said Bill explaining about background of the Bill; functions of Central Drugs Standard Control Organisation (CDSCO); functions of State Licensing authorities; main recommendations of Mashelkar Committee; salient features of 2007 Bill; main recommendations of the Parliamentary Standing Committee on Health and Family Welfare; salient features of the New Bill (2013), etc.

4. Thereafter, Members raised certain queries *viz.* which recommendations of the Parliamentary Standing Committee on the 2007 Bill were not accepted; measures being taken to strengthen the infrastructure and increase the manpower which was a *sine-qua-non* for effective implementation of any law passed by the Parliament; whether the decisions of the Drug Technical Advisory Board (DTAB) and Medical Devices Technical Advisory Board (MDTAB) would be binding on Drugs Controller General of India (DCGI); competence of DCGI in handling the issues relating to Medical devices and conduct of Clinical trials; justification for including seven Secretaries representing various Ministries in Central Drugs Authority (CDA); justification for keeping exports of drugs under the purview of the proposed Bill; rationale behind presence of the Secretary, Department of Health and Family Welfare as head of both the Central Drugs Authority (CDA) and the Central Government which would be an Appellate Authority for the decisions taken by CDA thereby leading to conflict of interest, etc. Some of the queries were answered. The Chairman directed the witnesses to furnish comprehensive written replies to the queries which remained unanswered, within a week's time.

III. * * *

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee adjourned at 3.20 P.M.

*** Relates to other matters.

XI

ELEVENTH MEETING

(2013-14)

The Committee met at 11.00 A.M. on Tuesday, the 12th November, 2013 in Committee Room 'B', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shri Mohd. Ali Khan
4. Dr. Prabhakar Kore
5. Dr. Vijaylaxmi Sadho

LOK SABHA

6. Shri Kirti Azad
7. Shri Kuvarjibhai M. Bavalia
8. Dr. Sucharu Ranjan Haldar
9. Dr. Sanjay Jaiswal
10. Shri Mahabal Mishra
11. Shrimati Jayshreeben Patel
12. Shri Harin Pathak
13. Shri Ramkishun
14. Dr. Arvind Kumar Sharma
15. Dr. Raghuvansh Prasad Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu *Joint Secretary*

Shri R.B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

WITNESSES

Prof. S.K. Gupta, Former Head, Department of Pharmacology, AIIMS, New Delhi.

Representatives from CII

1. Shri Pavan Choudhury, Chairman, CII Medical Equipment Division
2. Ms. Suneela Thatte, Executive Director, CII, Pharma Division

Representatives from FICCI

1. Mr. Gautam Khanna, Chairman – FICCI, MDF and Executive Director – Healthcare, 3 M India Ltd.
2. Dr. Surinder Kher, Chairman – FICCI Clinical Research Taskforce and CEO – Asia, Manipal Acunova Ltd.
3. Mr. Sanjay Banerjee, Co-Chair-FICCI MDF and Regional Managing Director, Zimmer India Pvt Ltd.
4. Mr. Anil Seth, Co-Chair – FICCI Clinical Research Taskforce and Director – Clinical Operations, Eli Lilly and Company
5. Dr. Shamsher Dwivedee, Neurologist, VIMHANS
6. Mr. Sudhakar Mairpadi, Co-Chairman-FICCI MEF and Director – Regulatory Affairs and Quality Assurance, Phillips Healthcare
7. Ms. Shobha Mishra Ghosh, Senior Director, FICCI
8. Mr. Tanmoy Bose, Additional Director, FICCI

Representative from ASSOCHAM

Ms. Manisha Singh

Representative from Ministry of Health and Family

Shri Arun Panda, Joint Secretary,

Representative from Legislative Department

Dr. Sanjay Singh, Additional Secretary

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

II. Opening Remarks

2. At the outset the Chairman of the Committee welcomed the Members and informed them about the agenda of the meeting *i.e.* to hear the view of the following stakeholders on the Drugs and Cosmetics (Amendment) Bill, 2013: (a) Prof. S.K. Gupta, former Head, Department of Pharmacology, AIIMS; (b) Shri Pavan Choudhury, Chairman, CII Medical Equipment Division and Ms. Suneela Thatte, Executive Director, CII Pharma Division; (c) Shri Gautam Khanna, Chairman, FICCI; (d) Ms. Manisha Singh, ASSOCAAM, and (e) Shri Rajiv Nath, Forum Co-ordinator, All India Medical Equipment Devices (AIMED) and ***** ***** *****

III. * * *

IV. Oral Evidence on the Drugs and Cosmetics (Amendment) Bill, 2013

4. The Committee first heard the views of Prof. S.K. Gupta, former Head, Department of Pharmacology on the said Bill. Shri Gupta delineated the following points for the Committee consideration:–

(i) The term 'Medical Devices' at page 4 of the Bill should include 'sensors and electronic devices';

(ii) The term 'Investigator' at page 5 and 35 of the Bill needs to be deleted;

*** Relates to other matters.

(iii) At page 6 of the Bill, composition of Central Drug Authority may be reworded as follows:–

"The Central Drugs Authority shall consist of the following Governing Council Members, namely" instead of "The Central Drugs Authority shall consists of following, namely"

(iv) there should be broad spectrum of qualification as a criteria for appointment of Drugs Controller General of India;

(v) the Ethics Committee as envisaged in the Bill may 'oversee' the Clinical Trials but should not be held responsible;

(vi) the name of Central Drugs Laboratory, should be adequately changed to include 'Medical Devices' as the term Central Drugs Laboratory may not be competent to regulate 'Medical Devices'; and

(vii) need to include a representative from the Dental Council on the Drugs, Cosmetics and Medical Devices Consultative Committee.

5. The Committee then heard the views of Shri Pawan Chaudhury, Chairman, Medical Equipment Division on the said Bill. Shri Choudhury delineated the following points for consideration of the Committee:–

(i) In the definition of 'Manufacture' the same should be replaced by 'Legal Manufacturers';

(ii) Definition of 'New Medical Device' needs to be framed properly;

(iii) Need to relook punitive clauses in respect to Medical Devices as the medical technology is still evolving and the knowledge in respect to such Medical Technology is still developing in the country and interpretation of the same on the basis of such nascent knowledge in this field would lead to enormous difficulties.

(iv) In section 7E *i.e.* Spurious Medical Device in Chapter IIA, Explanation of the term 'Spurious' may not apply to 'medical devices';

6. Thereafter Ms. Suneela Thattee of CII Pharma Division delineated the following points on the Bill for consideration of the Committee:-

(i) In Chapter I B section 4Q page 11 line 17, Principal Investigator/Sponsor should have primary onus in case of injury or death caused due to clinical trials;

(ii) In Chapter IB at page 11 line 20 i.e. section 4(R), the duration of medical treatment for the injury needs to be defined;

(iii) In Chapter IB, Section 4(T), there is a need to add to this provision on the need for subjecting 'Ethics Committees' to an audit/inspection by regulatory authorities either from India or outside of India say, USFDA, EMEA etc;

(iv) Need to delete the requirement of furnishing of 'Audit Reports by sponsors' from section 4(V) (3) of the Bill;

(v) The Bill is silent on the fate of the clinical Trials if the registration of Ethics Committee is cancelled; and

(vi) The Bill is silent regarding ongoing training and skill of regulatory officials.

7. Thereafter Mr. Gautam Khanna, Chairman – FICCI, MDF and Executive Director – Healthcare, 3 M India Ltd., delineated the following points on the Bill for the consideration of the Committee:–

(i) At page 4/line 15-17 of the Bill, in the definition of investigational Medical device, the word 'performance' should be used for medical devices instead of effectiveness:

(ii) In respect of 'Medical Devices' sufficient transition time (5 years) for implementation of the Bill as and when cleared in the Parliament must be given;

(iii) Lot of the provisions in the said Bill have been left for delegated legislation;

(iv) Size of Central Drugs Authority (CDA) is too large;

(v) Subordinate rules on compensation needs to be updated for clarity;

(vi) Need for more guidance on operation of compensation norms;

(vii) Body put in place a performance rating for Central Licensing Authority in the provisions of the Bill itself; and

(viii) Body of Clinical Experts must be there in the Clinical Body *i.e.* the Central Drugs Authority (CDA)

8. Shri Rajiv Nath, Forum Coordinator, All India Medical Equipments Devices (AIMED) submitted the following points for submission of the Committee:–

(i) U.S. and UK Medical Devices Regulation Laws must also be incorporated in India;

(ii) The Bill must consider the fact that Drugs and Cosmetics are different from Medical Devices and cannot be judged by the same yardstick; and

(iii) Chapter II A of the Bill which deals with 'Medical Devices' needs to bring international aspects of Medical Devices Safety and Performance, which seems to be missing in the chapter;

9. Thereafter Members asked certain queries which were answered to by the witnesses. The Chairman directed the witnesses to send any other information which they needed to supplement to the views given to the Committee within a weeks' time.

10. A Verbatim record of proceedings of the Committee was kept.

11. The Committee then adjourned at 1.00 P.M.

RECORD OF DISCUSSIONS
(2013-14)

The Committee met at 3.00 P.M. on Thursday, the 21st November, 2013 in Committee Room 'B', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Mohd. Ali Khan
3. Shri Arvind Kumar Singh

LOK SABHA

4. Shrimati Sarika Devandra Singh Baghel
5. Dr. Sucharu Ranjan Haldar
6. Dr. Monazir Hassan
7. Shri Harin Pathak
8. Shri Ramkishun
9. Shri P. T. Thomas

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*

WITNESSES

1. Dr. Ranjit Roy Choudhury, National Professor of Pharmacology and Former Member, Board of Governors, Medical Council of India;

2. Representatives of Lawyers Collective HIV/AIDS Unit, New Delhi

(i) Shri Anand Grover, Senior Advocate and Director
(ii) Ms. Geetanjali Sharma
(iii) Shri Apurba Kunda
(iv) Shri Rohit Kumar
(v) Ms. Shivani Tripathi
(vi) Ms. Lorraine Misquith

3. Shri P. K. Gupta, Chairman, Confederation of Indian Pharmaceutical Industry, New Delhi;

4. Representatives of SME Pharma Industries Confederation-New Delhi

(i) Shri Jagdeep Singh, Secretary General
(ii) Dr. Pradeep Blaggan
(ii) Shri Amit Kapoor
(iii) Shri Piyush Sharma
(iv) Shri Rakesh Singla
(v) Shri Sanjeev Vij
(vi) Shri Gian Prakash Sarwal
(vii) Shri Sudhir Pathak

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

Representative from Ministry of Health and Family Welfare

Shri Arun Kumar Panda, Joint Secretary

II. Opening Remarks

2. Shri Harin Pathak, at the outset, welcomed Members of the Committee and informed them that due to certain urgent work, the Chairman could not attend the meeting. The Committee, elected Shri Pathak to preside over the meeting. He apprised Members about the agenda of the meeting *i.e.* to hear the views of the above-mentioned stakeholders on the Drugs and Cosmetics (Amendment) Bill, 2013.

III. Oral Evidence on the Drugs and Cosmetics (Amendment) Bill, 2013

3. The Committee first heard the views of Dr. Ranjit Roy Choudhury, National Professor of Pharmacology and Former Member, Board of Governors, Medical Council of India on the said Bill. Dr. Choudhary delineated the following points for the Committee's consideration, *viz.* Ethics Committee should be sacrosanct; the Bill is silent on the procedure for selection of persons on the Ethics Committee; Chairman of the Ethics Committee should be selected from a pool of accredited persons and transparency must be ensured in selection of persons to the Ethics Committee.

4. The Committee then heard the views of Shri Anand Grover, Senior Advocate and Director, Lawyers Collective HIV/AIDS Unit, New Delhi on the said Bill. Shri Grover delineated the following points for the Committee's consideration, *viz.* Rules have taken over the Main Act whereas Rules should have followed from the Act; there was a need to ensure protection of participants of Clinical Trials in the Bill itself; need to set up proper infrastructure to check adverse effects of Clinical Trials; need to include provision of on-the-site visit by the Ethics Committee instead of relying on the Principal Investigator; distinct responsibilities, liabilities must be carved out and penalties must be provided for both the Sponsors and Investigators; contradictions between Act and Rules must be amended; why only government institutions are exempted from taking permission for clinical trials in bioequivalence and bioavailability studies; need to ensure availability of all data with respect to Clinical Trials on the website of the Drug Regulator including negative data on Clinical Trials, etc.

5. The representatives of Confederation of Indian Pharmaceutical Industry and SME Pharma Industries Confederation were not in favour of the present Bill and highlighted their concerns in respect of the following issues *viz.* need to strike a balance between quality, affordability and availability of drugs; likely closure of Small and Medium Enterprise (SME) Pharma Industries due to cost escalation arising out of excessive regulatory requirements as envisaged in the present Bill; false propaganda about the existence of spurious drugs in the Indian markets; creation of Central Drugs Authority and incurring of expenditure thereon not desirable; multinationals pushing for quality norms to scuttle Indian SME pharma companies; centralization of drug licensing and its adverse impact on the domestic pharma companies; need for level playing field for SME pharma companies; dual (*i.e.* Central as well as State) drug licensing policy and harassment of SME pharma companies due to centralization of powers; instead of bringing in centralized licensing, there is need to strengthen the State Drug Regulatory Authorities; dual system of drug licensing will undermine the export of medicines by SME pharma companies; poor testing standards of Central Drug Testing Laboratories; need for keeping injectibles and betalactams out of the purview of Central Drug Licensing Authority, etc.

6. Thereafter, the Joint Secretary, Ministry of Health and Family Welfare responded to some of the concerns raised by the representatives of Confederation of Indian Pharmaceutical Industry and SME Pharma Industries Confederation. The Joint Secretary submitted before the Committee that the Bill envisages central regulation of only 17 categories of critical, high-end drugs and these 17 categories accounted for only 10% of the total pharma industry. The Joint Secretary also touched upon some other issues like subsumation of CDSCO in CDA; need for strengthening of Central and State Drug Licensing Authorities by way of manpower augmentation, training and availability of sophisticated high-end equipments; violation of existing drug regulation laws, etc.

7. Thereafter Members asked certain queries which were answered by the witnesses. The Chairman directed the witnesses to send any information which they needed to supplement the views given to the Committee within a week's time.

8. A Verbatim record of proceedings of the Committee was kept.

9. The Committee then adjourned at 5.00 P.M.

XII

TWELFTH MEETING

(2013-14)

The Committee met at 11.00 P.M. on Friday, the 22nd November, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shri Mohd. Ali Khan

LOK SABHA

4. Shrimati Sarika Devendra Singh Baghel
5. Dr. Sucharu Ranjan Haldar
6. Dr. Monazir Hassan
7. Dr. Sanjay Jaiswal
8. Shri Chowdhury Mohan Jatua
9. Dr. Tarun Mandal
10. Shrimati Jayshreeben Patel
11. Shri Harin Pathak
12. Shri Ramkishun
13. Dr. Anup Kumar Saha

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

WITNESSES

I. Dr. M. K. Bhan, Former Secretary to the Government of India, Department of Biotechnology, Ministry of Science and Technology

II. Indian Drug Manufacturers Association, Mumbai

1. Shri M. U. Doshi, President
2. Dr. R. K. Sanghavi, Chairman – Medical sub-committee, IDMA
3. Shri S. M. Mudda, Chairman – Regulatory Affairs sub-committee, IDMA
4. Shri Ashok K. Madan, Executive Director, IDMA Delhi office

III. Representatives of Indian Beauty and Hygiene Association, Mumbai

1. Ms. Malathi Narayanan
2. Ms. Veena Balgi
3. Ms. Priyanka Bhat
4. Mr Rajendra Dobriyal

IV. Representatives of Consumer Online Foundation, New Delhi

1. Mr. Bejon Kumar Misra, Founder
2. Mr. Shambhu Nath Chaturvedi, Adviser
3. Dr. Rashmi Kulshreshta, Adviser
4. Mr. Pyush Misra, Director

V. Representatives of Federation of Pharma Entrepreneurs (FOPE)

1. Mr. Umesh Sanghi
2. Mr. Vinod Kalani
3. Mr. Navdeep Chawla
4. Mr. R. K. Chugh
5. Mr. R. K. Rustagi

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

Representatives from Ministry of Health and Family

Shri Arun Kumar Panda, Joint Secretary

II. Opening Remarks

2. At the outset the Chairman of the Committee welcomed the Members and informed them about the agenda of the meeting *i.e.* to hear the view of the above-mentioned stakeholders on the Drugs and Cosmetics (Amendment) Bill, 2013.

III. Oral Evidence on the Drugs and Cosmetics (Amendment) Bill, 2013

3. The Committee first heard the views of Dr. M. K. Bhan, Former Secretary to the Government of India, Department of Biotechnology, Ministry of Science and Technology. He delineated the following points for consideration of the Committee *viz.* need to find a middle path drug regulation which was neither too free space without regulation nor was so restricting so as to stifle innovation; Bill must guarantee a Regulatory system that ensure that the two pillars of regulation *i.e.*, ethics and competence must go together and one should not be ignored at the cost of other; need to ensure minimum Stature of Special Secretary of Government of India for the Drug Regulator; need to include more experts in the Drugs Regulatory Body instead of representatives of Ministries; need for external review of the performance of the Drug Regulator every two years with the reports made by the external reviewer being made public; need to include representatives of Biotechnology on the Drug Regulatory body; need to rephrase the term ‘injury

or death due to medical trials' which may be read as "death due to drug or due to lack of first class medical care"; need to include provision where in the 'Drug Controller General of India' can be appointed only by the Parliament so as to ensure his autonomy and also to ensure high standards attached to the office of the Drug Controller General of India; compulsory mandate of Drug Controller General of India to check any trials which include Human trials, etc.

4. Dr. B.K. Mishra of the Consumer Online Foundation delineated the following points for consideration of the Committee *viz.* need to educate common people on pharmacovigilance which is lacking in the Bill; adverse drug reporting must be made part of this Bill to ensure accountability; need to form a Central Body for maintaining data base of drugs; pharmaco-vigilance must be robust and time-bound but at the same time innovation should not suffer; need to have transparency in adverse drug reporting, etc.

5. The representatives of Indian Drug Manufacturers Association delineated the following points for consideration of the Committee *viz.* over-regulation and excessive centralization of powers must be avoided; new provision in the Bill with respect of clinical Trials will strangle the industry and the present provisions are sufficient; need to separate Bio-regulatory study from Bio-equivalence study in respect of clinical trials; etc.

6. The representatives of the Indian Beauty and Hygiene Association were of the view that cosmetics must be treated separately from Drugs in the present Bill.

7. The representatives of FOPE delineated the following points for consideration of the Committee *viz.* New regulations would increase paper work especially for small entrepreneurs as they do not have expertise for such huge paper work filing; penal provisions have been increased enormously in the new Bill; need to include 'Mensrea or knowability' clause in the penal provisions of the Bill so as to prevent its misuse; no definition of critical drugs in the 17 Drugs that are defined as critical; backdoor entry to include other drugs by notification in the critical drugs; vast powers given to Central Government to withdraw drugs approved by State Governments etc.

8. The Members of the Committee then sought clarifications from the above witnesses. The Chairman directed the witnesses to furnish replies in writing on the queries raised by Members within a week's time.

9. A verbatim record of proceedings of the Committee was kept.

10. The Committee then adjourned at 12.50 P.M.

XIII

THIRTEENTH MEETING

(2013-14)

The Committee met at 11.00 A.M. on Friday, the 29th November, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shri Mohd. Ali Khan
4. Shri Jagat Prakash Nadda
5. Shri Arvind Kumar Singh

LOK SABHA

6. Shri Kirti Azad
7. Dr. Tarun Mandal
8. Shrimati Jayshreeben Patel
9. Shri Harin Pathak
10. Shri Ramkishun
11. Dr. Anup Kumar Saha

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*

Shri R.B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

WITNESSES

Indian Pharmaceutical Alliance (IPA)

1. Shri Satish Reddy, Managing Director, Dr. Reddy's Laboratories and President, IPA
2. Shri A H Khan, Vice President,
3. Shri Dilip G. Shah, Secretary General

All India SME Pharma Manufaturers Association (AISPMA)

1. Shri Lalit Kumar Jain, Chairman
2. Dr. Niranjan Singh, Secretary
3. Shri Anil Maheshwari, Office Executive

Representatives from Ministry of Health and Family Welfare

Shri R.K. Jain, Additional Secretary

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

II. Opening Remarks

2. At the outset the Chairman of the Committee welcomed the Members and informed them about the agenda of the meeting *i.e.* (A) To consider and adopt draft *** * *** (B) to hear the views of the above-mentioned stakeholders on the Drugs and Cosmetics (Amendment) Bill, 2013.

III. * * *

IV. Oral Evidence on the Drugs and Cosmetics (Amendment) Bill, 2013

4. The Committee first heard the views of Shri Dilip G. Shah, Secretary General, Indian Pharmaceutical Alliance. He delineated the following points for consideration of the Committee:

(i) the drugs meant for export should be kept outside the purview of regulatory approvals;

(ii) Clause 6(C), which deals with the definition of 'New Drug', states that "A new drug shall continue to be a new drug for such period as may be prescribed", the timeline is not specified. Moreover, in the present Act, new drug was defined as any drug within four-years from its first approval in India. The new clause becomes discretionary and could be subjected to abuse and existing timeline of four-year should continue.

(iii) In Chapter 1B, Clause 4P(1) which deals with Bio-Availibility (BA)/Bio-Equivalence (BE) Studies, permission for such studies for more than four-year old drugs with proven safety and efficacy record should continue to be with Ethics Committee, instead of being given to Central Licensing Authority as per this new Clause in the Bill.

(iv) In Chapter 1B, Clause 4P (3), the new proviso requires registration of clinical trials with the Central Drug Authority (CDA) also. As per current regulations, all clinical trials are required to be registered with Clinical Trials Registry of India maintained by Indian Council of Medical Research (ICMR). The new proviso would lead to duplication and raise transaction cost.

(v) In Chapter 1B, Clause 4P (4), Department of Scientific and Industrial Research (DSIR) approved Pharmaceutical R&D Units should be exempted from obtaining permission of Central Licensing Authority (CLA).

(vi) In Chapter 1B, Clause 4 Q, relating to compensation for Clinical Trial injury or death, there was a need to include provisions to appoint an Appellate Authority who should

*** Relates to other matters.

give opportunity to the sponsors to present their assessment before arriving at a final decision.

(vii) With regard to Clause 4ZA, which deals with penal provisions for penalty for clinical trials for drugs/medical device without approval, there is a minimum penalty of imprisonment of three years and a fine upto 10 lakhs, the provison of minimum imprisonment of three years is very harsh, instead it should be modified as punishment which may range from imprisonment for minimum period of one year upto a maximum period of five years and fine upto Rs. 10 lakhs.

(viii) With regard to penal provisions in the Bill, it was submitted that the penal provisions were without adequate safeguards and prone to abuse and would discourage not only foreign investment but also domestic investment in the pharma manufacturing sector as well as research and development.

(ix) With regard to "compounding of offence", it was submitted that there should be a provision for "compounding of offence" which should be defined appropriately. This would help settle disputes effectively on the lines of other current regulations *viz.* Current Food Regulations/Legal Metrology Regulations, etc.

5. The Additional Secretary, Ministry of Health and Family Welfare responded to some of the concerns raised by IPA. He submitted before the Committee that in respect of Compensation for Clinical Trial Injury or Death, the said Bill had devised a unique formula for compensation based on several parameters, one of which was linking the compensation to the minimum wages in case of an unskilled workers age/health status of the person killed due to clinical trials. On the apprehension regarding abuse of penal provisions in the said Bill, he submitted that the penal provisions are an additional safeguard other than suspension of license of the clinical trials violations in case of willful obstruction in the duties of the drug regulator.

6. The Members of the Committee then sought clarifications from the above witnesses. The Chairman directed the witnesses to furnish replies in writing on the queries raised by Members within a week's time. The representatives of IPA then withdrew.

7. The Committee then heard the views of Shri Lalit Kumar Jain, Chairman, All India SME Pharma Manufacturers Association (AISPMA). He delineated the following points for consideration of the Committee *viz.* the said Bill attempts to inter-mix and confuse the existing Regulatory Provisions with the gambit of approval of clinical trials and control of its conduct for which any machinery from the office of DCGI or State Drug Controller is a big misfit as Clinical Trials relate to patients being subjected to trials for measuring and monitoring safety and efficacy of the drug, whereas the Regulatory mechanism under DCGI mainly relates to control of new drug approval based on data, manufacture, distribution and sale of drugs etc. only; the Central Drugs Authority (CDA) is filled with bureaucrats which would result in delays in approvals; need to separate clinical trials of new drugs under a separate body under a Physician and allow Drug Controller General of India both at Centre and State level to be made responsible for manufacture, testing and marketing of medicines, blood products and medical devices only, etc.

8. The Members of the Committee then sought clarifications from the above witnesses. The Chairman directed the witnesses to furnish replies in writing on the queries raised by Members within a week's time.

9. A verbatim record of proceedings of the Committee was kept.

10. The Committee then adjourned at 12.45 P.M.

RECORD OF DISCUSSIONS
(2013-14)

The Committee met at 3.00 P.M. on Monday, the 9th December, 2013 in Room '074', Ground Floor, Parliament Library Building, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Mohd. Ali Khan
3. Dr. Prabhakar Kore
4. Dr. R. Lakshmanan
5. Dr. Vijaylaxmi Sadho

LOK SABHA

6. Shri Kuvarjibhai M. Bavalia
7. Dr. Sucharu Ranjan Haldar
8. Dr. Sanjay Jaiswal
9. Shri Harin Pathak

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*

WITNESSES

Representatives from Ministry of Health and Family

Shri Keshav Desiraju, Secretary
Shri R.K. Jain, Additional Secretary
Dr. G.N. Singh, DCG(I)
Shri Arun Panda, Joint Secretary

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri R.K. Pattanayak, Deputy Legislative Counsel
4. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

II. Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, to hear the Secretary, Department of Health and Family Welfare in connection with the Clause-by-Clause consideration of the Drugs and Cosmetics (Amendment) Bill, 2013.

II. Oral evidence on Drugs and Cosmetics (Amendment) Bill, 2013

3. Thereafter, the Committee heard the views of the Secretary, Department of Health and Family Welfare on the Drugs and Cosmetics (Amendment) Bill, 2013. The Secretary submitted that an essential element of Universal Health Coverage is the availability of good quality, safe and efficacious drugs. These are regulated under the provisions of the Drugs and Cosmetics Act, 1940 by the Central Drugs Standard Control Organization (CDSCO) in the Central Government and the Drug Control Departments in the States. They also regulate the quality, safety and efficacy of medical devices, cosmetics and clinical trials. Over the decades though the pharmaceutical industry has witnessed unprecedented growth there has not been a concomitant change in the drug regulatory set-up. The Mashelkar Committee, appointed by the Government in 2003, had made several recommendations including strengthening and restructuring the CDSCO as a Central Drug Administration, centralised licensing of manufacture of drugs, strengthening the State Drug Control Departments, appropriate regulatory mechanism for medical devices, etc. The Drugs and Cosmetics (Amendment) Bill, 2007 was a step in that direction. However, several provisions of that Bill required reconsideration in view of the States' reservations and further requirements in other areas like clinical trials and medical devices, especially in view of the comprehensive recommendations of the Parliamentary Standing Committee on the 2007 Bill. Hence, this very comprehensive Bill of 2013 has been brought in place of the 2007 Bill.

4. He further informed that the Drugs and Cosmetics (Amendment) Bill, 2013 which is under examination by the Committee was introduced in the House on 29th August, 2013 and so far the Department has received 72 memoranda from the Secretariat containing comments, suggestions and objections from NGOs, experts, Industry associations, etc. The Department had examined these memoranda and submitted clause wise responses for the consideration of the Committee. He submitted that a majority of the suggestions/objections, which have been raised, relate to the following provisions of the Bill:

- Section 4A and 4B — Constitution and composition of the proposed Central Drugs Authority (CDA)
- Section 4-I(d) and 33Q— Powers of CDA to cancel/suspend licenses granted by the State Licensing Authority (SLA)
- Section 33R— CDA as appellate authority for actions/decisions taken by the SLA
- Section 18D— Regulation of Exports by Central Licensing Authority (CLA)
- Section 18(3) — Licensing of 17 categories of Drugs by CLA
- Section 7B, 7F(1)(b)— Regulatory provisions for Medical Devices with respect to Licensing and Standards.
- Section 4ZA to 4ZH, 7K, 7L, 13, 13A, 18E, 18F, 34AAA — Penal provisions for certain offences

5. He was of the view that many of the suggestions received related to the procedural aspects of various activities which could be considered at the time of framing the Rules after the Bill is passed.

6. He further drew the attention of the Committee on the following issues where the Department is of the view that some Sections of the Bill may need reconsideration in the light of the comments/suggestions/objections received from the stakeholders:

(a) As per Section 4B (1) of the Bill, the CDA has 11 *ex-officio* members including 9 Secretaries/Addl.Secretaries/Joint Secretaries of various Departments, four experts and four State Licensing Authorities. It has been suggested to have more experts than *ex-officio* members.

(b) As per Section 33R of the Bill the CDA will be the Appellate Authority for the actions/ decisions taken by the Central Licensing Authority as well as State Licensing Authorities. Suggestions have been received that State Governments should continue to be the appellate authority for the actions/decisions taken by the SLA.

(c) As per Section 18D of the Bill, no drug, cosmetic and medical devices will be exported except in accordance with the conditions of license or permission or approval issued by the CLA. Concerns have been raised that such provisions will delay/affect the exports adversely.

(d) Seventeen categories of drugs as mentioned in the Third Schedule are proposed to be under Central Licensing. Objections have been raised on such Central Licensing, especially for two categories of drugs namely Betalactum and Cephalosporin Antibiotics and Parenteral preparations.

(e) Concerns have been raised that the penal provisions laid down in Section 4ZA to 4ZH, 7J, 7K, 7L, 13, 13A, 18E, 18F, 34AAA of the Bill for certain offences are extremely harsh and may cause harassment to legitimate players.

7. He further submitted before the Committee that there are certain suggestions which Ministry has decided not to accept in public interest which are as under:

(a) Suggestion to omit the provision relating to power of CDA to cancel/suspend licenses granted by the SLA. CDA should have this power to ensure that SLAs grant licenses strictly in accordance with the provisions of Drugs and Cosmetics Act and Rules made thereunder.

(b) Separate authority for regulation of Medical Devices, is not acceptable because creation of entirely a separate authority with new infrastructure, manpower etc., will not give any additional value.

(c) Suggestion to delete completely the proposed Central Licensing of 17 categories of drugs listed in the Third Schedule will go against the core recommendation of the Mashelkar Committee and the report of the Parliamentary Standing Committee in 2008.

(d) Suggestion to give power to the SLA to launch prosecution for violations of provisions related to Clinical Trials is not acceptable because the Clinical Trials are regulated by the DCGI.

8. He concluded by submitting that the Department awaits the valuable recommendations of this Committee before the provisions of the Bill are finalized and hoped that this exercise will lead to a strengthening of the principal Act and more effective regulatory systems.

9. Thereafter, Members raised certain queries on the said Bill. The Chairman directed the Health Secretary to furnish comprehensive written replies to the queries which remained unanswered, within three days time.

10. A Verbatim record of proceedings of the Committee was kept.

11. The Committee adjourned at 3.45 P.M.

XIV

FOURTEENTH MEETING

(2013-14)

The Committee met at 3.00 P.M. on Monday, the 16th December, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Dr. Harin Pathak — *In the Chair*

RAJYA SABHA

2. Shri Mohd. Ali Khan
3. Dr. R. Lakshmanan
4. Shri Jagat Prakash Nadda
5. Dr. Vijaylaxmi Sadho
6. Shri Arvind Kumar Singh

LOK SABHA

7. Shri Kuvarjibhai M. Bavalia
8. Shrimati Priya Dutt
9. Dr. Sucharu Ranjan Haldar
10. Shri Chowdhury Mohan Jatua
11. Shri Mahabal Mishra
12. Dr. Anup Kumar Saha

SECRETARIAT

Shri P. P. K. Ramacharyulu, *Joint Secretary*

Shri R. B. Gupta, Director

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

II. Opening Remarks

2. Shri Harin Pathak, at the outset, welcomed Members of the Committee and informed them that due to certain urgent work, the Chairman could not attend the meeting. The Committee, elected Shri Pathak to preside over the meeting. He apprised Members about the agenda of the meeting *i.e.* to consider and adopt draft * * * (ii) 79th Report on the Drugs and Cosmetics (Amendment) Bill, 2013.

*** Relates to other matters.

III. Adoption of the Draft Reports

3. The Committee then considered and discussed the *** * *** draft Report* * * mentioned above. The Chairman invited Members to share their specific suggestions, if any, for incorporation in the said Draft Report* * *. The Members of the Committee highlighted certain suggestions for incorporation in the said Report* * *. The Committee decided to further consider and adopt the said Report* * * with the said modifications in its meeting to be held on 17th December, 2013.

4. The Committee adjourned at 3.30 P.M.

*** Relates to other matters.

XV

FIFTEENTH MEETING

(2013-14)

The Committee met at 10.30 A.M. on Tuesday, the 17th December, 2013 in Room No. 63, First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Shri Mohd. Ali Khan
4. Dr. R. Lakshmanan
5. Shri Jagat Prakash Nadda
6. Shri Arvind Kumar Singh

LOK SABHA

7. Shri Kuvarjibhai M. Bavalia
8. Shrimati Priya Dutt
9. Mohd. Asrarul Haque
10. Dr. Sanjay Jaiswal
11. Shri Harin Pathak
12. Dr. Anup Kumar Saha

SECRETARIAT

Shri P. P. K. Ramacharyulu, *Joint Secretary*

Shri R. B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Deputy Director*

Shri Pratap Shenoy, *Committee Officer*

II. Opening Remarks

2. At the outset the Chairman of the Committee welcomed the Members and informed them about the agenda of the meeting *i.e.* to further consider and adopt draft *** * *** (ii) 79th Report on the Drugs and Cosmetics (Amendment) Bill, 2013.

*** Relate to other matters.

III. Adoption of the Draft Reports

3. The Committee then further considered and discussed the ******* draft Report******* mentioned above. The Chairman invited Members to share their specific suggestions, if any, for incorporation in the said Draft Report*** * ***. After some discussions, the Committee adopted *** * *** with some modifications *** * *** in the report on Drugs and Cosmetics (Amendment) Bill, 2013 in chapter 1B, 4Q relating to compensation for injury or death due to clinical trial.

4. The Committee, thereafter, decided that the said Report*** * *** may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Wednesday, the 18th December, 2013. The Committee authorized its Chairman and in his absence, Shri Mohd. Ali Khan and Shri Jagat Prasad Nadda to present the Reports in Rajya Sabha, and Shri Harin Pathak, and in his absence, Dr. Anup Kumar Saha to lay the Report*** * *** on the Table of the Lok Sabha.

5. The Committee adjourned at 10.40 A.M.

*** Relates to other matters.

ANNEXURES

ANNEXURE-I

TO BE INTRODUCED IN THE RAJYA SABHA

Bill No. LVIII of 2013

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2013

A

BILL

further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Sixty-fourth Year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetcs (Amendment) Act, 2013.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

Provided that different dates may be appointed for different provisions of this Act, and any reference in any such provision to the commencement of this Act shall be construed as a reference to the coming into force of that provision.

Amendment of long title and preamble.

23 of 1940.

2. In the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), for the long title and first paragraph of the preamble, the following shall be substituted, namely:—

"An Act to regulate the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto.

WHEREAS it is expedient to regulate the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto.".

Amendment of section 1.

3. In section 1 of the principal Act, in sub-section (*1*), for the words "and Cosmetics", the words ", "Cosmetics and Medical Devices" shall be substituted.

Substitution of words "Drugs Control Officer" for word "Inspector".

4. Throughout the principal Act, for the word "Inspector", wherever it occurs, the words "Drugs Control Officer" shall be substituted.

Amendment of section 2.

5. In section 2 of the principal Act, for the words and figures "the Dangerous Drugs Act, 1930", the words and figures "the Narcotic Drugs and Psychotropic Substances Act, 1985" shall be substituted. 2 of 1930. 61 of 1985.

Amendment of section 3.

6. In section 3 of the principal Act,—

(*i*) after clause (*a*), the following clauses shall be inserted, namely:—

'(*aA*) "bioavailability study" means a study to assess the rate and extent to which the active drug is absorbed from a pharmaceutical formulation and becomes available in the systemic circulation or availability of drug at the site of action;

(*aB*) "bioequivalence study" means a study to establish the absence of a significant difference in the rate and extent of absorption of an active drug from a pharmaceutical formulation in comparison to the reference formulation having the same active drug when administered in the same molar dose under similar conditions;';

(*ii*) in clause (*aa*), after sub-clause (*ii*), the following sub-clause shall be inserted, namely:—

"(*iii*) in relation to Medical Devices, the Medical Device Technical Advisory Board constituted under section 5A;";

(*iii*) after clause (*aa*), the following clauses shall be inserted, namely:—

'(*ab*) "Central Drugs Authority" means the Central Drugs Authority of India constituted under sub-section (*1*) of section 4A;

(*ac*) "Central Drugs Laboratory" means a drug testing laboratory established by the Central Government, by whatever name, for carrying out the functions assigned to it under this Act and rules made thereunder;

(*ad*) "Central Licensing Authority" means the Drugs Controller General of India designated as such under sub-section (*2*) of section 4J;

(*ae*) "Chairperson" means the Chairperson of the Central Drugs Authority;

(*af*) "clinical trial" means—

(*i*) in respect of drugs, any systematic study of new drug, investigational new drug or bioavailability or bioequivalence study of any drug in human subjects to generate data for discovering or verifying its clinical, pharmacological (including pharmacodynamic and pharmacokinetic) or adverse effects with the objective of determining safety, efficacy or tolerance of the drug;

(*ii*) in respect of cosmetics, the systematic study, including dermatological study, of a cosmetic including a new cosmetic on human subjects to generate data for discovering or verifying its adverse effects with the objective of determining safety, efficacy or tolerance of the cosmetic;

(*iii*) in respect of medical devices, the systematic clinical investigation or study of a medical device, investigational medical device or a new medical device, in, or on human subjects to assess the safety or performance of the medical device;';

(*iv*) in clause (*aaa*), after the words "component of cosmetic", the words "and includes new cosmetic" shall be inserted;

(*v*) in clause (*b*),—

(*A*) in sub-clause (*ii*), after the words "destruction of vermin or insects", the words "or microbes" shall be inserted;

(*B*) sub-clause (*iv*) shall be omitted;

(*C*) after sub-clause (*iv*), the following sub-clause shall be inserted, namely:—

'(*v*) any new drug for which permission has been granted by the Central Licensing Authority under the first proviso to clause (*c*) of sub-section (*1*) of section 18.

Explanation I.—In this sub-clause, "new drug" means—

(*i*) a drug, including bulk drug substance, which has not been used in the country to any significant extent under the prescribed conditions, recommended or suggested in the labelling thereof and has not been recognised as effective and safe by the Central Licensing Authority for the expected claims and its limited use, if any;

(*ii*) a drug approved by the Central Licensing Authority for certain claims, which is proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration;

(*iii*) a fixed dose combination of two or more drugs, individually approved earlier for certain claims, which are proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in a marketed combination is proposed to be changed, with certain claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration;

(*iv*) all vaccines, recombinant Deoxyribonucleic Acid derived products, Living Modified Organisms, monoclonal anti-bodies, stem cells, gene therapeutic products and xenografts which are intended to be used as drugs;

Explanation II.—A new drug shall continue to be a new drug for such period as may be prescribed except the type of new drug specified in clause (*iv*) of *Explanation* I which shall always remain a new drug;';

(*vi*) after clause (*b*), the following clauses shall be inserted, namely:—

'(*ba*) "Drugs Control Officer" means—

(*i*) in relation to Ayurvedic, Siddha or Unani drug, a Drugs Control Officer appointed by the Central Government or a State Government under section 33G;

(*ii*) in relation to any other drug or cosmetic, a Drugs Control Officer appointed by the Central Drugs Authority or a State Government under section 21;

(*iii*) in relation to any medical device, the Medical Device Officer appointed by the Central Drugs Authority under section 7H;

(*bb*) "Drugs Controller General of India" means an officer appointed by the Central Government under sub-section (*1*) of section 4G;

(*bc*) "Ethics Committee" means the Ethics Committee constituted under section 4T;';

(*vii*) in clause (*c*), in sub-clause (*ii*), for the words "Central Government", the words "Central Drugs Authority" shall be substituted;

(*viii*) after clause (*c*), the following clauses shall be inserted, namely:—

'(*d*) "Indian Pharmacopoeia" means the official book of standards for drugs which specifies the standards of identity, purity and strength for the drugs mentioned therein;

(*da*) "investigational medical device" means a device, which is an object of a clinical investigation or research or development involving one or more subjects to determine the safety or effectiveness of a device;

(*db*) "investigational new drug" means chemical entity or substance which is under investigation in clinical trial regarding its safety and efficacy and which is required to be approved by the Central Drugs Authority;

(*dc*) "investigator" means a person who is responsible for the conduct of a clinical trial and responsible for the rights, health, safety and well being of the study subjects on the study site;';

(*ix*) clause (*e*) shall be omitted;

(*x*) for clause (*f*), the following clause shall be substituted, namely:—

'(*f*) "manufacture" means—

(*i*) in relation to any drug (except human blood and its components, or any cosmetic) includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or

adapting any drug or cosmetic with a view to its sale, export, stocking or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business;

(*ii*) in relation to human blood and its components includes any process or part of a process of collection, processing, storage, packing, labelling and testing for its use, sale, export or distribution for transfusion in human beings;

(*iii*) in relation to any medical device, includes any process or part of process for making, assembling, altering, ornamenting, finishing, packing, labelling, or adapting any medical device with a view to its sale or stock or export or distribution but does not include assembling or adapting a device already on the market for an individual patient;';

(*xi*) after clause (*f*), the following clauses shall be inserted, namely:—

'(*fa*) "medical device" means—

(*i*) any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of,—

(*A*) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(*B*) diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or handicap;

(*C*) investigation, replacement or modification or support of the anatomy or of a physiological process;

(*D*) supporting or sustaining life;

(*E*) disinfection of medical devices;

(*F*) control of conception,

and which does not achieve its primary intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means;

(*ii*) an accessory to such an instrument, apparatus, appliance, material or other article;

(*iii*) a device which is reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination thereof intended to be used for examination and providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body or animals;

(*iv*) any new medical device;

(*fb*) "Member" means a Member of the Central Drugs Authority and includes the Chairperson and the Member-Secretary;';

(*xii*) in clause (*h*), in sub-clause (*ii*), for the words "Central Government", the words "Central Drugs Authority" shall be substituted;

(*xiii*) after clause (*i*), the following clauses shall be inserted, namely:—

'(*j*) "protocol" means a document that states the background, objectives, rationale, design, methodology (including but not limited to the methods for dealing with adverse events or withdrawals) and statistical considerations of the clinical trial and also states the conditions under which the trial shall be performed and managed;

(*k*) "regulations" means the regulations made by the Central Drugs Authority under this Act;

(*l*) "sponsor" means and includes an investigator, an individual or a company or an institution responsible for the initiation, financing and management of a clinical trial;

(*m*) "State Government" includes the administrator of a Union territory appointed by the President under article 239 of the Constitution;

(*n*) "State Licensing Authority" means an officer designated as such by the State Government under sub-section (*3*) of section 7F or sub-section (*2*) of section 18;

(*o*) "Schedule" means a Schedule appended to this Act;'.

Insertion of new Chapter IA and Chapter IB.

7. After Chapter I of the principal Act, the following Chapters shall be inserted, namely:—

‘CHAPTER IA

CENTRAL DRUGS AUTHORITY

Constitution of Central Drugs Authority.

4A. **(*1*) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority to exercise the powers conferred on, and perform the functions assigned to it by or under this Act.**

(*2*) The Central Drugs Authority shall be a body corporate by the name aforesaid, having perpetual succession and a common seal, with power to acquire, hold and dispose of property, both movable and immovable, and to contract, and shall, by the said name, sue or be sued.

(*3*) The head office of the Central Drugs Authority shall be in the National Capital Region.

(*4*) The Central Drugs Authority may, with the prior approval of the Central Government, by notification in the Official Gazette, establish its offices at such other places in India as it considers necessary.

Composition of Central Drugs Authority.

4B. **(*1*) The Central Drugs Authority shall consist of the following, namely:—**

(*a*) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Health and Family Welfare— *Chairperson, ex-officio*;

(*b*) Secretary to the Government of India, Ministry of Health and Family Welfare, Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy— *Member, ex-officio;*

(*c*) Secretary, Department of AIDS Control and Director General, National AIDS Control Organisation, Ministry of Health and Family Welfare— *Member, ex-officio*;

(*d*) Secretary to the Government of India, Ministry of Commerce and Industry, Department of Commerce— *Member, ex-officio;*

(*e*) Secretary to the Government of India, Ministry of Chemicals and Fertilisers, Department of Pharmaceuticals— *Member, ex-officio;*

(*f*) Secretary, Department of Health Research and Director General, Indian Council of Medical Research, Ministry of Health and Family Welfare— *Member, ex-officio*;

(*g*) Secretary to the Government of India, Ministry of Science and Technology, Department of Bio-technology— *Member, ex-officio;*

(*h*) Director General Health Services, Directorate General of Health Services, New Delhi— *Member, ex-officio;*

(*i*) Additional Secretary or Joint Secretary and Legislative Counsel in the Legislative Department, Ministry of Law and Justice in charge of the Group dealing with the work relating to the Ministry of Health and Family Welfare— Member, *ex-officio*;

(*j*) Additional Secretary or Joint Secretary in charge of the Drugs Quality Control Division in the Ministry of Health and Family Welfare— *Member, ex-officio*;

(*k*) four experts having such qualifications and experience to be nominated by the Central Government in such manner as may be prescribed— *Member*;

(*l*) four State Licensing Authorities to be nominated by the Central Government in such manner as may be prescribed— *Member*;

(*m*) Drugs Controller General of India— Member-Secretary, *ex-officio.*

(*2*) The Members appointed under clause (k) of sub-section (*1*) shall hold office for a period of three years from the date of their nomination, and shall be eligible for renomination;

(*3*) The Central Drugs Authority shall meet at such time and place and shall observe such rules of procedure in regard to the transaction of business at its meeting and allowances payable to a Member for attending such meetings as may be specified by regulations.

Transfer of assets, liabilities, etc., of Central Drugs Standards Control Organisation to Central Drugs Authority constituted under this Act and other provisions, etc.

4C. (*1*) On and from the date of constitution of the Central Drugs Authority,—

(a) any reference to the Central Drugs Standards Control Organisation in any law other than this Act or in any contract or other instruction shall be deemed as a reference to the Central Drugs Authority;

(b) all properties and assets, movable and immovable, of, or belonging to, the Central Drugs Standards Control Organisation, shall vest in the Central Drugs Authority;

(c) all rights and liabilities of the Central Drugs Standards Control Organisation shall be transferred to, and be the rights and liabilities of, the Central Drugs Authority;

(d) without prejudice to the provisions of clause (*c*), all debts, obligations and liabilities incurred, all contracts entered into and all matters and things engaged to be done by, with or for, the Central Drugs Standards Control Organisation immediately before the said date, for or in connection with the purpose of the said Central Drugs Standards Control Organisation shall be deemed to have incurred, entered into or engaged to be done by, with or for, the Central Drugs Authority;

(e) all sums of money due to the Central Drugs Standards Control Organisation immediately before that date shall be deemed to be due to the Central Drugs Authority;

(f) all suits and other legal proceedings instituted or which could have been instituted by or against the Central Drugs Standards Control Organisation immediately before that date may be continued or may be instituted by or against the Central Drugs Authority;

(g) every employee of the Central Drugs Standards Control Organisation holding any office under the Central Drugs Standards Control Organisation immediately before that date shall hold his office in the Central Drugs Authority by the same tenure and upon the same terms and conditions of service as respects remuneration, leave, provident fund, retirement and other terminal benefits as he would have held such office if the Central Drugs Authority had not been constituted and shall continue to do so as an employee of the Central Drugs Authority or until the expiry of the period of six months from that date if such employee opts not to be the employee of the Central Drugs Authority within such period:

Provided that the salaries, allowances and other conditions of service of such employees shall not be varied to their disadvantage on exercise of their option to become the employee of the Central Drugs Authority.

(*2*) Notwithstanding anything in the Industrial Dispute Act, 1947 or in any other law for the time being in force, absorption of any employee by the Central Drugs Authority in its regular service under this section shall not entitle such employee to any compensation under that Act or any other law and no such claim shall be entertained by any court, tribunal or other authority. 14 of 1947.

Member not to participate in meetings in certain cases.

4D. Any Member having any direct or indirect interest, whether pecuniary or otherwise, in any matter coming up for consideration at a meeting of the Central Drugs Authority, shall, as soon as possible after the relevant circumstances have come to his knowledge, disclose the nature of his interest at such meeting and such disclosure shall be recorded in the proceedings of the Authority, and the Member shall not take any part in any deliberation or decision of the Authority with respect to that matter.

Vacancies, etc., not to invalidate proceedings.

4E. No act or proceeding of the Central Drugs Authority shall be invalidated merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Central Drugs Authority; or

(*b*) any defect in the nomination of a person as a Member of the Central Drugs Authority; or

(*c*) any irregularity in the procedure of the Authority not affecting the merits of the case.

Resignation.

4F. A Member of the Central Drugs Authority nominated under clause (*k*) of sub-section (*1*) of section 4B may, by notice in writing under his hand addressed to the Central Government, resign his office:

Provided that the Member shall, unless he is permitted by the Central Government to relinquish his office sooner, continue to hold office until the expiry of three months from the date of receipt of such notice or until a person duly appointed as his successor enters upon office or until the expiry of his term of office, whichever is the earliest.

Appointment of Drugs Controller General of India.

4G. ***(1)*** **The Central Government shall appoint the Drugs Controller General of India or other person having such specialised qualifications and experience as may be prescribed to perform the functions and discharge the duties assigned to the Drugs Controller General of India by or under this Act.**

(*2*) The salaries, allowances and pensions payable to the Drugs Controller General of India, appointed under sub-section (1) shall be such as may be determined by the Central Government.

Staff of Central Drugs Authority.

4H. ***(1)*** **The Central Government may, in consultation with the Central Drugs Authority create, such number of posts as it considers necessary for the efficient discharge of the functions and exercise of the powers by the Central Drugs Authority under this Act.**

(*2*) The manner of appointment of officers and employees of the Central Drugs Authority, their salaries, allowances and pension and other conditions of service shall be such as may be determined by the Central Drugs Authority by regulations with the approval of the Central Government.

Powers and functions of Central Drugs Authority.

4 I. The Central Drugs Authority shall—

(a) specify, by regulations, the guidelines, norms, structures and requirements for effective functioning of the Central Licensing Authority and the State Licensing Authorities;

(b) assess periodically the functioning of the Central Licensing Authority and the State Licensing Authorities;

(c) have power to issue directions to the Central Licensing Authority and the State Licensing Authorities to ensure compliance with the guidelines, norms, structures and requirements specified by it under clause (*a*);

(d) review, suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or the State Licensing Authorities;

(e) specify, by regulations, the fees or charges for issue or renewal of licences, certificates, approvals and permissions by the Central Licensing Authority and the State Licensing authorities;

(f) coordinate, mediate and decide upon the disputes arising out of the implementation of the provisions of the Act and rules and regulations made thereunder between two or more States Licensing Authorities;

(g) constitute such committees or sub-committees as it considers necessary for the efficient discharge of its functions and exercise of its powers under this Act;

(h) recommend to the Central Government the measures as regards the standards of drugs, cosmetics and medical devices for effective implementation of the provisions of this Act;

(i) perform such other functions as may be prescribed by the Central Government.

Powers and functions of Drugs Controller General of India.

4J. (*1*) The Drugs Controller General of India shall exercise the powers conferred upon him under this Act or the rules made thereunder.

(*2*) The Drugs Controller General of India shall act as the Central Licensing Authority and shall have powers to—

(a) issue, renew, suspend or cancel licences or certificates or permission, as the case may be, for import, export or manufacture of drugs, cosmetics or medical devices or permission for conducting clinical trials;

(b) recall or direct to recall any drug, cosmetic or medical device;

(c) collect the fees or charges for issue or renewal of licences, certificates, approvals and permissions issued by the Central Licensing Authority under this Act;

(d) discharge any other functions as may be assigned to him by the Central Drugs Authority;

(*3*) The Drugs Controller General of India may, with the prior approval of the Central Drugs Authority, delegate such of his powers to the officers of the Central Drugs Authority as may be considered necessary.

(*4*) The Drugs Controller General of India shall be the legal representative of the Central Drugs Authority, and shall be responsible for day-to-day administration of the Central Drugs Authority.

(*5*) The Drugs Controller General of India shall have administrative control over the officers and employees of the Central Drugs Authority.

Grants by Central Government.

4K. The Central Government may, after due appropriation made by Parliament by law in this behalf, make to the Central Drugs Authority grants of such sums of money as are required by it.

Accounts and audits.

4L. (*1*) The Central Drugs Authority shall maintain proper accounts and other relevant records and prepare an annual statement of accounts in such form as may be prescribed by the Central Government in consultation with the Comptroller and Auditor-General of India.

(*2*) The accounts of the Central Drugs Authority shall be audited by the Comptroller and Auditor-General of India at such intervals as may be specified by him and any expenditure incurred in connection with such audit shall be payable by the Central Drugs Authority to the Comptroller and Auditor-General.

(*3*) The Comptroller and Auditor-General of India and any other person appointed by him in connection with the audit of the accounts of the Central Drugs Authority shall have the same rights and privileges and authority in connection with such audit as the Comptroller and Auditor-General generally has, in connection with the audit of the Government accounts and, in particular, shall have the right to demand the production of books, accounts, connected vouchers and other documents and papers and to inspect any of the offices of the Central Drugs Authority.

(*4*) The accounts of the Central Drugs Authority as certified by the Comptroller and Auditor-General of India or any other person appointed by him in this behalf, together with the audit report thereon, shall be forwarded annually to the Central Government and that Government shall cause the same to be laid, as soon as may be after it is received, before each House of Parliament.

Annual report.

4M. (*1*) The Central Drugs Authority shall prepare every year an annual report in such form and manner and at such time as may be prescribed by the Central Government, giving summary of its activities during the previous year and copies of the report shall be forwarded to the Central Government.

(*2*) A copy of the report forwarded under sub-section (*1*) shall be laid, as soon as may be after it is received, before each House of Parliament.

Power to make rules.

4N. (*1*) The Central Government may, after consultation with or on the recommendation of the Central Drugs Authority and subject to previous publication, by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter.

(*2*) Without prejudice to the generality of the foregoing powers, such rules may provide for all or any of the following matters, namely:—

(*a*) the form and manner in which the accounts of the Central Drugs Authority shall be maintained under sub-section (*1*) of section 4L;

(*b*) the form and manner in which and the time within which annual report is to be prepared under sub-section (*1*) of section 4M.

Power to make regulations.

4 O. (*1*) The Central Drugs Authority may, with the approval of the Central Government, by notification in the Official Gazette, make regulations consistent with this Act and the rules made thereunder.

(*2*) In particular, and without prejudice to the generality of the foregoing powers, such regulations may provide for all or any of the following matters, namely:—

(*a*) the allowances payable to a Member for attending the meetings of the Central Drugs Authority under sub-section (*3*) of section 4B;

(*b*) the manner of appointment of the officers and employees of the Central Drugs Authority, their salaries, allowances and pension and other conditions of service under sub-section (*2*) of section 4H;

(*c*) the matters specified under clauses (*a*) and (*e*) of section 4 I;

(*d*) the functions of the Central Drugs Laboratory and the functions of the Director of the Central Drugs Laboratory under the proviso to sub-section (*1*) of section 6.

CHAPTER IB

CLINICAL TRIALS

No clinical trial without permission.

4P. (*1*) No person shall initiate or conduct any clinical trial in respect of a new drug or investigational new drug or medical device or investigational medical device or cosmetic or bioavailability or bioequivalence study of any drug in human subjects except under, and in accordance with, the permission granted by the Central Licensing Authority in such manner as may be prescribed.

(*2*) No person shall initiate or conduct any clinical trial unless it is approved by the Ethics Committee constituted under section 4T, in such manner as may be prescribed.

(*3*) No person shall initiate or conduct any clinical trial before it is registered with the Central Drugs Authority in such manner as may be prescribed.

(*4*) No permission from the Central Licensing Authority under this Chapter shall be required to initiate or conduct any bioequivalence or bioavailability studies of approved drugs by the Government Institutes, Hospitals, autonomous medical or Pharmacy institutions for academic or research purposes.

Decision.

4Q. In case of injury or death of a person in course of a clinical trial, whether such injury or death has been caused due to the clinical trial, shall be decided by the Drugs Controller General of India or such authority in such manner as may be prescribed.

Medical treatment and compensation for injury due to clinical trial.

4R. (*1*) In case of a person having been injured as a result of his participation in a clinical trial, he shall be provided by the person conducting the clinical trial, such medical treatment in such manner as may be prescribed.

(*2*) In case injury or death of a person occurs due to the clinical trial, the person conducting such clinical trial shall give him, or as the case may be, his legal heir, such compensation as may be decided by the Drugs Controller General of India or such authority, in such manner as may be prescribed.

Deferment of clinical data requirements by the Central Licensing Authority.

4S. Notwithstanding anything contained in this Chapter, the Central Licensing Authority may, in public interest, abbreviate, defer or omit the pre-clinical and clinical data requirements for approval of clinical trial of drugs indicated in life threatening or serious diseases or diseases of special relevance to the country.

Registration of Ethics Committee.

4T. (*1*) The Ethics Committee, constituted for the purpose of giving approval to a clinical trial protocol and other related matters, shall be registered with the Central Licensing Authority in such manner as may be prescribed.

(*2*) The registration of the Ethics Committee shall be valid for a period of five years and may be renewed in such manner as may be prescribed.

Composition of Ethics Committee.

4U. (*1*) The Ethics Committee shall consist of at least seven members including three or more persons from medical field, one legal expert, one social scientist and one person from community having such qualifications and experience as may be prescribed.

(*2*) The Ethics Committee shall appoint, from amongst its members, a Chairperson (who is from outside the institution), and a member-convenor.

Functions and responsibilities of Ethics Committee.

4V. (*1*) The Ethics Committee shall give its approval to the clinical trial protocol and other related documents in such manner as may be prescribed.

(*2*) The Ethics Committee shall be responsible to safeguard the rights, safety and well being of all trial participants enrolled in the clinical trial.

(*3*) The Ethics Committee shall make periodic review of the trial, based on the study progress reports furnished by the investigators, or monitoring and internal audit reports furnished by the Sponsor, or by visiting the study sites in such manner as may be prescribed.

(*4*) The Ethics Committee shall have power to revoke its approval to a clinical trial, for reasons to be recorded in writing and shal communicate such decision to the investigator as well as to the Central Licensing Authority.

(*5*) The Ethics Committee shall perform such other functions and responsibilities as may be prescribed.

Action against Ethics Committee.

4W. (*1*) In case the Ethics Committee fails to discharge its functions and responsibility under this Act, action shall be taken by the Central Licensing Authority against the Ethics Committee for suspension or cancellation of its registration.

(2) On the suspension or cancellation of the registration of the Ethics Committee under sub-section (*1*), the Central Licensing Authority shall review the approval granted by the Ethics Committee for continuance or otherwise of the clinical trial in such manner as may be prescribed.

(*3*) If the registration of the Ethics Committee is cancelled under sub-section (*1*), the members of such Committee shall be disqualified for becoming a member of any other Ethics Committee for a period of five years under this Act.

Inspection by Drugs Control Officer, etc.

4X. Any person conducting clinical trial shall allow the Drugs Central Officer or Medical Device Officer of the Central Drugs Authority or any other officer authorised by the Central Licensing Authority to enter with or without prior notice into any premises related to clinical trial to inspect the facilities, any record, data, documents, books, drugs including investigational new drugs, medical devices including investigational medical devices and cosmetics and that officer can seek clarifications, information and records wherever required so as to ensure that the clinical trial is being conducted in acordance with the provisions of this Act and the rules made thereunder.

Disclosure of name, address, etc., of persons involved in clinical trials.

4Y. Every person, sponsor, clinical research organisation or any other organisation or investigator conducting a clinical trial or his agent shall, if so required, disclose to the Drugs Control Officer or the Medical Device Officer or any other officer authorised by the Central Licensing Authority, the name, address and other particulars of the persons involved in conducting the clinical trials, including the trial participants.

Maintenance of records and furnishing of information.

4Z. Every person, sponsor, clinical research organisation or any other organisation or investigator conducting a clinical trial or his agent holding a permission under this Chapter shall keep and maintain such data, records, registers and other documents as may be prescribed and shall furnish such information as may be required by the Central Drugs Authority or any officer authorised by it.

Penalty for conducting clinical trial of any drug or investigational new drug or any medical device or investigational medical device without permission.

4ZA. Whoever, himself or by any other person on his behalf, conducts clinical trial with any drug or investigational new drug or any medical device or investigational medical device in contravention of section 4P and the rules made thereunder, shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which may extend to ten lakh rupees:

Provided that whoever, himself or by any other person on his behalf, conducts clinical trial with any drug or investigational new drug or medical device or investigational medical device in contravention of the provisions of section 4P and the rules made thereunder, which caused grievous hurt to or death of any trial participant of clinical trial, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to ten years and shall also be liable to fine which shall not be less than twenty lakh rupees:

Provided further that the fine imposed under this section shall be paid to the trial participant or, as the case may be, his legal heirs:

Provided also that any person convicted of an offence under this section shall not be permitted to conduct any clinical trial.

Penalty for repeat offence.

4ZB. Whoever, having been convicted of an offence under section 4ZA, is again convicted under that section, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to ten years and shall also be liable to fine which shall not be less than thirty lakh rupees.

Penalty for conducting clinical trial of cosmetics without permission.

4ZC. Whoever, himself or by any other person on his behalf, conducts clinical trials with cosmetics in contravention of section 4P and the rules made thereunder, shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than five lakh rupees:

Provided that whoever, himself or by any other person on his behalf, conducts clinical trials with any cosmetics in contravention of the provisions of section 4P and the rules made thereunder, which caused grievous hurt or death of trial participant of the clinical trial shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than ten lakh rupees:

Provided further that the fine imposed under this section shall be paid to the trial participant or, as the case may be, his legal heirs:

Provided also that any person convicted of an offence under this section shall not be permitted to conduct any clinical trial.

Penalty for repeat offence.

4ZD. Whoever having been convicted of an offence under section 4ZC, is again convicted under that section, shall be punishable with imprisonment for a term which shall not be less than five years and shall also be liable to fine which shall not be less than five lakh rupees.

Penalty for violation of conditions of permission.

4ZE. Whoever, himself or by any other person on his behalf, conducts clinical trials with any drug or investigational new drug or medical device or investigational medical device or cosmetic in contravention of conditions of permission issued under section 4P and rules made thereunder shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than five lakh rupees:

Provided that whoever, himself or by any other person on his behalf, conducts clinical trials with any drug or investigational new drug or medical device or investigational medical device or cosmetic in contravention of conditions of permission issued under section 4P and rules made thereunder, which caused resulted in grievous hurt or death of a subject during the clinical trial shall be punished with imprisonment for a term which shall not be less than three years but which may be extended to seven years and shall also be liable to fine which shall not be less than ten lakh rupees:

Provided further that the fine imposed on and realised from the person convicted under this section shall be paid, by way of compensation to the legal heirs of the person who had suffered the grievous hurt or death during such clinical trial referred to in this clause:

Provided also that whoever, having been convicted of an offence under this section shall be debarred from conducting any further clinical trial.

Penalty for repeat offence.

4ZF. Whoever, having been convicted of an offence under section 4ZE, is again convicted of an offence under that section, shall be punished with imprisonment for a term which shall not be less than five years and fine which shall not be less than ten lakh rupees.

Penalty for failure to provide compensation.

4ZG. Whoever responsible to provide compensation for clinical trial related injury or death under this chapter fails to do so, he shall be punishable with imprisonment which may extend to two years and with fine which shall not be less than twice the amount of the compensation.

Penalty for contravention of any provision of this chapter.

4ZH. Whoever initiates or conducts clinical trial of any drug or investigational new drug or medical device or investigational medical device or cosmetic in contravention to any provisions under

this Chapter not covered under section 4P, section 4Q, section 4R, section 4S, section 4T, section 4U, section 4W, section 4X, section 4Y or section 4Z or any other rules made under this chapter shall be punishable with imprisonment which may extend to two years and with fine which shall not be less than fifty thousand rupees.

Confiscation of stock, etc.

4ZI. Where any person has been convicted for contravening any provision of this Chapter or any rule made thereunder, the stock of the drug or investigational new drug or medical device or investigational medical device or cosmetic in respect of which the contravention has been made as well as any implements or machinery, vehicle, vessel or other conveyances used in or for the purposes of conducting clinical trials shall be liable to confiscation.

Cognizance of offences.

4ZJ. (*1*) No prosecution under this Chapter shall be instituted, except on a complaint made by—

(*a*) a Drugs Control Officer or a Medical Device Officer appointed by the Central Drugs Authority; or

(*b*) a gazetted officer of the Central Government authorised by that Government by an order made in this behalf; or

(*c*) the person aggrieved; or

(*d*) any recognised consumer association.

(*2*) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

Powers of Central Government to make rules.

4ZK. (*1*) The Central Government may, after consultation with the Central Drugs Authority, and after previous publication, by notification in the Official Gazette, make rules to provide for—

(*a*) the guidelines and requirements for conducting clinical trials;

(*b*) the forms and fees for the purposes of this Chapter;

(*c*) the conditions for issue of the permission under section 4P;

(*d*) the norms and procedure for approval of any clinical trial by the Ethics Committee under sub-section (*2*) of section 4P and sub-section (*1*) of section 4V;

(*e*) the norms and procedure for registration of any clinical trial under sub-section (*3*) of section 4P;

(*f*) the manner in which the Central Lisensing Authority shall review the approval granted by the Ethics Committee for continuance of clinical trial under sub-section (*2*) of section 4W;—

(*g*) the records, registers or other documents to be kept and maintained under this Chapter;

(*h*) the manner in which copies of documents relating to clinical trial are to be obtained and certified;

(*i*) the conditions subject to which small quantities of drugs or cosmetics or medical devices may be imported or manufactured for the purpose of conducting clinical trials;

(*j*) the powers and duties of Drugs Control Officers or Medical Device Officers;

(*k*) the norms and procedures for deciding whether injury or death of a trial participant has been caused due to clinical trial, under section 4Q;

(*l*) the norms and procedures for providing medical treatment to the trial participants under sub-section (*1*) of section 4R;

(*m*) the norms and procedures for providing compensation to the trial participants or their legal heirs under sub-section (*2*) of section 4R;

(*n*) the norms and procedures for registration and renewal of Ethics Committees under section 4T;

(*o*) additional functions and responsibilities of the Ethics Committee under sub-section (*5*) of section 4V;

(*p*) the norms and procedures for conducting inspections relating to conduct of clinical trials under sections 4X and 4Y.

Chapter not to apply to Ayurvedic, Homeopathy, Siddha or Unani drugs.

4ZL. Nothing contained in this Chapter shall apply to Ayurvedic, Homeopathy, Siddha or Unani drugs.'.

Substitution of new heading for Chapter II.

8. In Chapter II of the principal Act, for the Chapter heading "THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE", the Chapter heading "TECHNICAL ADVISORY BOARDS, CENTRAL DRUGS LABORATORIES AND CONSULTATIVE COMMITTEE" shall be substituted.

Amendment of section 5.

9. In section 5 of the principal Act,—

(*a*) in sub-section (*1*),—

(*i*) for the words "as soon as may be, constitute", the words "by notification in the Official Gazette, constitute" shall be substituted;

(*ii*) after the words "to advise the Central Government", the words "the Central Drugs Authority" shall be inserted;

(*b*) for sub-section (*2*), the following sub-section shall be substituted, namely:—

"(*2*) The Board shall consist of the following members, namely:—

(*i*) the Director General of Health Services, *ex-officio*, who shall be Chairperson;

(*ii*) the Drugs Controller General of India, *ex-officio*;

(*iii*) one Director of the Central Drugs Laboratory to be nominated by the Central Government, *ex-officio*;

(*iv*) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex-officio*;

(*v*) two experts to be nominated by the Central Government from amongst persons who are in charge of drugs control in the States;

(*vi*) one expert, to be elected by the Executive Committee of the Pharmacy Council of India, from amongst teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(*vii*) one expert, to be elected by the authority established for regulating the medical education, from amongst teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto;

(*viii*) one person to be nominated by the Central Government from the pharmaceutical industry;

(*ix*) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(*x*) one person to be elected by the Central Council of the Indian Medical Association;

(*xi*) two Government Analysts appointed under this Act, to be nominated by the Central Government;

(*xii*) the Director of the National Institute of Biologicals, *ex-officio*;

(*xiii*) the Secretary-cum-Scientific Director of Indian Pharmacopoeia Commission, *ex-officio*;

(*xiv*) the Director of a National Institute of Pharmaceutical Education and Research to be nominated by the Department of Pharmaceuticals;

(*xv*) one expert to be nominated by the Department of Bio-technology;

(*xvi*) one expert to be nominated by the Central Government from the Medical institutes or institutions controlled by the Central Government or State Governments from amongst persons involved in the conduct of clinical trials;

(*xvii*) one person representing recognised consumer associations or consumer interests to be nominated by the Ministry of Consumer Affairs.";

(*c*) in sub-section (*3*),—

(*i*) for the words "but shall be eligible for re-nomination and re-election", the words "and shall be eligible for re-nomination or, as the case may be, re-election for not more than two consecutive terms" shall be substituted;

(*ii*) in the proviso, for the words, brackets and figures "clause (*ix*) or clause (*x*) or clause (*xi*) or clause (*xvi*) of sub-section (*2*)", the words, brackets and figures "clause (*v*) or clause (*vi*) or clause (*vii*) or clause (*xi*) of sub-section (*2*)" shall be substituted;

(*d*) in sub-section (*4*), after the words "The Board may", the words "in consultation with the Central Drugs Authority and" shall be inserted;

(e) for sub-section (*7*), the following sub-section shall be substituted, namely:—

"(*7*) The Central Drugs Authority shall appoint a person to be the Secretary of the Board and shall provide the Board with such staff as the Central Drugs Authority considers necessary.".

Insertion of new section 5A.

10. After section 5 of the principal Act, the following section shall be inserted, namely:—

Constitution of Medical Devices Technical Advisory Board.

"5A. (*1*) The Central Government shall, by notification in the Official Gazette, constitute, a Medical Devices Technical Advisory Board to advise the Central Government, the Central Drugs Authority and State Governments on technical matters pertaining to medical devices, arising out of

the administration of this Act and to carry out other functions assigned to it by or under this Act.

(*2*) The Board shall consist of the following members, namely:—

(*a*) the Director General, Indian Council of Medical Research, who shall be the Chairperson, *ex-officio*;

(*b*) the Drugs Controller General of India, *ex-officio*;

(*c*) one expert each from the following, having qualifications and experience in the field of medical devices, to be nominated by—

(*i*) the Department of Science and Technology;

(*ii*) the Department of Atomic Energy;

(*iii*) the Department of Electronic and Information Technology;

(*iv*) the Central Government from the Government testing laboratories connected with the testing of medical devices;

(*v*) the Indian Council of Medical Research;

(*vi*) the Bureau of Indian Standard;

(*vii*) the Defence Research and Development Organisation;

(*d*) one expert from the field of biomedical technology from recognised technical educational institutions, to be nominated by the Central Government;

(*e*) one expert from the field of biomaterial or polymer technology from recognised technical educational institutions, to be nominated by the Central Government;

(*f*) one person representing recognised consumer associations to be nominated by the Ministry of Consumer Affairs;

(*g*) one pharmacologist to be nominated by the Central Government from recognised medical or research institute in the field of medical devices;

(*h*) one expert to be nominated by the Central Government from recognised medical or research institute from amongst persons involved in conduct of clinical trials;

(*i*) one person to be nominated by the Central Government from the medical device industry.

(*3*) The nominated members of the Board shall hold office for a period of three years, and shall be eligible for re-nomination for not more than two consecutive terms:

Provided that the person nominated under clause (*c*) of sub-section (*2*) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated as a member of the Board.

(*4*) The Board may, in consultation with the Central Drugs Authority, and subject to the previous approval of the Central Government, make bye-laws fixing quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(*5*) The Board may constitute sub-committees and may appoint to such sub-committees for such periods not exceeding three years, as it may decide, for the consideration of particular matters, persons who are not members of the Board.

(*6*) The functions of the Board may be exercised notwithstanding any vacancy therein.

(*7*) The Central Drugs Authority shall appoint a person to be the Secretary of the Board and shall provide the Board with such staff as the Central Drugs Authority considers necessary.".

Amendment of section 6.

11. In section 6 of the principal Act,—

(*a*) for sub-section (*1*), the following sub-section shall be substituted, namely:—

"(*1*) The Central Drugs Authority may, with the prior approval of the Central Government, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Drugs Authority, to carry out the functions entrusted to it by this Act or any rules made thereunder:

Provided that the Central Drugs Authority may, in consultation with the Central Government, specify by regulations the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics or medical device or class of medical devices to be performed by any other laboratory and the powers of the Director of the Central Drugs Laboratory shall be exercised by the Director of the laboratory to whom the functions have been assigned.";

(*1A*) The Central Drugs Authority may, by notification, designate any Central Drugs Laboratory—

(*a*) for testing of drugs or class of drugs or cosmetics or class of cosmetics or medical devices or class of medical devices;

(*b*) as an Appellate Laboratory for testing of drugs or class of drugs or cosmetics or class of cosmetics or medical devices or class of medical devices;

(*b*) in sub-section (*2*),—

(*i*) in the opening portion, for the words "after consultation with the Board", the words "in consultation with the Central Drugs Authority" shall be substituted;

(*ii*) in clause (*d*), for the words, figures and letter "under Chapter IV or Chapter IVA of samples of drugs or cosmetics", the words, figures and letters "under Chapter IIA, Chapter III, Chapter IV or Chapter IVA of samples of drugs or cosmetics or medical devices" shall be substituted.

Substitution of new section for section 7.

12. For section 7 of the principal Act, the following section shall be substituted, namely :—

Drugs, Cosmetics and Medical Devices Consultative Committee.

7. (*1*) The Central Government may constitute an advisory committee to be called "the Drugs, Cosmetics and Medical Devices Consultative Committee" to advise the Central Government, the Central Drugs Authority, the State Governments, the Drugs Technical Advisory Board and the Medical Device Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.

(*2*) The Drugs, Cosmetics and Medical Devices Consultative Committee shall consist of the following members, namely:—

(*a*) the Drugs Controller General of India, who shall be the chairperson, *ex-officio*;

(*b*) two representatives of the Central Drugs Authority nominated by it;

(*c*) the Secretary-cum-Scientific Director of the Indian Pharmacopoeia Commission;

(*d*) one representative of the Pharmaceuticals Export Promotion Council nominated by it;

(*e*) one representative of the Department of Revenue, Ministry of Finance, Government of India dealing with the administration of the Narcotic Drugs and Psychotropic Substances Act, 1985; and

61 of 1985.

(*f*) one representative of each State Government who is in-charge of the matters relating to regulation of drugs, cosmetics and medical devices in that State.

(*3*) The Drugs, Cosmetics and Medical Devices Consultative Committee shall meet at least twice in a year or when required to do so by the Central Government or, as the case may be, the Central Drugs Authority and shall have power to regulate its own procedure.

Insertion of new Chapter IIA.

13. After Chapter II of the principal Act, the following Chapter shall be inserted, namely:—

‘CHAPTER IIA

IMPORT, MANUFACTURE, SALE, DISTRIBUTION AND EXPORT OF MEDICAL DEVICES

Standards quality of medical device.

7B. For the purposes of this Chapter, the expression “standard quality” in relation to medical device, means the medical device which conforms such standards as may be prescribed.

Misbranded medical device.

7C. For the purposes of this Chapter, a medical device shall be deemed to be misbranded—

(a) if it is so coloured, coated, or polished so as to conceal any damage or if it is made to appear of better or greater therapeutic or functional value than it really is; or

(b) if it is not labelled in the prescribed manner; or

(c) if its label or container or anything accompanying the medical device bears any statement, design or device which makes any false claim.

Adulterated medical device.

7D. For the purposes of this Chapter, a medical device shall be deemed to be adulterated—

(*a*) if it consists, in whole or in part, of rusted or corroded or filthy or putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been rendered injurious to health; or

(*c*) if it contains any harmful or toxic substance or parts which may render it dangerous to use or injurious to health; or

(*d*) if any substance or part has been mixed or added thereto or substituted or removed therefrom so as to reduce its quality or strength or which may render it dangerous to use or injurious to health; or

(*e*) if its container is composed, in whole or in part, of any deleterious substance which may render it dangerous to use or injurious to health.

Spurious medical device.

7E. For the purposes of this Chapter, a medical device shall be deemed to be spurious—

(a) if it is imported, manufactured, sold, distributed or exported under a name which belongs to another medical device; or

(b) if it is an imitation of, or a substitute for, another medical device or resembles another medical device in a manner likely to deceive or bears upon it or upon its label or container the name of another medical device unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other medical device; or

(c) if the label or the container bears the name of an individual or firm or company purporting to be the manufacturer of the medical device, which individual or firm or company is fictitious or does not exist; or

(*d*) if it has been substituted wholly or in part by another medical device or substance; or

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Prohibition of import, manufacture and export of certain medical devices.

7F. (*1*) No person shall himself or by any other person on his behalf,—

(*a*) import, or manufacture for sale or for export, or export—

(*i*) any medical device which is not of standard quality;

(*ii*) any misbranded medical device;

(*iii*) any adulterated medical device;

(*iv*) any spurious medical device;

(*v*) any software or part or component or instrument or the list of the software or part or ingredient or instrument contained in it, unless displayed in the prescribed manner on the label or container thereof;

(*vi*) any medical device which by means of any statement, design or accessory accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect;

(*vii*) any medical device containing any component which may render it unsafe or harmful for use under the directions indicated or recommended;

(*viii*) any medical device which has been imported or manufactured in contravention of any of the provisions of this Chapter or rules made thereunder;

(*b*) import or manufacture for sale or for export, or export any medical device, except under, and in accordance with the conditions of, a licence or certificate issued by the Central Licensing Authority for the purpose of this Chapter in such manner and on such conditions as may be prescribed:

Provided that nothing contained in clause (*a*) shall apply to import or manufacture of any medical device in small numbers for the purpose of examination, test, analysis, demonstration or for personal use subject to such conditions as may be prescribed:

Provided further that the Central Government may, in consultation with the Central Drugs Authority, by notification in the Official Gazette, permit, subject to any conditions specified therein, the import or manufacture of any medical device or class of medical devices not approved in the country or not of standard quality for sale or for distribution, stocking or exhibiting or offering for sale or distribution of such medical device under this Act.

(*2*) No person shall himself or by any other person on his behalf—

(*a*) sell, or stock or distribute or exhibit or offer for sale any medical device referred to in clause (*a*) of sub-section (*1*);

(*b*) sell, or stock or exhibit or offer for sale or distribute any medical device which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(*c*) sell, or stock or exhibit or offer for sale or distribute any medical device, except under, and in accordance with the conditions of, a licence issued by the State licensing authorities for the purposes of this Chapter in such manner and on such conditions as may be prescribed.

(*3*) The State Government may, for the purposes of this Chapter by notification, designate one or more person, having such qualifications and experience, as the State Licensing Authority, with such powers and functions and on such terms and conditions, as may be prescribed.

Application of law relating to sea customs and powers of Customs Officers.

7G. (*1*) The law for the time being in force relating to customs and to goods, the import of which is prohibited by the Customs Act, 1962 or rules made or notifications issued thereunder or any other law for the time being in force shall, subject to the provisions of section 7J, section 7K and section 7L of this Act, apply in respect of medical device, the

52 of 1962.

import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act or law to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such medical device as they have for the time being in respect of such goods as aforesaid.

(*2*) Without prejudice to the provisions of sub-section (*1*), the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any medical device, the import of which is prohibited under this Chapter or any other law for the time being in force and shall forthwith report such detention to the Drugs Controller General of India and, if necessary, forward the package or sample of any suspected medical device found therein to the Laboratory prescribed for the purpose:

Provided that in the event of that package or sample of that medical device found in contravention of any of the provisions of this Chapter or any rule made thereunder, the same shall not be allowed to be imported from that or any other port of entry in the country.

Medical Device Officers and their duties and powers.

7H. (*1*) The Central Drugs Authority may, by notification in the Official Gazette, appoint such persons, as it thinks fit, having such qualification and experience as may be prescribed, to be the Medical Device Officers for such areas as may be assigned to them by the Central Drugs Authority.

(*2*) The powers which may be exercised by a Medical Device Officer and the duties which may be performed by him, the medical devices or classes of medical devices in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

(*3*) No person who has any financial interest in the import, export, manufacture or sale of medical devices shall be appointed to be a Medical Device Officer under this section.

(*4*) Every Medical Device Officer shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code and shall be officially subordinate to such authority having the prescribed qualifications, as the Central Drugs Authority may specify in this behalf.

45 of 1860.

Power of Central Government to regulate, restrict or prohibit import or manufacture, etc., of medical device in public interest.

7 I. Without prejudice to any other provisions contained in this Chapter, if the Central Government is satisfied that the use of any medical device is likely to involve any risk to human beings or animals or that any medical device does not have the functional value claimed or purported to be claimed for it or which is not safe or effective for use or for which there is no functional justification and that in the public interest it is necessary or expedient so to do, then, it may, by

notification in the Official Gazette, regulate, restrict or prohibit the import or manufacture, sale or distribution of such medical device.

Offences for import, manufacture, sale, etc., of medical device in contravention of this Chapter.

7J. Whoever, himself or by any other person on his behalf, imports or manufactures for sale or for export or for distribution or sells or exports or stocks or exhibits or offer for sale,—

(*a*) any medical device deemed to be adulterated under section 7D or spurious under section 7E and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such bodily harm which amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such medical device being spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the medical device confiscated, whichever is more: 45 of 1860.

Provided that the fine imposed under this clause shall be paid to the person who had used the adulterated or spurious medical device:

Provided further that where the use of adulterated or spurious medical device referred to in this clause has caused the death of a person who used such medical device, the fine imposed shall be paid to his legal heir;

(*b*) any medical device—

(*i*) deemed to be adulterated under section 7D or misbranded under section 7C, but not being a medical device referred to in clause (*a*); or

(*ii*) without a valid licence as required under clause (*b*) of sub-section (*1*) or clause (*c*) of sub-section (*2*) of section 7F,

shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than one lakh rupees or three times the value of the medical device confiscated, whichever is more:

Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one lakh rupees;

(*c*) any medical device deemed to be spurious under section 7E, but not being a medical device referred to in clause (*a*) shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than five lakh rupees or three times the value of the medical device confiscated, whichever is more:

Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and of fine of less than one lakh rupees;

(*d*) any medical device, other than a medical device referred to in clause (*a*) or clause (*b*) or clause (*c*), in contravention of any other provisions of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and shall also be liable to fine which shall not be less than one lakh rupees.

Penalty for import, manufacture, etc., of medical device in contravention of section 7 I.

7K. Whoever himself or by any other person on his behalf imports or manufactures or sells or exports or distributes any medical device in contravention of the provisions of any notification issued under section 7 I, shall be punishable with imprisonment for a term which shall not be less than three years and shall also be liable to fine which shall not be less than one lakh rupees.

Penalty for repeat offences.

7L. (*1*) Whoever having been convicted of an offence,—

(*a*) under clause (*b*) of section 7J, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and shall also be liable to fine which shall not be less than two lakh rupees:

Provided that the court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees;

(*b*) under clause (*c*) of section 7J, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees;

(*c*) under clause (*d*) of section 7J, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to five years and shall also be liable to fine which shall not be less than two lakh rupees.

(*2*) Whoever having been convicted of an offence under section 7K is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than two lakh rupees.

Confiscation.

7M. (*1*) Where any person has been convicted under this Chapter for contravening any provision of this Chapter or any rule made thereunder, the stock of the medical device in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of—

(*a*) import or manufacture of any medical device deemed to be misbranded under section 7C or adulterated under section 7D or spurious under section 7E; or

(*b*) import or manufacture for sale or for export or for distribution, sale, export or stocking or exhibiting or offering for sale or for export, or distribution of any medical device without a valid licence as required under clause (*b*) of sub-section (*1*) or clause (*c*) of sub-section (*2*) of section 7F, any implements or machinery used in such import or manufacture, sale, export or distribution and any receptacles, packages or coverings in which such medical device is contained and the animals, vehicles, vessels or other conveyances used in carrying such medical device shall also be liable to confiscation.

(*2*) Without prejudice to the provisions contained in sub-section (*1*) where the court is satisfied, on the application of a Medical Device Officer or otherwise and after such inquiry as may be necessary that the medical device is not of standard quality is a misbranded, adulterated or spurious medical device, such medical device shall be liable to confiscation.

Powers of Central Government to make rules.

7N. The Central Government may after consultation with or on the recommendation of the Central Drugs Authority and subject to previous publication, by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter which may—

'(*a*) provide for classification of medical devices into different classes based on the degree of risk associated with their use or application;

(*b*) prescribe standards for different classes of medical devices and the organisations or bodies for developing such standards;

(*c*) prescribe procedures for assessment of conformity to the standards and quality assurance;

(*d*) provide for use of standards as prescribed from time to time for manufacturing or developing new medical device;

(*e*) prescribe conditions for import or manufacture of custom made devices and devices for clinical investigations;

(*f*) prescribe procedures for reporting adverse events, post marketing surveillance and recall of medical devices;

(*g*) prescribe requirements for approval of laboratories, institutions or bodies for carrying out conformity assessment of medical devices;

(*h*) prescribe procedures for overseas inspections;

(*i*) prescribe the qualifications of Medical Device Officer and Government Analysts for medical devices;

(*j*) prescribe the methods of test or analysis to be employed in determining whether a medical device is of standard quality;

(*k*) prescribe the forms of licences or the certificates, as the case may be, for import, manufacture for sale, for distribution or for export or for sale, of medical devices, the form of application for such licences or certificates, as the case may be, the conditions subject to which such licences or certificates, as the case may be, may be issued, the authority empowered to issue the same, the qualification of such authority and the fees payable therefor and provide for the suspension or cancellation of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(*l*) prescribe the records, registers or other documents to be kept and maintained;

(*m*) prescribe the fees for the inspection including overseas inspection (for the purposes of grant or renewal of licence) of premises, wherein any medical device is being or is proposed to be manufactured;

(*n*) prescribe the manner in which copies are to be certified;

(*o*) specify the diseases or ailments or conditions which a medical device may not purport or claim to prevent, cure or mitigate and such other effects which a medical device may not purport or claim to have;

(*p*) prescribe the conditions subject to which small quantities of medical device may be imported or manufactured for the purpose of examination, test, analysis, demonstration or for personal use;

(*q*) require the date of manufacture and the date of validity or expiry to be clearly or truly stated on the label or container of any specified medical device or class of medical device, and prohibit the sale, import, export, stocking or exhibition for sale or for export, or distribution of the said medical device or class of medical device after the expiry of a specified period from the date of manufacture or after the expiry of the date of validity or expiry as applicable;

(*r*) prescribe the conditions to be observed in the packing in packages, and other containers of medical device, including the use of packing material which comes into direct contact with the medical device and prohibit the sale, import, stocking or exhibition for sale or for export, or distribution of medical device packed in contravention of such conditions;

(*s*) regulate the mode of labelling of packed medical device, and prescribe the matter which shall or shall not be included in such labels;

(*t*) prescribe the powers and duties of Medical Device Officers and the qualifications of the authority to which such Medical Device Officers shall be subordinate and specify the medical device or classes of medical device in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;

(*u*) prescribe the forms of report to be given by the prescribed laboratory, and the manner of application for test or analysis and the fees payable therefor;

(*v*) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified medical device or class of medical device;

(*w*) specify the places at which medical device may be imported, and prohibit their import at any other place;

(*x*) regulate the submission by importers, and the securing of samples of such medical device, as may be specified, for examination, test or analysis by the prescribed laboratory, and specify the fees, if any, payable for such examination, test or analysis;

(*y*) specify the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of medical device sought to be imported, the procedure for officers of Customs in dealing with such evidence, and the manner of storage at places of import of medical device detained pending admission;

(*z*) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of medical device imported for the purpose only of transport through, and export from, India;

(*za*) require that the accepted scientific name of any specified software or part or instrument shall be displayed in the prescribed manner on the label or wrapper of any imported, medical device containing such part or ingredient or instrument;

(*zb*) prescribe procedures for assigning unique identification number to medical devices;

(*zc*) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 7M;

(*zd)* sum which may be specified by the Central Government under section 32-B'.

Amendment of section 8.

14. In section 8 of the principal Act, in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted.

Insertion of new section 9E.

15. After section 9D of the principal Act, the following section shall be inserted, namely:—

Adulterated Cosmetics.

"9E. For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,—

(*a*) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(*b*) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(*c*) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(*d*) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(*e*) if it contains any harmful or toxic substance which may render it injurious to health; or

(*f*) if any substance has been mixed therewith so as to reduce its quality or strength.".

Amendment of section 10.

16. In section 10 of the principal Act,—

(*i*) after clause (*bb*), the following clause shall be inserted, namely:—

"(*bba*) any adulterated cosmetic;";

(*ii*) in the second proviso, for the word "Board", the words "Central Drugs Authority" shall be substituted.

Amendment of section 11.

17. In section 11 of the principal Act, in sub-section (*2*), the following proviso shall be inserted, namely:—

"Provided that in the event of that package or sample of that drug or cosmetic found in contravention of any of the provisions of this Chapter or any rule made thereunder, the same shall not be allowed to be imported from that or any other port of entry in the country.".

Amendment of section 12.

18. In section 12 of the principal Act, in sub-section (*1*), for the word "Board", wherever it occurs, the words "Central Drugs Authority" shall be substituted.

Substitution of new section for section 13.

19. For section 13 of the principal Act, the following sections shall be substituted, namely:—

Penalty for import of drugs or cosmetics in contravention of this Chapter.

"13. Whoever, himself or by any other person on his behalf, imports,—

(*a*) any drug deemed to be adulterated under section 9A or spurious under section 9B and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such bodily harm which amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, 45 of 1860.

solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:

Provided that the fine imposed under this clause shall be paid to the person who had used the adulterated or spurious drugs:

Provided further that where the use of adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed shall be paid to his legal heir;

(*b*) any drug—

(*i*) deemed to be adulterated under section 9A, but not being a drug referred to in clause (*a*); or

(*ii*) without a valid licence as required under clause (*c*) of section 10,

shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one lakh rupees;

(*c*) any drug deemed to be spurious under section 9B, but not being a drug referred to in clause (*a*) shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than three lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and of fine of less than one lakh rupees;

(*d*) any drug, other than a drug referred to in clause (*a*) or clause (*b*) or clause (*c*), in contravention of any other provisions of this Chapter or any rule

made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and shall also be liable to fine which shall not be less than one lakh rupees:

Provided that the court may, for any adequate and special reasons, to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year;

(*e*) any cosmetic deemed to be adulterated under section 9E or spurious under section 9D and which when used by any person is likely to cause his death or is likely to cause such bodily harm which amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such cosmetics being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the cosmetics confiscated, whichever is more: 45 of 1860.

Provided that the fine imposed under this clause shall be paid to the person who had used the adulterated or spurious cosmetic:

Provided further that where the use of adulterated or spurious cosmetic referred to in this clause has caused the death of a person who used such cosmetic, the fine imposed shall be paid to his legal heir;

(*f*) any cosmetic,—

(*i*) deemed to be spurious under section 9D or adulterated under section 9E but not being a cosmetic referred to in clause (*e*);

(*ii*) without a valid licence as required under clause (*c*) of section 10, shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than fifty thousand rupees;

(*g*) any cosmetic other than a cosmetic referred to in clause (*e*) or clause (*f*), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which shall not be less than one year and shall also be liable to fine which shall not be less than twenty thousand rupees;

(*h*) any cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which shall not be less than two years and shall also be liable to fine which shall not be less than fifty thousand rupees.

Penalty for repeat offences.

13A. Whoever having been convicted of an offence—

(*a*) under clause (*b*) of section 13 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and shall also be liable to fine which shall not be less than two lakh rupees:

Provided that the court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees;

(*b*) under clause (*c*) of section 13 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than three lakh rupees;

(*c*) under clause (*d*) of section 13 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years and shall also be liable to fine which shall not be less than fifty thousand rupees;

(*d*) under clause (*f*) or clause (*g*) or clause (*h*) of section 13 is again convicted under that clause, shall be punishable with imprisonment for a term which shall not be less than three years, and shall also be liable to fine which shall not be less than one lakh rupees;

Amendment of section 16.

20. In section 16 of the principal Act, in sub-section (*2*), for the word "Board", the words "Central Drugs Authority" shall be substituted.

Substitution of new section for section 18.

21. For section 18 of the principal Act, the following section shall be substituted, namely:—

Prohibition of manufacture and sale of certain drugs and cosmetics.

"18. *(1)* Save as otherwise provided in sub-section (*3*), no person shall himself or by any other person on his behalf—

(a) manufacture for sale or for export or for distribution, or sell, or stock or exhibit or offer for sale or distribute—

(*i*) any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

(*ii*) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;

(*iii*) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(*iv*) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

(*v*) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(*vi*) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(*b*) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(*c*) manufacture for sale or for export or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of a licence issued for such purposes under this Chapter:

Provided that no licence for manufacture of any new drug shall be issued except in accordance with the prior permission granted by the Central Licensing Authority, in such manner as may be prescribed:

Provided further that the State Licensing Authority shall, before issuing any licence for manufacture of any new drug, ensure that the permission from the Central Licensing Authority is obtained:

Provided also that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided also that the Central Government may, after consultation with the Central Drugs Authority, by notification in the Official Gazette, permit, subject to any condition specified in the notification, the manufacture for sale, or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

(*2*) The State Government may for the purposes of this Chapter by notification in the Official Gazette, designate one or more person, having such qualifications and experience, as the State Licensing Authority, with such powers and functions and on such terms and conditions, as may be prescribed.

(*3*) On and from the commencement of the Drugs and Cosmetics (Amendment) Act, 2013, the Central Licensing Authority shall have power to issue a licence or a certificate, as the case may be, for the manufacture for sale or for export of drugs specified in the Third Schedule to this Act:

Provided that no licence for manufacture of any drug specified under the Third Schedule shall be issued by the State Licensing Authorities.

(*4*) The Central Government, after consultation with the Central Drugs Authority and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Third Schedule for the purposes of this Chapter, and thereupon the Third Schedule shall be deemed to be amended accordingly.

Amendment of section 18A.

22. In section 18A of the principal Act,—

(*a*) for the words "drug or cosmetic", at both the places where they occur, the words "drug or cosmetic or medical device" shall be substituted;

(*b*) after the word "Inspector", the words "or Medical Device Officer" shall be inserted.

Amendmentof section 18B.

23. In section 18B of the principal Act, for the words, brackets, letter and figures "clause (*c*) of section 18", the words, brackets, letter and figures "clause (*b*) of sub-section (*1*) or clause (*c*) of sub-section (*2*) of section 7F or clause (*c*) of section (*10*) or clause (*c*) of sub-section (*1*) of section 18" shall be substituted.

Insertion of new sections 18D, 18E and 18F.

24. After section 18C of the principal Act, the following sections shall be inserted, namely:—

Prohibition of export of certain drugs, cosmetics and medical devices.

"18D. No drug or cosmetic or medical device shall be exported except in accordance with the conditions of a permission or licence or certificate, as the case may be, issued by the Central Licensing Authority, in such manner, as may be prescribed.

Penalty for export of drugs and cosmetics in contravention of section 18D.

18E. Whoever, himself or by any other person on his behalf, exports any drug, cosmetic or medical device in contravention of the provisions of section 18D shall be punishable with imprisonment for a term which shall not be less than one year and shall also be liable to fine which shall not be less than two lakh rupees or three times value of the drug, cosmetic or medical device exported or confiscated, whichever is more.

Penalty for repeat offences.

18F. Whoever having been convicted of an offence under section 18E is again convicted of an offence under that section, shall be punishable with imprisonment for a term which shall not be less than two years and with fine which shall not be less than five lakh rupees or three times value of the drug, cosmetic or medical device exported or confiscated, whichever is more.".

Amendment of section 19.

25. In section 19 of the principal Act,—

(*a*) for the words "drug or cosmetic", wherever they occur, the words "drug or cosmetic or medical device" shall be substituted;

(*b*) for the words, "this Chapter", the words, figures and letter "Chapter IIA or Chapter III or Chapter IV" shall be substituted;

(*c*) in sub-section (*2*),—

(*i*) in the opening portion, for the words, figures and "section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality", the words, figure and letter "section 7F, a medical device shall not be deemed to be misbranded or adulterated or spurious or not of standard quality, or for the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality or shall a cosmetic be deemed to be misbranded or adulterated or spurious or to be below standard quality" shall be substituted;

(*ii*) in clause (*a*), after the word "consumption", the words "or use" shall be inserted;

(*d*) in sub-section (*3*), in the opening portion, for the word and figures "section 18", the words, figures and letter "section 7F or section 18" shall be substituted.

26. In section 20 of the principal Act,— Amendment of section 20.

(*a*) in sub-section (*1*), for the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics", the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics or such medical devices or classes of medical devices" shall be substituted;

(*b*) in sub-section (*2*),—

(*i*) for the words "Central Government", the words "Central Drugs Authority" shall be substituted;

(*ii*) for the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics", the words "such drugs or classes of drugs or such cosmetics or classes of cosmetics or such medical devices or classes of medical devices" shall be substituted;

(*c*) in sub-section (*3*), for the words "Central Government", the words "Central Drugs Authority" shall be substituted;

(*d*) in sub-section (*4*), for the words "import, manufacture or sale of drugs or cosmetics", the words "import, export, manufacture or sale of drugs or cosmetics or medical devices" shall be substituted.

27. In section 21 of the principal Act,— Amendment of section 21.

(*a*) in sub-section (*1*), for the words "Central Government or" at both the places where they occur, the words "Central Drugs Authority or" shall be substituted;

(*b*) in sub-section (*3*), for the words "import, manufacture or sale", the words "import, export, manufacture or sale" shall be substituted;

(*c*) after sub-section (*4*), the following sub-section shall be inserted, namely:—

"(*5*) Any person appointed as the Inspector under this section, before the commencement of the Drugs and Cosmetics (Amendment) Act, 2013, shall, after such commencement, be deemed to have been appointed as the Drugs Control Officer for the purposes of this section and shall continue to discharge his functions as the Drugs Control Officer unless his appointment is terminated or withdrawn.".

28. In section 22 of the principal Act,— Amendment of section 22.

(*a*) for the word "Inspector", wherever it occurs, the words "a Drugs Control Officer or a Medical Device Officer" shall be substituted;

(*b*) for the words "drug or cosmetic", wherever they occur, the words "drug or cosmetic or medical device" shall be substituted;

(*c*) for the words "this Chapter", wherever they occur except in clause (*cca*) of sub-section (*1*), the words, figures; and letter "Chapter IIA or Chapter IV" shall be substituted;

(*d*) in sub-section (*1*),—

(*A*) in clause (*a*), for sub-clause (*ii*), the following sub-clause shall be substituted, namely:—

"(*ii*) any premises wherein any drug or cosmetic or medical device is being sold, or exported, or stocked or exhibited or offered for sale, or export, or distributed;";

(*B*) in clause (*b*), for sub-clause (*i*), the following sub-clause shall be substituted, namely:—

"(*i*) which is being imported or manufactured or sold or exported or is stocked or exhibited or offered for sale, or for export, or is being distributed;";

(*C*) in clause (*cca*), for the words "manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution", the words "manufacture for sale, or for export or for distribution, stocking, exhibition for sale or for export, offer for sale or for export or for distribution" shall be substituted;

(*D*) in clause (*d*), for the words "exercise such other powers", the words "exercise such other powers and perform such functions" shall be substituted;

(*E*) after clause (*d*), the following proviso shall be inserted, namely:—

"Provided that in case the stocks of the drugs or cosmetics or medical devices, and the records, registers, documents or any other material objects connected or related thereto are seized, he shall, as soon as may be, inform the Judicial Magistrate and take his orders as to the custody thereof.";

(*e*) in sub-section (*3*), for the words "may extend to three years, or with fine,", the words "shall not be less than three years and shall also be liable to fine which shall not be less than fifty thousand rupees" shall be substituted.

Substitution of new section for section 23.

29. For section 23 of the principal Act, the following section shall be substituted, namely:—

"23. The Drugs Control Officer or the Medical Device Officer shall take sample of drugs or cosmetics or medical devices, as the case may be, for test and examination under Chapter IIA or Chapter IV, as the case may be, in such manner as may be prescribed.".

Substitution of new section for section 24.

30. For section 24 of the principal Act, the following section shall be substituted, namely:—

Persons bound to disclose place where medical device or drugs or cosmetics are manufactured or kept.

"24. Every person for the time being in charge of any premises whereon any drug or cosmetic or medical device is being manufactured or is kept for sale or distribution shall, on being required by any Drugs Control Officer or, as the case may be, the Medical Device Officer so to do, be legally bound to disclose to the Drugs Control Officer or, as the case may be, the Medical Device Officer, the place where the drug or cosmetic or medical device is being manufactured or is kept, as the case may be.".

Substitution of new section for section 25.

31. For section 25 of the principal Act, the following section shall be substituted, namely:—

Reports of Government Analysts.

"25. The Government Analyst shall submit report in relation to samples of drugs or cosmetics or medical devices and action shall be taken thereon, in such manner as may be prescribed.".

Amendment of section 26.

32. In section 26 of the principal Act, for the words "drug or cosmetic", the words "drug or cosmetic or medical device" shall be substituted;

Substitution of new section for section 26A.

33. For section 26A of the principal Act, the following section shall be substituted, namely:—

Powers of Central Government to prohibit manufacture, etc., of drug, cosmetic and medical device in public interest.

"26A. Without prejudice to any other provisions contained in Chapter IIA and Chapter IV, if the Central Government is satisfied, that the use of any drug or cosmetic or medical device is likely to involve any risk to human beings or animals or that any drug or medical device does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic or medical device.".

Amendment of section 26B.

34. In section 26B of the principal Act, for the word "drug", wherever it occurs, the words "drug or medical device" shall be substituted.

Amendment of section 27.

35. In section 27 of the principal Act,—

(*i*) in the opening portion, for the words "manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes", the words "manufactures for sale or for export or for distribution, or sells, or exports, or stocks or exhibits or offers for sale or for export or distributes" shall be substituted;

(*ii*) in clause (*a*), in the second proviso,—

(*a*) for the word "relative", the words "legal heir" shall be substituted;

(*b*) the *Explanation* shall be omitted.

Amendment of section 27A.

36. In section 27A of the principal Act, for the words "manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale", the words "manufactures for sale or for export or for distribution, or sells, or exports, or stocks or exhibits or offers for sale or for export" shall be substituted.

Amendment of section 28.

37. In section 28 of the principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "shall not be less than three years and shall also be liable to fine which shall not be less than three lakh rupees" shall be substituted.

Amendment of section 28A.

38. In section 28A of the principal Act, for the words "may extend to one year or with fine which shall not be less than twenty thousand rupees or with both", the words "shall not be less than three years and shall also be liable to fine which shall not be less than three lakh rupees" shall be substituted.

Amendment of section 28B.

39. In section 28B of the principal Act, for the words "may extend to three years and shall also be liable to fine which may extend to five thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than five lakh rupees" shall be substituted.

Amendment of section 29.

40. In section 29 of the principal Act,—

(*a*) for the words "drug or cosmetic", the words "drug or cosmetic or medical device" shall be substituted;

(*b*) for the words "which may extend to five thousand rupees", the words "which shall not be less than fifty thousand rupees" shall be substituted.

Amendment of section 30.

41. In section 30 of the principal Act,—

(*a*) in sub-section (*1A*), for the words "may extend to two years or with a fine which may extend to two thousand rupees", the words "shall not be less than three years and shall also be liable to fine which shall not be less than ten lakh rupees" shall be substituted;

(*b*) in sub-section (*2*), for the words "may extend to two years, or with fine which shall not be less than ten thousand rupees or with both", the words "shall not be less than two years and shall also be liable to fine which shall not be less than one lakh rupees" shall be substituted;

(*c*) after sub-section (*2*), the following sub-section shall be inserted, namely:—

"(*3*) Whoever having been convicted of an offence under section 28A or section 28B is again convicted of an offence under that section shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and shall also be liable to fine which shall not be less than five lakh rupees.".

Amendment of section 31.

42. In section 31 of the principal Act, in sub-section (*1*),—

(*a*) in clause (*ii*),—

(*A*) for the words "manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale, or distribution", the words "manufacture for sale or for export or for distribution, sale, export, or stocking or exhibiting or offering for sale or for export or for distribution" shall be substituted;

(*B*) for the words, brackets, letter and figures "clause (*c*) of section 18", the word and figures "section 18" shall be substituted.

(*b*) in the opening portion, after clause (*ii*), for the words "manufacture, sale or distribution" the words "manufacture, sale, export or distribution" shall be substituted.

Amendment of section 31A.

43. In section 31A of the principal Act,—

(*a*) for the words and figures "this Chapter except those contained in section 31", the words, figures and letters "Chapter IB, Chapter IIA and Chapter IV except those contained in section 4ZI, section 7M and section 31" shall be substituted;

(*b*) for the words "manufacture, sale or distribution", at both the places where they occur, the words "manufacture, sale, export or distribution" shall be substituted.

Amendment of section 32.

44. In section 32 of the principal Act,—

(*a*) for the words "this Chapter", wherever they occur, the words, figures and letter "Chapter IIA or Chapter IV" shall be substituted;

(*b*) in sub-section (*1*), for clause (*a*), the following clause shall be substituted, namely:—

"(*a*) a Drugs Control Officer or a Medical Device Officer; or".

Amendment of section 33.

45. In section 33 of the principal Act,—

(*a*) in sub-section (*1*), for the word "Board", wherever it occurs, the words "Central Drugs Authority" shall be substituted;

(*b*) in sub-section (*2*),—

(*i*) in clause (*e*), for the words "manufacture for sale or for distribution, for the sale and for the distribution", the words "manufacture for sale or for export or for distribution for the sale, for the export and for the distribution" shall be substituted;

(*ii*) in clause (*h*), for the words "sale, stocking or exhibition for sale, or distribution", the words "sale, export, stocking or exhibition for sale, or export, or distribution" shall be substituted;

(*iii*) in clause (*i*), for the words "sale, stocking or exhibition for sale, or distribution", the words "sale, export, stocking or exhibition for sale, or export, or distribution" shall be substituted;

(*iv*) in clause (*k*), for the words "manufacture, sale or stocking or exhibition for sale, or distribution", the words "manufacture, sale, export or stocking or exhibition for sale, or for export or distribution" shall be substituted.

Amendment of section 33P.

46. In section 33P of the principal Act, for the words "any State Government", the words "any State Government or the Central Drugs Authority" shall be substituted.

Insertion of new sections 33Q and 33R.

47. After section 33P of the principal Act, the following sections shall be inserted, namely:—

Power of Central Drugs Authority to suspend or cancel permission, licence or certificate granted under this Act.

"33Q. The Central Drugs Authority may suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or the State Licensing Authority, in the public interest and for the reasons to be recorded in writing or if the permission, licence or certificate, as the case may be, is found not to have been issued in accordance with the provisions of this Act and the rules and regulations made thereunder, in the manner as may be prescribed.

Appeals.

33R. (*1*) Any person aggrieved by any action or decision of any State Licensing Authority or the Central Licensing Authority, may prefer an appeal to the Central Drugs Authority within such period and in such manner as may be prescribed.

(*2*) Any person aggrieved by any action or decision of the Central Drugs Authority, may prefer an appeal to the Central Government within such period and in such manner as may be prescribed.".

Amendment of section 34A.

48. In section 34A of the principal Act,—

(*a*) for the words, figures and letter "Chapter IV or Chapter IVA", at both the places where they occur, the words, figures and letters "Chapter IB, Chapter IIA, Chapter III, Chapter IV or Chapter IVA" shall be substituted;

(*b*) for the words "manufacture, sale or distribution of drugs", the words "clinical trial, import, manufacture, sale, export or distribution of drugs, cosmetics or medical devices" shall be substituted.

Amendment of section 34AA.

49. In section 34AA of the principal Act,—

(*i*) in clause (*c*), for the words "any drug or cosmetic", the words "any drug or cosmetic or medical device" shall be substituted;

(*ii*) in clause (*d*), for the words "one thousand rupees", the words "one lakh rupees" shall be substituted.

Insertion of new section 34AAA.

50. After section 34AA of the principal Act, the following section shall be inserted, namely:—

Penalty for submission of misleading or wrong information or refusal to furnish information.

"34AAA. Whoever himself or by any other person on his behalf imports, manufactures, stocks, sells, distributes or exports, or intends to do so, any drug or cosmetic or medical device and submits misleading or wrong information or refuses to provide correct information in that regard as required by the licensing authority under this Act shall be punishable with imprisonment for a term which shall not be less than three years and shall also be liable to fine which shall not be less than one lakh rupees.".

Insertion of new sections 35A and 35B.

51. After section 35 of the principal Act, the following sections shall be inserted, namely:—

Liability to bear storage cost of seized article, drugs, etc..

"35A. Any person convicted for an offence under this Act shall be liable to bear the cost of storage of any article related to such offence, seized under this Act.

Mandatory destruction of seized spurious or adulterated or not of standard quality drugs, cosmetics and medical devices.

35B. The seized spurious or misbranded or adulterated or not of standard quality drugs, cosmetics and medical devices, having been proved so and after their use as evidence in the case before the court is over, shall be destroyed by the official authority in custody of these products in the manner as may be prescribed and the convicted person shall be liable to bear the cost of destruction of seized articles.".

Substitution of new section for section 38.

52. For section 38 of the principal Act, the following section shall be substituted, namely:—

Rules and regulations to be laid before Parliament.

"38. Every rule and every regulation made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.".

Insertion of new Schedule.

53. After the Second Schedule to the principal Act, the following Schedule shall be inserted, namely:—

"THE THIRD SCHEDULE

[*See* section 18(*3*)]

CATEGORIES OF DRUGS WHICH THE CENTRAL LICENSING AUTHORITY IS EMPOWERED TO ISSUE LICENCE:

1. Sera;

2. Solution of serum proteins intended for injection;

3. Vaccines; and includes DNA vaccines and vaccines containing living genetically engineered organisms;

4. Toxins;

5. Antigens and anti-toxins;

6. Anti-biotics (betalactums and cephalosporins);

7. Parenteral preparations meant for parenteral administration;

8. Hormones and preparations containing hormones;

9. r-DNA derived drugs;

10. RNA interference based products;

11. Monoclonal anti-bodies;

12. Cellular products and stem cells;

13. Gene therapeutic products;

14. Xenografts;

15. Cytotoxic substances (anti-Cancer drugs);

16. Blood products;

17. Modified Living Organisms.".

STATEMENT OF OBJECTS AND REASONS

The Drugs and Cosmetics Act, 1940 is a consumer protection law, which is concerned with the standards and quality of drugs and cosmetics and regulates their import, manufacture, sale and distribution in the country.

2. In January, 2003, the Central Government constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Research (CSIR) to undertake a comprehensive examination of drug regulatory issues, including the menace of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee noted that the problems in the drug regulatory system in the country are primarily due to inadequate or weak drug control infrastructure at the State and Central level and therefore, recommended centralised licensing of manufacture of drugs. The Committee further recommended for a strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organisation (CDSCO) which may be given the status of Central Drug Administration reporting directly to the Central Government.

3. With a view to give effect to the recommendations of the Mashelkar Committee, the Central Government introduced the Drugs and Cosmetics (Amendment) Bill, 2007 in the Rajya Sabha on 21st August, 2007, which, *inter alia*, provided for centralised licensing of manufacture of drugs, regulatory provisions for clinical trials and export of drugs and cosmetics, creation of strong, well equipped, empowered, self managed and independent Central Drugs Authority in place of the existing central drugs regulatory body *i.e.* the CDSCO and do away with the Drugs Technical Advisory Board.

4. The said Bill was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare for examination and Report. The Committee in its 30th Report made several recommendations, including for creation of a separate Chapter for regulating medical devices. The provisions relating to regulation of clinical trials and exports in the Bill also needed to be made more comprehensive and therefore, the Central Government decided to withdraw the Bill of 2007 and introduce a new Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2013 excluding the provisions relating to AYUSH drugs for which a separate Bill will be brought before Parliament.

5. The new Bill contains, *inter alia*, a revised approach to the centralised licensing, in respect of seventeen categories of very critical drugs included in the proposed Third Schedule to the Act,

a separate Chapter containing regulatory provisions for Medical Devices, more comprehensive provisions for regulating clinical trials and exports and a revised composition of the Central Drugs Authority consisting of, *inter alia*, Secretaries of seven Ministries and Departments of the Central Government, four State Drugs Controllers and four experts, with the Drugs Controller General (India) as its Member-Secretary. The Drugs Technical Advisory Board has been retained.

6. In the Bill certain other amendments are also proposed which are consequential in nature. The Bill also seeks to harmonise different provisions of the Act.

7. The notes on clauses explain in detail the various provisions of the Bill.

8. The Bill seeks to achieve the above objects.

NEW DELHI;
The 16*th August,* 2013.

GHULAM NABI AZAD

Notes on clauses

Clause 1.—This clause provides for the short title and commencement of the proposed legislation.

Clause 2.—This clause seeks to amend the long title and preamble of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the Act). It is proposed to insert "Medical Device" with "Drugs and Cosmetics" in the long title and "regulation of safety, efficacy, quality, etc. of medical devices, export of drugs and clinical trials" in the preamble.

Clause 3.—This clause seeks to amend sub-section (*1*) of section 1 of the Act, to substitute the words "and Cosmetics", with the words "Cosmetics and Medical devices" in the short title.

Clause 4.—This clause seeks to substitute the word "Inspector" with the words "Drugs Control Officer" throughout the Act.

Clause 5.—This clause seeks to amend section 2 of the Act so as to substitute the "Dangerous Drugs Act,1930" with "the Narcotic Drugs and Psychotropic Substances Act, 1985".

Clause 6.—This clause seeks to amend section 3 of the Act relating to definitions, to define "bioavailability study", "bioequivalence study", "Medical Device Technical Advisory Board", "Central Drugs Authority", "Central Drugs Laboratory", "Central Licensing Authority", "Chairperson", "clinical trial", "New Drug", "Drugs Control Officer", "Medical Device Officer", "Drugs Controller General of India", "Ethics Committee", "Indian Pharmacopoeia", "investigational medical device", "investigational new drug", "Investigator", "manufacture", "medical device" "member", "protocol", "regulations", "sponsor", "State Government", "State Licensing Authority", "Schedule" and to amend the definitions of "cosmetic" to insert " new cosmetics", "drugs" to insert "or microbes" after the words "destruction of vermin or insects", to omit the provisions of "medical device" and to insert the provisions relating to "new drug", to substitute "manufacture" to take care of "exports", "human blood and its components" and "medical devices", to substitute the words "Central Government" with the words "Central Drugs Authority" etc.

Clause 7.—This clause seeks to insert new Chapters, CHAPTER IA titled "CENTRAL DRUGS AUTHORITY" containing proposed new sections 4A to 4-O and CHAPTER IB with chapter heading "CLINICAL TRIALS" containing proposed new sections 4P to 4ZL.

The proposed new section 4A provides for the constitution of the Central Drugs Authority, which shall be a body corporate having perpetual succession and common seal, its location of head office and empowers the Central Drugs Authority to establish its offices in other places in India.

The proposed new section 4B provides for composition of the Central Drugs Authority, terms of office of its Members and conduct of its meetings.

The proposed new section 4C provides for the reference of Central Drugs Authority *vis-a-vis* the Central Drugs Standards Control Organisation; ownership of property, assets, etc.; rights and liabilities to be transferred; debts, obligations and liabilities incurred and contracts entered, by, with or for before the date of constitution of the Central Drugs Authority shall be deemed to have been vested, transferred, incurred, and entered in or by the Central Drugs Authority; money due shall be deemed to be due and suits and legal proceedings in the name of Central Drugs Standards Control Organisation may be continued or instituted by or against the Central Drugs Authority and the employees of the Central Drugs Standards Control Organisation shall be transferred to the Central Drugs Authority with same terms and conditions and their absorption therein.

The proposed new section 4D provides for declaration of conflict of interests by the Members of Central Drugs Authority.

The proposed new section 4E provides that any vacancy in, or any defect in the constitution of the Central Drugs Authority, or any defect in the nomination of a person as a member, or any irregularity in its procedure not affecting the merits of a case, shall not invalidate its proceedings.

The proposed new section 4F provides for the manner of resignation of a nominated Member and further provides that unless permitted to relinquish, to continue in office until the expiry of three months from the date of receipt of notice of resignation or until a person duly appointed as his successor or until the expiry of his term of office, which is the earliest.

The proposed new section 4G empowers the Central Government to appoint the Drugs Controller General of India and to determine his salaries, allowances and pensions.

The proposed new section 4H empowers the Central Government to create posts in the Central Drugs Authority and to determine the manner of appointment, salaries, allowances, pensions and other conditions of service of its officers and employees.

The proposed new section 4-I enumerates the powers and functions of the Central Drugs Authority such as, to specify by regulations the guidelines, norms, etc.; assess periodically the functioning of the Central and State Licensing Authorities; power to

issue directions to ensure compliance of guidelines, norms, etc., to review, suspend or cancel permission, licence or certificate issued by the Central or State Licensing Authority; to specify the fees, or charges for issue or renewal of licenses; coordinate, mediate and decide upon the disputes arising out of the implementation of the provisions of the Act, rules, etc., recommend to the Central Government the measures as regards the standards of Drugs, cosmetics, etc.

The proposed new section 4J provides for the powers and functions of the Drugs Controller General of India. Sub-section (*2*) of the aforesaid section provides that the Drugs Controller General of India shall exercise the powers such as, to issue, renew, suspend, or cancel licence for import, export or manufacture of drugs, cosmetics or medical device or for permission for conduct criminal trials; to recall or direct to recall any drug, cosmetic or medical device; collect fees or charges for licenses, etc. Sub-section (*3*) empowers the Drugs and Controller General of India to delegate his powers with the prior approval of Central Drugs Authority; Sub-section (*4*) provides that the Drugs Controller General of India shall be the legal representative of the Central Drugs Authority and sub-section (*5*) provides that the Drugs Controller General of India shall have administrative control over the officers and employees of the Central Drugs Authority.

The proposed new section 4K provides for financial grants to be made by the Central Government to the Central Drugs Authority.

The proposed new section 4L provides for maintenance of proper accounts by the Central Drugs Authority and the details regarding procedure for auditing of its accounts.

The proposed new section 4M provides for preparation of an annual report by the Central Drugs Authority, which shall be forwarded to the Central Government and also be laid before each House of Parliament.

The Proposed new section 4N lays down the powers of the Central Government to make rules for giving effect to the provisions as contained in CHAPTER IA.

The Proposed new section 4-O lays down the power of the Central Drugs Authority to make regulations consistent with this Act and the rules made thereunder.

The proposed new section 4P prohibits clinical trial without permission. Sub-section (*1*) of the aforesaid section prohibits the conduct of clinical trials in respect of a new drug or investigational new drug or medical device or investigational medical device or cosmetic or bioavailability or bioequivalence study of any drug in human subjects without due permission from the Central Licensing Authority. Sub-section (*2*) prohibits conduct of any clinical trial unless approved by the Ethics Committee. Sub-section (*3*) prohibits conduct of clinical trial before registration with the Central Drugs

Authority. Sub-section (*4*) provides that no permission from Central Licensing Authority is required by the Government Institute, Hospital, etc., to initiate or conduct any bioequivalence or bioavailability studies of approved drugs.

The proposed new section 4Q empowers the Drugs Controller General of India or any other prescribed authority to decide the cause of injury or death of person which may occur in course of or due to clinical trial, and the manner thereof.

The proposed new section 4R provides for the person conducting clinical trial to give medical treatment and compensation in case of an injury or death of a person as a result of his participation in clinical trial, and the manner thereof.

The proposed new section 4S empowers the Central Licensing Authority in public interest to abbreviate, defer or omit the pre-clinical and clinical data requirements for approval of clinical trial indicated in life threatening or serious diseases or diseases of special relevance to the country.

The proposed new section 4T provides for the registration of Ethics Committee constituted for the purpose with the Central Licensing Authority, the period of its validity and its renewal.

The proposed new section 4U provides for the composition of the Ethics Committee.

The proposed new section 4V provides for the functions and responsibilities of the Ethics Committee such as, to give its approval for clinical trial protocol and other related documents; to safe guard the rights, safety and wellbeing of all trial participants enrolled in the clinical trial; to make periodic review of the trial, based on the study progress reports; to revoke its approval to a clinical trial, etc..

The proposed new section 4W empowers the Central Licensing Authority to suspend or cancel the registration of Ethics Committee and disqualification of its members on such cancellation, in case the Ethics Committee fails to discharge its functions and responsibility under the Act.

The proposed new section 4X empowers the Central Licensing Authority to carry out inspections of clinical trials and provides that the person conducting clinical trial shall allow the Drugs Control Officer or Medical Device Officer to enter with or without prior notice in to any premises related to clinical trial to inspect the facilities, record, data, document books and can also seeks clarifications, information's, etc..

The proposed new section 4Y provides for the person, sponsor and organisation conducting clinical trial to disclose name, address and other particulars of the persons involved in conducting the clinical trials, including the trial participants.

The proposed new section 4Z provides for the person, sponsor and organisation to mantain of data, records, registers and other documents and furnishing of information related to clinical trials to the Central Drugs Authority.

The proposed new section 4ZA provides for penalty for conducting clinical trials in respect of any drug or investigational new drug or any medical device or investigational medical device without permission.

The proposed new section 4ZB provides for penalty for repeat offence for conducting clinical trials in respect of any drug or investigational new drug or any medical device or investigational medical device without permission.

The proposed new section 4ZC provides for penalty for conducting clinical trial of cosmetics without permission.

The proposed new section 4ZD provides for penalty for repeat offence for conducting clinical trial of cosmetics without permission.

The proposed new section 4ZE provides for penalty for violation of conditions of permission for clinical trials in respect of any drug or investigational new drug or any medical device or investigational medical device or cosmetic. It further provides enhancement of penalty for resulting grievous hurt or death during clinical trial.

The proposed new section 4ZF provides for penalty for repeat offence for contravention of conditions of permission for clinical trials in respect of any drug or investigational new drug or any medical device or investigational medical device or cosmetics.

The proposed new section 4ZG provides for penalty for failure to provide compensation for clinical trial related injury or death.

The proposed new section 4ZH provides for penalty for contravention to any provisions under the Chapter IB not covered under section 4P, section 4Q, section 4R, section 4S section 4T, section 4U, section 4W, section 4X, section 4Y, section 4Z or any rule made under Chapter IB.

The proposed new section 4ZI provides for confiscation, upon conviction of the persons contravening any provisions of Chapter IB, of the stock of the drug or investigational new drug or medical device or investigational medical device or cosmetic in respect of which the contravention has been made as well as any implements or machinery, vehicle, vessel or other conveyances used in or for the purposes of conducting clinical trials.

The proposed new section 4ZJ provides that no court shall take cognizance of offence under Chapter IB pertaining to Clinical Trials except on complaint made by persons mentioned therein.

The proposed new section 4ZK empowers the Central Government to make rules after consultation with the Central Drugs Authority, to give effect to the provisions of Chapter IB.

The proposed new section 4ZL excludes the application of provisions of Chapter IB to Ayurvedic, Homoeopathic, Siddha or Unani drugs.

Clause 8.—This clause provides for substitution of the existing heading of Chapter II of the Act with the heading "TECHNICAL ADVISORY BOARDS, CENTRAL DRUGS LABORATORIES AND CONSULTATIVE COMMITTEE".

Clause 9.—This clause seeks to amend section 5 of the Act which provides for constitution, composition, functions, manner for nomination or election of members of the Drugs Technical Advisory Board to advise the Central Government and the State Governments on technical matters.

Clause 10.—This clause seeks to insert a new section 5A so as to provide for constitution, composition, functions, manner for nomination or election of members Medical Devices Technical Advisory Board to advise the Central Government, the Central Drugs Authority and the State Government.

Clause 11.—This clause seeks to amend section 6 of the Act with in respect to establishment and determination of functions of a Central Drugs Laboratory by the Central Drugs Authority and the rule making powers of the Central Government in that regard.

Clause 12.—This clause seeks to amend section 7 of the Act for renaming the Drugs Consultative Committee as the "Drugs, Cosmetics and Medical Device Consultative Committee", its composition and provides for the Committee to meet at least twice in a year and the power to regulate its own procedure.

Clause 13.—This clause seeks to insert a new Chapter, CHAPTER IIA, titled "IMPORT, MANUFACTURE, SALE, DISTRIBUTION AND EXPORT OF MEDICAL DEVICES" containing proposed new sections 7B to 7N".

The proposed new section 7B provides for definition of "standard quality" for in relation to medical devices.

The proposed new section 7C provides for definition of "misbranded medical device".

The proposed new section 7D provides for definition of 'adulterated medical device'.

The proposed new section 7E provides for definition of "spurious medical device".

The proposed new section 7F provides for prohibition, with certain exemptions of, (i) import, manufacture for sale or export of any medical device which is not of standard quality; misbranded,

adulterated, spurious, not displayed on the lable in prescribed manner, with therapeutic claims, with components which render it unsafe or harmful to use or in violation of any provision of Chapter IIA or rules made thereunder; import, manufacture for sale or export of medical devices except under and in accordance with the conditions of a licence or certificate issued by the Central Licensing Authority; (ii) prohibits sell or stock or distribute or exhibit or offer for sale of medical device; sell or stock or exhibit or offer for sale of medical device which has been imported or manufactured in contravention of any provisions of the Act; sell, stocking, exhibiting, offering for sale or distribution of medical devices except under a licence issued by the Licensing Authority. It further provides for the State Government to designate one or more persons as State Licensing Authority.

The proposed new section 7G provides for the law relating to customs and goods shall subject to the provisions of sections 7J,7K, and 7L apply in respect of medical device the import of which is prohibited under Chapter IIA and empowers the customs officers to exercise the powers under this Act regarding import of medical device. It further provides for the Commissioner of Customs or any other officer of the Central Government to detain any imported package suspected to have contained medical device which is prohibited for import and shall report of such detention to the Drugs Controller General of India and if necessary, forward it to laboratory and further in the event the package or sample of that medical device found in contravention of any of the provisions of this Chapter or rules made thereunder, the same shall not be allowed to be imported.

The proposed new section 7H provides for the appointment of Medical Device Officers by the Central Drugs Authority and their powers and duties. It further provides that the Medical Device Officers so appointed shall be deemed to be public servant.

The proposed new section 7 I provides for power of the Central Government to regulate, restrict or prohibit import, manufacture, sale or distribution of any medical device in public interest which is likely to involve any risk to human beings or animals, etc.

The proposed new section 7J provides for offences of import, manufacture for sale, stocking, exhibiting, offering for sale of medical device or distribution or export of any adulterated, spurious or not of standard quality medical device, grievous injury or death caused thereby, the penalties therefor and payment of fines to the person or his legal heir who had used such medical device, causing him grievous hurt or his death.

The proposed new section 7K provides for penalty for import, manufacture, sell, export or distribution of any medical device in contravention of provisions of any notification issued under section 7 I.

The proposed new section 7L provides for penalty for committing repeat offences specified under sections 7J and 7K.

The proposed new section 7M provides for confiscation of medical device, implements, machinery, receptacles, packages, coverings, animals, vehicles, vessels or other conveyances of persons convicted for offences under Chapter IIA or rules made thereunder. It further provides that the Court may on the application of the Medical Device Office after inquiry pass an order of confiscation, if the medical device is not of standard quality or is misbranded, adulterated, etc.

The proposed new section 7N lays down the powers of the Central Government to make rules for giving effect to the provisions as contained in this Chapter.

Clause 14.—This clause seeks to amend section 8 of the Act to substitute the word "Board" with "Central Drugs Authority" in respect of consultation by the Central Government with the words Central Drugs Authority, instead of with the Drug Technical Advisory Board, for amending the Second Schedule of the Act relating to standards of drugs for the purpose of Chapter III relating to import of drugs and cosmetics.

Clause 15.—This clause seeks to insert new section 9E to provide for definition of adulterated cosmetics.

Clause 16.—This clause seeks to amend section 10 of the Act for including "adulterated cosmetics" under prohibited cosmetics, and substituting "Board" with "Central Drugs Authority" for advising the Central Government on permitting import of not-of-standard quality drugs.

Clause 17.—This clause seeks to amend section 11 of the Act by inserting a proviso in sub-section (*2*) for prohibiting import of drug or cosmetic from that or any other port in the country, if the package of such drug or cosmetic is found in contravention of provisions of Chapter III of the Act.

Clause 18.—This clause seeks to amend sub-section (*1*) of section 12 of the Act to substitute the word "Board" with the words "Central Drugs Authority".

Clause 19.—This clause seeks to substitute section 13 of the Act by new sections 13 and 13A. The proposed new section 13 provides for offences of import of any adulterated, spurious or not of standard quality drug or cosmetics, grievous injury or death caused thereby, punishment and penalties therefor and payment of fines to the person or his legal heir who had used such drugs or cosmetics, causing him grievous hurt or death.

The proposed new section 13A provides for penalty for committing repeat offences mentioned under section 13 relating to import of adulterated drugs, cosmetics, etc.

Clause 20.—This clause seeks to amend section 16 of the Act to substitute the word "Board" with the words "Central Drugs Authority", in respect of consultation by the Central Government with the Central Drugs Authority, instead of with the Drug Technical Advisory Board, for amending the Second Schedule of the Act.

Clause 21.—This clause seeks to substitute section 18 of the Act to provide for prohibition on issuance of licence by the State Government for manufacture for sale, etc., of new drugs without prior permission of the Central Licensing Authority and putting responsibility for ensuring thereof on the State Government; designation of persons as State Licensing Authorities on prescribed terms and conditions by the State Governments, and their powers and functions; power of Central Licensing Authority to issue of licence or certificate for manufacture for sale or for export of drugs included in the Third Schedule and prohibition on issuance of licence for manufacture of any drugs included in the Third Schedule by the State Licensing Authorities; power of Central Government to amend the Third Schedule in consultation with the Central Drugs Authority by notification with the prior publication in the Official Gazette, etc.

Clause 22.—This clause seeks to amend section 18A of the Act to substitute the words "drug or cosmetic" with the words "drug or cosmetic or medical device" relating to disclosure of name of manufacturer, etc., from whom any person has acquired such products, and empowering Medical Device Officers also, alongwith Drug Inspectors, to whom such disclosures are to be made.

Clause 23.—This clause seeks to amend section 18B of the Act to provide for including licenses under Chapter IIA relating to medical devices and Chapter III relating to import of drugs and cosmetics requiring them to maintain prescribed records, registers and other documents and information and to furnish the required information to the appropriate officer or authority.

Clause 24.—This clause seeks to insert new sections 18D, 18E and 18F in the Act.

The proposed new section 18D empowers the Central Licensing Authority to issue permission or licence or certificate, as the case may be, for export of drugs, cosmetics or medical devices.

The proposed new section 18E provides for penalty for contravention of provisions of section 18D relating to export of drugs, cosmetics or medical devices.

The proposed new section 18E provides for penalty for committing repeat offences specified under section 18E relating to export of drugs, cosmetics or medical devices.

Clause 25.—This clause seeks to amend section 19 of the Act relating to "Pleas" to insert provisions for covering matters relating to Chapter IIA, Chapter III, adulterated and spurious cosmetics under Chapter IV as well as exports under new section 18D.

Clause 26.—This clause seeks to amend section 20 of the Act to provide for appointment of Government Analysts for medical devices or classes of medical device also, appointment of Government Analysts in the Central Government by the Central Drugs Authority instead of by the Central Government and bringing financial interests in exports also within the purview of disqualifications for appointment as Government Analysts.

Clause 27.—This clause seeks to amend section 21 of the Act to provide for appointment of Drug Inspectors in the Central Government by the Central Drugs Authority instead of by the Central Government, bringing financial interests in exports also within the purview of disqualifications for appointment as Inspector and to insert a new sub-section (*5*) to provide that the Inspector appointed before the commencement of the amendment Act shall after commencement of such Act be deemed to have been appointed as Drugs Control Officer and shall continue to discharge his function as Drugs Control Officer.

Clause 28.—This clause seeks to amend section 22 of the Act to substitute the word "Inspector" with the words "Drugs Control Officer and Medical Device Officer"; bringing Chapter IIA, relating to medical devices, and exports also within the purview of application of this section; the procedure for taking custody of materials seized by the Drugs Control Officer or the Medical Device Officer and for enhancing the penalty for obstructing him from performing his duties.

Clause 29.—This clause seeks to substitute section 23 of the Act to provide that the sample of drugs or cosmetics or medical devices shall be taken by the Drugs Control Officer or the Medical Device Officer in the manner as may be specified in the rules.

Clause 30.—This clause seeks to substitute section 24 of the Act to provide for disclosure of information relating to manufacture of Medical Devices as well, and to empower the Medical Device Officer who can also exercise the powers under the section.

Clause 31.—This clause seeks to substitute section 25 of the Act to provide that the Government Analyst shall submit report in relation to samples of drugs or cosmetics or medical devices and the action to be taken thereon, in the manner as may be specified in the rules.

Clause 32.—This clause seeks to amend section 26 of the Act to substitute the words "drug or cosmetic" with the words "drug or cosmetics or medical device" to enable a purchaser to submit samples of medical devices also to a Government Analyst for test and analysis and receive report thereof.

Clause 33.—This clause seeks to substitute section 26A of the Act empowering the Central Government to regulate, restrict or prohibit the manufacture, sale or distribution of drugs or cosmetic or medical device if use of such drug, cosmetic or medical device

is likely to involve any risk to human beings or animals or that any drug or medical device does not have the therapeutic value claimed, etc.

Clause 34.—This clause seeks to amend section 26B of the Act to substitute the word "drug" with the words "drug or medical device" to regulate or restrict the manufacture, sale or distribution of Medical Devices as well in case of emergency and in public interest.

Clause 35.—This clause seeks to amend section 27 of the Act to bring export of drugs within the purview of the penalty provided in this section; to enable the "legal heir" instead of "relative" of the deceased for receiving the financial claims realised from the convict and to omit the "explanation" containing the details of the relatives entitled for receiving such claims.

Clause 36.—This clause seeks to amend section 27A of the Act so as to provide the export of cosmetics also within the purview of the penalty provided in the section.

Clause 37.—This clause seeks to amend section 28 of the Act to enhance penalty for non-disclosure of the name of the manufacturer, place of manufacture, etc., in contravention of provisions of sections 18A and 24 of the Act.

Clause 38.—This clause seeks to amend section 28A of the Act to enhance penalty for not keeping of documents, non-disclosure of information, etc., in contravention of provisions of section 18B of the Act.

Clause 39.—This clause seeks to amend section 28B of the Act to enhance penalty in contravention of provisions of section 26A relating to drugs, cosmetics and medical devices whose manufacture, sale or distribution has been regulated, restricted or prohibited under that section.

Clause 40.—This clause seeks to amend section 29 of the Act to include medical devices also within the purview of the penalty for use of report of Government Analyst for advertisement of drug or cosmetic and to enhance the penalty therefor.

Clause 41.—This clause seeks to amend section 30 of the Act to enhance the penalties for repeat offences relating to manufacture, sale, etc., of cosmetics in contravention of provisions of Chapter IV and for use of report of Government Analyst for the purpose of advertisement of the product and to insert a new sub-section (*3*) to provide for penalty for repeat offence for non-disclosure of the name of the manufacturer, place of manufacture, etc., and for not keeping of documents, non-disclosure of information, etc., in contravention of provisions of sections 28A and 28B of the Act.

Clause 42.—This clause seeks to amend section 31 of the Act relating to confiscation so as to include "exports" within its purview and expanding its purview to the provisions of new section 18

pertaining to prohibition on manufacture, sale, distribution, etc., without licence, which would now include licenses issued by the Central Licensing Authority as well.

Clause 43.—This clause seeks to amend section 31A of the Act to provide for application of provisions of new Chapter IB relating to clinical trials and new Chapter IIA relating to import, manufacture, sale, distribution and export of Medical Devices, along with chapter IV exempting the provisions of sections 4ZI and 7M relating to confiscation.

Clause 44.—This clause seeks to amend section 32 of the Act relating to cognizance of offences and to substitute the word "Inspector" with the words "Drugs Control Officer or Medical Device Officer" and to insert new Chapter IIA within its purview.

Clause 45.—This clause seeks to amend section 33 of the Act relating to power of Central Government to make rules and to provide for consulting the "Central Drugs Authority" in place of the "Drug Technical Advisory Board" and for including exports as well within the purview of these rules.

Clause 46.—This clause seeks to amend section 33P of the Act relating to power of the Central Government to give directions by including the Central Drugs Authority also within the purview of these directions.

Clause 47.—This clause seeks to insert new sections 33Q and 33R in the Act.

The proposed new section 33Q empowers the Central Drugs Authority to suspend or cancel any permission, licence or certificate issued by the Central Licensing Authority or the State Licensing Authority, in the public interest if such permission, licence or certificate is found not to have been issued in accordance with the provisions of the Act.

The proposed new section 33R provides for preferring appeal to the Central Drugs Authority against any action or decision of any State Licensing Authority or the Central Licensing Authority and to the Central Government against any action or decision of the Central Drugs Authority.

Clause 48.—This clause seeks to amend section 34A of the Act relating to offences by Government Department so as to insert the new Chapter IB relating to Clinical Trials, new Chapter IIA relating to import, manufacture, sale, distribution and export of Medical Devices within the purview of this section.

Clause 49.—This clause seeks to amend section 34AA of the Act relating to penalty for vexatious search or seizure so as to include medical devices within the purview of the section and to enhance the penalty provided therefor.

Clause 50.—This clause seeks to insert a new section 34AAA to provide for penalty for submission of misleading or wrong information or refusal to furnish information as required by the licensing authority.

Clause 51.—This clause seeks to insert new sections 35A and 35B in the Act.

The proposed new section 35A imposes the liability to bear the cost of storage of any article seized for any offence under this Act on the person convicted for that offence.

The proposed new section 35B provides for destruction of the seized spurious, misbranded, adulterated or not-of-standard quality drugs, cosmetics and medical devices after their use in the court as evidence and placing the liability to bear the cost of such destruction on the convicted person.

Clause 52.—This clause seeks to substitute section 38 of the Act relating to laying of rules and regulations made under the Act.

Clause 53.—This clause seeks to insert a new Schedule, namely, "THE THIRD SCHEDULE", in the Act relating to Categories of drugs which the Central Licensing Authority is empowered to issue licence containing seventeen categories of drugs.

FINANCIAL MEMORANDUM

Clause 7 of the Bill proposes to insert, *inter alia*, new section 4A relating to constitution of Central Drugs Authority. Sub-section (*4*) of the aforesaid section empowers the Central Drugs Authority to establish its offices. Sub-section (*3*) of the proposed new section 4B provides for allowances payable to members on account of holding of meetings of the Central Drugs Authority. The proposed new sub-section (*2*) of section 4G provides for salaries, allowances and pensions of the Drugs Controller General of India. The proposed new section 4H empowers the Central Drugs Authority to create posts. Sub-section (*2*) of the aforesaid section 4H provides for salaries, allowances and pensions to the officers and employees of the Central Drugs Authority which shall be determined by the Central Government.

2. The Bill, if enacted and brought into operation, may involve expenditure from the Consolidated Fund of India and is not likely to involve any other expenditure whether of a recurring or non-recurring nature.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 7 of the Bill proposes to insert new Chapters IA and IB (containing new sections 4A to 4ZL) in the Drugs and Cosmetics Act, 1940.

The proposed new section 4 I provides that the Central drugs Authority shall specify, by regulations, (i) the guidelines, norms, structures and requirements for effective functioning of the Central Licensing Authority and the State Licensing Authorities and (ii) the fees or charges for issue or renewal of licenses, certificates, approvals and permissions by the Central Licensing Authority and the State Licensing Authorities.

The proposed new section 4N empowers the Central Government to make rules for giving effect to the provisions of Chapter IA after consultation with, or on the recommendation of, the Central Drugs Authority and subject to previous publication by notification in the Official Gazette.

The proposed new section 4 O empowers the Central Drugs Authority to make regulations consistent with the Act and the rules made thereunder, with the approval of the Central Government, by notification in the Official Gazette.

The proposed new section 4ZK empowers the Central Government to make rules for giving effect to the provisions of Chapter IB after consultation with, the Central Drugs Authority and after previous publication by notification in the Official Gazette.

2. Clause 10 of the Bill proposes to insert a new section 5A in the Act. Sub-section (*4*) of the proposed new section 5A confers power on the Medical Device Technical Advisory Board, in consultation with the Central Drugs Authority, and subject to the previous approval of the Central Government, to make bye-laws fixing quorum and regulating its own procedure and the conduct of all business to be transacted by it.

3. Clause 11 of the Bill proposes to amend section 6 of the Act. The proposed sub-section (*1*) of the aforesaid section provides, *inter alia,* that the Central Drugs Authority may, in consultation with the Central Government, specify by regulations the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics or medical device or class of medical devices to be performed by any other laboratory.

4. Clause 13 of the Bill proposes to insert a new Chapter IIA (containing new sections 7B to 7N) in the Act. The proposed new section 7N empowers the Central Government to make rules for

giving effect to the provisions of Chapter IIA after consultation with, or on the recommendation of, the Central Drugs Authority and after previous publication, by notification in the Official Gazette.

5. The matters in respect of which the rules or regulations may be made under the aforementioned provisions are matters of procedure or administrative details and it is not practicable to provide for them in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

ANNEXURE

EXTRACTS FROM THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

* * * * *

AN ACT to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

WHEREAS it is expendient to regulate the import, manufacture, distribution and sale of drugs and cosmetics:

* * * * *

CHAPTER 1

INTRODUCTORY

1. (*1*) The Act may be called the Drugs and Cosmetics Act, 1940. Short title, extent and commencement.

* * * * *

2. The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 and any other law for the time being in force. Application of other laws not barred.

2 of 1930.

3. In this Act, unless there is anything repugnant in the subject or context,— Definitions.

* * * * *

(*aaa*) "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic;

(*b*) "drug" includes·—

* * * * *

(*ii*) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

* * * * *

(*iv*) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

(*c*) "Government Analyst" means—

* * * * *

(*ii*) in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;

(*e*) "lnspector" means—

* * * * *

(*i*) in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

(*ii*) in relation to any other drug or cosmetic, an inspector appointed by the Central Government or a State Government under section 21;

(*f*) "manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

* * * * *

(*h*) "patent or proprietary medicine" means,—

* * * * *

(*ii*) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;

* * * * *

CHAPTER II

THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

The Drugs Technical Advisory Board.

5. (*1*) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

(2) The Board shall consist of the following members, namely:—

(*i*) the Director General of Health Services, *ex-officio.* who shall be Chairman;

(*ii*) the Drugs Controller, India, *ex-officio;*

(*iii*) the Director of the Central Drugs Laboratory, Calcutta, *ex-officio;*

(*iv*) the Director of the Central Research Institute, Kasauli, *ex-officio;*

(*v*) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex-officio;*

(*vi*) the President of the Medical Council of India, *ex-officio;*

(*vii*) the President of the Pharmacy Council of India, *ex-officio;*

(*viii*) the Director of the Central Drug Research Institute, Lucknow, *ex-officio;*

(*ix*) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(*x*) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian University or a college affiliated thereto;

(*xi*) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian University or a college affiliated thereto;

(*xii*) one person to be nominated by the Central Government from the pharmaceutical industry;

(*xiii*) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(*xiv*) one person to be elected by the Central Council of the Indian Medical Association;

(*xv*) one person to be elected by the Council of the Indian Pharmaceutical Association;

(*xvi*) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

(*3*) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (*ix*) or clause (*x*) or clause (*xi*) or clause (*xvi*) of sub-section (*2*) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(*4*) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(*7*) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

The Central Drugs Laboratory.

6. (*1*) The Central Government shall. as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(*2*) The Central Government may, after consultation with the Board, make rules prescribing—

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(*d*) the procedure for the submission of the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

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7. (*1*) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act. The Drugs Consultative Committee.

(*2*) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(*3*) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

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CHAPTER III

IMPORT OF DRUGS AND COSMETICS

8. (*1*) * * * * * Standards of quality.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months, notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

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10. From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import— Prohibition of import of certain drugs or cosmetics.

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(*ee*) any cosmetic containing any ingredient which may render it unsafe or harmful or use under the directions indicated or recommended:

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Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any condition specified in the notification, the import of any drug or class of drugs not being of standard quality.

11. (*1*) * * * * * Application of law relating to sea customs and powers of Customs Officers.

(*2*) Without prejudice to the provisions of sub-section (*1*) the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug or cosmetic the import of which is prohibited under this Chapter and

shall forthwith report such detention to the Drugs Controller, India, and if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory.

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Power of Central Government to make rules.

12. (*1*) The Central Government may, after consultation with or on the recommendation of the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

Offences.

13. (*1*) Whoever himself or by any other person on his behalf imports,—

(*a*) any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 90 or any cosmetic of the nature referred to in clause *(ee)* of section 10, shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees;

(*b*) any drug or cosmetic other than a drug or cosmetic referred to in clause (*a*), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both;

(*c*) any drug or cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(*2*) Whoever having been convicted of an offence—

(*a*) under clause *(a)* or clause *(c)* of sub-section *(I)*, is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both:

(b) under clause *(b)* of sub-section (*1*), is again convicted of an offence under the clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

(*3*) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provisions of section 11.

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CHAPTER IV

MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS AND COSMETICS

16. (*1*) * * * * * Standards of quality.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

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18. From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf— Prohibition of manufacture and sale of certain drugs and cosmetics.

(*a*) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute—

(*i*) any drug which is not of a standard quality, or is misbranded, adulterated or spurious:

(*ii*) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;

(*iii*) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities, thereof;

(*iv*) any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment. or to have any such other effect as may be prescribed;

(*v*) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(*vi*) any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

(*b*) sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

(*c*) manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

Disclosure of the name of the manufacturer etc.

18A. Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the *Inspector* the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

Maintenance of records and furnishing of information.

18B. Every person holding a licence under clause *(c)* of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

Pleas.

19. (*1*) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug or cosmetic in respect of which the offence has been committed or of the circumstances of its manufacture or import or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(*2*) For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality only by reason of the fact that—

(*a*) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug or cosmetic as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drug or cosmetic or to conceal its inferior quality or other defects; or

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(*3*) A person, not being the manufacturer or a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves—

(*a*) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(*b*) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(*c*) that the drug or cosmetic, while in his possession was properly stored and remained in the same state as when he acquired it.

Government Analysts.

20. (*1*) The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notifications.

(*2*) The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

(*3*) Notwithstanding anything contained in sub-section (*1*) or sub-section (*2*), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

(*4*) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (*1*) or sub-section (*2*) of this section.

Inspectors.

21. (*1*) The Central Government or a State Government may by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

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(*3*) No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be an Inspector under this section.

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Powers of Inspectors.

22. (*1*) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,—

(a) inspect,—

(*i*) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic:

(*ii*) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

(*b*) take samples of any drug or cosmetic,—

(*i*) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

(*ii*) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee:

(*c*) at all reasonable times, with such assistance, if any, as he considers necessary,—

(*i*) search any person, who, he has reason to believe, has secreted about his person. any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or

(*ii*) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or

(*iii*) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed, and

order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being committed. not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;

(*cc*) examine any record, register, document or any other material object found with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (*c*),

and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the Rules made thereunder;

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(*cca*) require any person to produce any record, register, or other document relating to the manufacture for. sale or for distribution, stocking, exhibition for sale offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

(*d*) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

2 of 1974.

(*2*) The provisions of the Code of Criminal Procedure, 1973 shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.

(*2A*) Every record, register or other document seized under clause *(cc)* or produced under clause (*cca*) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production. as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.

(*3*) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or refuses to produce any record, register or other document when so required under clause (*cca*) of sub-section (*1*), he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

Procedure of Inspectors.

23. (*1*) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may require a written acknowledgement therefor.

(*2*) Where the price tendered under sub-section (*1*) is refused or where the Inspector seizes the stock of any drug or cosmetic under clause (*c*) of section 22, he shall tender a receipt therefor in the prescribed form.

(*3*) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:

Provided that where the sample is taken form permises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(*4*) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the reminder and dispose of the same as follows:—

(*i*) one portion or container he shall forthwith send to the Government Analyst for test or analysis;

(*ii*) the second, he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic; and

(*iii*) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(*5*) Where an Inspector takes any action under clause (*c*) of section 22,—

(*a*) he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of section 18 and, if it is ascertained that the drug or cosmetic does not so contravene forthwith revoke the order passed under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

(*b*) if he seizes the stock of the drug or cosmetic, he shall as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof;

(*c*) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(*6*) Where an Inspector seizes any record, register, document or any other material object under clause (*cc*) of sub-section (*1*) of section 22, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

Persons bound to disclose place where drugs or cosmetics are manufactured or kept.

24. Every person for the time being in charge of any premises whereon any drug or cosmetic is being manufactured or is kept for sale or distribution shall, on being required by any Inspector so to do, be legally bound to disclose to the Inspector the place where the drug or cosmetic is being manufactured or is kept, as the case may be.

Reports of Government Analysts.

25. (*1*) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(*2*) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(*3*) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(*4*) Unless the sample has already been tested or analysed in the Central Drugs Laboratory. where a person has under sub-section (*3*) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of it own motion or in its discretion at the request either of the complainant or the accused: cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (*4*) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(*5*) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (*4*) shall be paid by the complainant or accused as the Court shall direct.

Purchaser of drug or cosmetic enabled in obtain test or analysis.

26. Any person or any recognised consumer association, whether such person is a member of that association or not shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug or cosmetic purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst.

Explanation.—For the purposes of this section and section 32. "recognised consumer association" means a voluntary consumer association registered under the Companies Act, 1956 or any other law for the time being in force.

1 of 1956.

Powers of Central Government to prohibit manufacture, etc., of drug and cosmetic in public interest.

26A. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therepcutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture. sale or distribution of such drug or cosmetic.

Power of Central Government to regulate or restrict, manufacture, etc., of drug in public interest.

26B. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.

Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.

27. Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,—

(*a*) any drugs deemed to be adulterated under section 17A or spurious under section 17B and which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more: 45 of 1860.

Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation.—For the purposes of the second proviso, the expression "relative" means—

(*i*) spouse of the deceased person; or

(*ii*) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

(*iii*) parent of the minor victim; or

(*iv*) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(*v*) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of this death,—

(*a*) the parent; or

(*b*) a minor brother or an unmarried sister; or

(*c*) a widowed daughter in-law; or

(*d*) a widowed sister; or

(*e*) a minor child of a pre-deceased son; or

(*f*) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(*g*) the paternal grandparent if no parent of the member is alive.

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Penalty for manufacture, sale, etc., of cosmetics in contravcation of this Chapter.

27A. Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale-

(*i*) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times to value of the cosmetics confiscated, whichever is more;

(*ii*) any cosmetic other than a cosmetic referred to in clause (*i*) in contravention or any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both.

Penalty for non-disclosure of the name of the manufacturer, etc.

28. Whoever contravenes the provisions of section 18A or section 24 shall be punishable with imprisonment for a term which may extend to one year, or with fine which shall not be less than twenty thousand rupees or with both.

Penalty for not keeping documents, etc., andfor non-disclosure of information.

28A. Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than twenty thousand rupees or with both.

Penalty for manufacture, etc., for drugs or cosmetics in contravention of section 26A.

28B. Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.

Penalty for use of Government Analyst's report for advertising.

29. Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug for cosmetic, shall be punishable with fine which may extend to five thousand rupees.

Penalty for subsequent offences.

30. (*1*) Whoever having been convicted of an offence,—

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(*IA*) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both.

(*2*) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section, shall be punishable with imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees or with both.

Confiscation.

31. (*1*) Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug or cosmetic in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of—

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(*ii*) manufacture for sale, or for distribution, sale, or stocking or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under clause (*c*) of section 18,

any implements or machinery used in such manufacture, sale or distribution and any receptacles. packages or converings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be lable to confiscation.

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31A. The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person. Application of provisions to Government departments.

32. (*1*) No prosecution under this Chapter shall be instituted except by— Cognizance of offences.

(*a*) an inspector; or

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33. (*1*) The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purposes of giving effect to the provisions of this Chapter: Power of Central Government to make rules.

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(*2*) Without prejudice to the generality of the foregoing power, such rules may—

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(*e*) prescribe the forms of licences for the manufacture for sale or for distribution, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with:

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(*h*) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(*i*) prescribe the conditions to be observed in the packing in bottles, packages, and other containers of drugs or cosmetics, including the use of packing material which comes into direct

contact with the drugs and prohibit the sale, stocking or exhibition for sale, or distribution of drugs or cosmetics packed in contravention of such conditions;

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(*k*) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder.

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CHAPTER V

MISCELLANEOUS

Power to give disrections.

33P. The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.

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Offences by Government departments.

34A. Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.

Penalty for vexatious search or seizure.

34AA. Any Inspector exercising powers under this Act or the rules made thereunder, who,—

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(*c*) vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object; or

(*d*) commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty,

shall be punishable with fine which may extend to one thousand rupees.

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Rules to be laid before Parliament.

38. Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

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RAJYA SABHA

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BILL

further to amend the Drugs and Cosmetics Act, 1940.

(*Shri Ghulam Nabi Azad, Minister of Health and Family Welfare*)

ANNEXURE-II

भारतीय संसद
PARLIAMENT OF INDIA

प्रेस विज्ञप्ति
PRESS RELEASE

राज्य सभा सचिवालय
RAJYA SABHA SECRETARIAT

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE INVITES SUGGESTIONS ON THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2013

The Drugs and Cosmetics (Amendment) Bill, 2013 as introduced in the Rajya Sabha on 29th August, 2013 and pending therein, has been referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare headed by **Shri Brajesh Pathak,** M.P., Rajya Sabha on 9th September, 2013 for examination and report thereon within a period of two months.

2. **The Drugs and Cosmetics (Amendment) Bill, 2013** contains, *inter alia*, a revised approach to (i) the centralised licensing, in respect of seventeen categories of very critical drugs included in the proposed Third Schedule to the Act; (ii) a separate Chapter containing regulatory provisions for Medical Devices; (iii) more comprehensive provisions for regulating clinical trials and exports; and (iv) a revised composition of the Central Drugs Authority consisting of, *inter alia*, Secretaries of seven Ministries and Departments of the Central Government, four State Drugs Controllers and four experts, with the Drugs Controller General (India) as its Member-Secretary.

3. In order to have wider consultations, the Committee has decided to invite written memoranda containing suggestions/views/comments of individuals/institutions/organizations interested in the subject matter of the Bill.

4. Those desirous of submitting memoranda to the Committee may send two copies thereof, either in English or Hindi, to **Shrimati Arpana Mendiratta, Joint Director, Room No. 222, Rajya Sabha Secretariat, Parliament House Annexe, New Delhi - 110001 [Tel: 23035428 (O), Fax: 23012007]** within 15 day of publication of the advertisement. Besides, those who are also desirous of giving oral evidence before the Committee on the Bill are requested to indicate so, for consideration of the Committee.

5. Copies of the Bill may be obtained on requisition from **Shri Dinesh Singh, Deputy Director, Room No. 218, Rajya Sabha Secretariat, Parliament House Annexe, Sansad Marg, New Delhi-110001** or downloaded from the Rajya Sabha website rajyasabha.nic.in under the head 'Committees' – sub-head – 'Bills with the Committee and Press release seeking opinions/ suggestions from public'.

6. The memoranda submitted to the Committee will form part of the records of the Committee and would be treated as strictly confidential and may not be made public as such an act would constitute breach of privilege of the Committee.

***Website**: – rajyasabha.nic.in*
***E-mail**: rs-chfw@sansad.nic.in*

ANNEXURE-III

List of individuals/organisations from whom memoranda were received

Sl. No.	Individual/Associations
1	2
1.	Shri Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AIMED), New Delhi
2.	Shri Subhash Chandra Agarwal, Guiness Record Holder and RTI Activist, New Delhi
3.	Shri C.V. Ramiah, President, Drugs Control Department Retired Officers Association, Chennai
4.	Shri Tausif Ahmad, Individual
5.	Shri Ashim Sanyal, COO and Secretary, Voluntary Organisation in Interest of Consumer Education (Voice), New Delhi
6.	Shri Manoj Tongra, Individual
7.	Dr. Roop Narayan Gupta, Expert Member, National Formulary of India, Indian Pharmacoepia Commission, Ranchi
8.	Prof. P. N. Murthy, Principal, Royal College of Pharmacy and Health Sciences, Odisha
9.	Shri S.D. Joag, Hon. General Secretary, The Indian Pharmaceutical Association, Mumbai
10.	Prof. (Dr.) Arun Garg, Organizing Secretary-65th IPC, 2013, School of Medical and Allied Sciences, Gurgaon
11.	Dr. Atmaram Pawar, Dean, Pharmaceutical Sciences, Bharati Vidyapeeth Deemed University, Vice-Principal and Head, Deptt. of Doctor of Pharmacy, Pune
12.	Shri M.U. Doshi, President, Indian Drug Manufacturers Association (IDMA), Mumbai
13.	Shri Vishal Agrawal, Shri Upender Vurugonda, Shri Pradip Parmar, Ms. Dhara Dave, Ms. Karishma Pandya, Department of Medical Devices, NIPER-Ahmedabad
14.	Shri Saugata Saha, Joint Secretary, Central Drugs Laboratory Staff Association, Kolkata
15.	Shri Anand Grover, Senior Advocate, Director, Lawyers Collective, Lawyers Collective HIV/AIDS Unit, New Delhi
16.	Shri Amba Salelkar, Inclusive Planet Centre for Disability Law and Policy, Chennai
17.	Prof. (Dr.) N.V. Satheesh Madhav, Director, DIT, Faculty of Pharmacy, DIT University
18.	Shri Bejon Kumar Misra, International Consumer Policy Expert and Founder, New Delhi

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19.	Ms. Amy Hariani, Director and Legal Policy Counsel, U.S.-India Business Council (USIBC), NW Washington DC
20.	Shri R. Murugan, Secretary General, Federation of South Indian Pharmaceutical Manufacturers Association, Chennai
21.	Shri R. Desikan, Chairman, CONCERT
22.	Prabhari Adhikari Pharmacy, Combined District Hospital, Ambedkar Nagar
23.	Shri Ravi Uday Bhaskar, Secretary General, All India Drugs Control Officers' Confederation (AIDCOC), Mumbai
24.	Shri R.K. Rustagi, Executive Secretary, Federation of Pharma Entreprenur (FOPE), New Delhi
25.	Shri Pavan Choudhary, Chairman, Confederation of Indian Industry (CII) Medical Equipment Division, New Delhi
26.	Shri Prasanta Sahu, Regulatory and System Compliance Manager, Invent Bio Med. Pvt. Ltd.
27.	Shri P.K. Gupta, Chairman, Confederation of Indian Pharmaceutical Industry
28.	President, Indian Pharmaceutical Graduate Association, Haryana
29.	Dr. Viney Chawla, Director, Gyani Inder Singh Institute of Professional Studies, Dehradun
30.	Ms. Shubhra Mathur, Head Healthcare, American Chamber of Commerce (AMCHAM)
31.	Shri Ashish Dutt Gajja, Drug Control Officer, Officer of the Drug Control Office, Jaisalmer
32.	Shri Achintya Sinha, President, Joint Platform of Action of Government and Associate Services Employees Organisation, Kolkata
33.	Mr. Prafull D. Sheth, Vice-President, International Pharmaceutical Federation, New Delhi
34.	Shri O.S. Sadhwani, Joint Commissioner and Controlling Authority, Food and Drug Administration, Maharashtra State
35.	Shri Anil Raghavan, Managing Director, QUINTILES, Bangaluru
36.	Shri Rajiv Shukla, Director, Organisation of Pharmaceutical Producers of India, Mumbai
37.	Dr. Tulsi Chakrabati, President, The Indian Pharmaceutical Association, Mumbai
38.	Shri A. Sarangapajni, B. Pharma, Rtd. Director of Drugs Control, Tamil Nadu
39.	Shrimati Mrudula Nujella, Associate, Albright Stonebridge Group India, AdvaMed
40.	Shri Sasikant Misra, Director, Confederation of Indian Industry, New Delhi
41.	Shri M.K. Bhan, Individual, New Delhi

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42.	Shri Prahlad Gunari, Hon. Secretary, North Karnatak Drugs and Pharmaceuticals Manufacutreres Welfare Association, HUBLI
43.	Shri Anjani Kumar, JD (Drugs), President, IPGA, Jharkhand Branch, Drugs control Directorate, Jhakhand
44.	Dr. C.L. Kaul, Ex-Director, Pune
45.	Dr. Prem K. Gupta, former Drugs Controller (I), New Delhi
46.	Shri K.G. Kalyanaraman, Chennai
47.	Dr. Suresh Menon, Chair-Regulatory Council and Executive Committee Member of ISCR, Indian Society for Clinical Research, Mumbai
48.	Secretary General, SME Pharma Industries Confederation (I), New Delhi
49.	Rajasthan Pharmaceutical Manufactureres Association R.P.M.A, Jaipur
50.	Shri R.P. Yajurvedi (Rao), President, Society for Awareness of Civil Rights
51.	Professor B.D. Miglani, Hospital Pharmacist, Educationist and Journalist, New Delhi
52.	Shri Rajiv Boolchand Jain, New Delhi
53.	Shri Chirag H. Doshi, Chairman, Indian Drug Manufacturers Association- Gujarat State Board, Ahemadabad
54.	President, Punjab Drugs Manufacturers Association, Mohali
55.	Shri Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AIMED), New Delhi
56.	Shri M.U. Doshi, President, Indian Drug Manufacturers Association (IDMA), Mumbai
57.	Shri Dinesh Dayal, President, Indian Beauty and Hygiene Association, Mumbai
58.	Dr. G.S. Bhuvaneshwar, (Exp.), Director- Innovation and Edn.,Trivitron Healthcare Pvt. Ltd., Chennai
59.	Secretary General, SME Pharma Industries Confederation (I), New Delhi
60.	Dr. Muktipada Rana, Secretary, The Technical Officers Association (Directorate of Drugs Control), West Bengal
61.	Prof. Allyson Pollock, Professor of Public Health Research and Policy, Mr. Nerges Mistry, Director, Foundation for Research in Community Health, Barts and the London/ The Foundation for Research in Community Health, London E1 2AB
62.	Shri J.Y. Yadav, Secretary General, Drug Inspectors Welfare Association (DIWA), Maharashtra State, Mumbai
63.	Shri A. Didar Singh, Secretary General, FICCI, New Delhi
64.	Dr. H.G. Koshia, Commissioner, Food and Drugs Control Administration, Gujarat Government, Gandhinagar

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65.	Professor S.K. Gupta, *Formerly* Professor and Head, Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi; President, Indian Pharmacological Society, New Delhi
66.	Dr. Nitya Nand, Ex-Director, CDRI, Lucknow
67.	Shri D.S. Rawat, Secretary General, ASSOCHAM, New Delhi
68.	Shri D.G. Shah, Secretary General, Indian Pharmeuceutical Alliance, Mumbai
69.	Shri Lalit Kumar Jain, Chairman, All India SME Pharma Manufacturers Association (AISPMA), New Delhi
70.	Secretary, West Bengal Pharmaceutical Manufacturers Association, Kolkata
71.	Dr. D. B. Anantha Narayana
72	President, Karnataka State Registered Pharmacists Association, Gangavati
73.	Shri Rajesh Singh, President, Indigenous Medical Device Manufacturers Association (IMDMA), New Delhi

ANNEXURE-IV

List of Witnesses heard by the Committee

26th September, 2013

WITNESSES

Representatives of Department of Health and Family Welfare (Ministry of Health and Family Welfare)

1. Shri Keshav Desiraju, Secretary
2. Shri R.K. Jain, Additional Secretary and Director General (CGHS)
3. Shri C.K. Mishra, Additional Secretary

Legislative Department (Ministry of Law and Justice)

Dr. Sanjay Singh, Additional Secretary

12th November, 2013

Witnesses

Prof. S.K. Gupta, former Head, Department of Pharmacology, AIIMS, New Delhi.

Representatives from CII

1. Shri Pavan Choudhury, Chairman, CII Medical Equipment Division
2. Ms. Suneela Thatte, Executive Director, CII, Pharma Division

Representatives from FICCI

1. Mr. Gautam Khanna, Chairman – FICCI, MDF and Executive Director - Healthcare, 3 M India Ltd.
2. Dr. Surinder Kher, Chairman – FICCI Clinical Research Taskforce and CEO – Asia, Manipal Acunova Ltd.
3. Mr. Sanjay Banerjee, Co-Chair-FICCI MDF and Regional Managing Director, Zimmer India Pvt. Ltd.
4. Mr. Anil Seth, Co-Chair – FICCI Clinical Research Taskforce and Director – Clinical Operations, Eli Lilly and Company
5. Dr. Shamsher Dwivedee, Neurologist, VIMHANS
6. Mr. Sudhakar Mairpadi, Co-Chairman-FICCI MEF and Director – Regulatory Affairs and Quality Assurance, Phillips Healthcare

7. Ms. Shobha Mishra Ghosh, Senior Director, FICCI

8. Mr. Tanmoy Bose, Additional Director, FICCI

Representative from ASSOCHAM

Ms. Manisha Singh

Representative from Ministry of Health and Family

Shri Arun Panda, Joint Secretary

Representative from Legislative Department

Dr. Sanjay Singh, Additional Secretary

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

21st November, 2013

Witnesses

Dr. Ranjit Roy Choudhury, National Professor of Pharmacology and Former Member, Board of Governors, Medical Council of India

Representatives of Lawyers Collective HIV/AIDS Unit, New Delhi

1. Shri Anand Grover, Senior Advocate and Director

2. Shri P. K. Gupta, Chairman, Confederation of Indian Pharmaceutical Industry, New Delhi;

Representatives of SME Pharma Industries Confederation-New Delhi

1. Shri Jagdeep Singh, Secretary General

2. Dr. Pradeep Blaggan

3. Shri Amit Kapoor

4. Shri Piyush Sharma

5. Shri Rakesh Singla

6. Shri Sanjeev Vij

7. Shri Gian Prakash Sarwal

8. Shri Sudhir Pathak

Ministry of Law and Justice

Representatives from Legislative Department

1 Dr. Sanjay Singh, Additional Secretary

2 Shri Udaya Kumara, Addl. Legislative Counsel

3 Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

Representative from Ministry of Health and Family

Shri Arun Kumar Panda, Joint Secretary

22nd November, 2013

Witnesses

Dr. M.K. Bhan, Former Secretary to the Government of India, Department of Biotechnology, Ministry of Science and Technology

Indian Drug Manufacturers Association, Mumbai

1. Shri M.U. Doshi, President
2. Dr. R. K. Sanghavi, Chairman – Medical Sub-Committee, IDMA
3. Shri S.M. Mudda, Chairman – Regulatory Affairs Sub-Committee, IDMA
4. Shri Ashok K. Madan, Executive Director, IDMA Delhi office

Representatives of Indian Beauty and Hygiene Association, Mumbai

1. Ms. Malathi Narayanan
2. Ms. Veena Balgi
3. Ms. Priyanka Bhat
4. Mr Rajendra Dobriyal

Representatives of Consumer Online Foundation, New Delhi

1. Mr. Bejon Kumar Misra, Founder
2. Mr. Shambhu Nath Chaturvedi, Adviser
3. Dr. Rashmi Kulshreshta, Adviser
4. Mr. Pyush Misra, Director

Representatives of Federation of Pharma Entrepreneurs (FOPE)

1. Mr. Umesh Sanghi
2. Mr. Vinod Kalani
3. Mr. Navdeep Chawla
4. Mr. R. K. Chugh
5. Mr. R. K. Rustagi

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary

2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

Representative from Ministry of Health and Family

Shri Arun Kumar Panda, Joint Secretary

29th November, 2013

Witnesses

Indian Pharmaceutical Alliance (IPA)

1. Shri Satish Reddy, Managing Director, Dr. Reddy's Laboratories & President, IPA
2. Shri A. H. Khan, Vice-President,
3. Shri Dilip G. Shah, Secretary General

All India SME Pharma Manufaturers Association (AISPMA)

1. Shri Lalit Kumar Jain, Chairman
2. Dr. Niranjan Singh, Secretary
3. Shri Anil Maheshwari, Office Executive

Representative from Ministry of Health and Family Welfare

Shri R.K. Jain, Additional Secretary

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

9th December, 2013

Witnesses

Representatives from Ministry of Health and Family

Shri Keshav Desiraju, Secretary

Shri R.K. Jain, Additional Secretary

Shri Arun Panda, Joint Secretary

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Sanjay Singh, Additional Secretary
2. Shri Udaya Kumara, Addl. Legislative Counsel
3. Shri R.K. Pattanayak, Deputy Legislative Counsel
4. Shri K.V. Kumar, Deputy Legislative Counsel

Representative from Department of Legal Affairs

Shri Ramayan Yadav, Joint Secretary and Legal Advisor

ANNEXURE-V

Department of Commerce

Comments of DoC on the proposed amendments in the Drugs and Cosmetics (Amendment) Bill, 2013 (*provisions relating to other than Chapter II A*)

1. ***Clause 2 of the Bill***

The inclusion of the words "export" for the first time in Act will bring export explicitly within the ambit of the Drugs and Cosmetics Act, 1940 and Rules, 1945. However, definition has not been given; such words need to be defined in the Act to avoid any ambiguity and variation in their interpretation and understanding since the provisions are to be implemented by different Authorities. Absence of a clear-cut definitions may lead to avoidable litigation.

2. ***Incorporation of "Export" in Sections 18 and 27 (clause 24 and 35 respectively of the Bill)***

The amendment to Sections 18 and 27 to include the words "export" in the said sections are likely to put the exporters to stringent penalty under the Act for non compliance of regulations or on the basis of drug reported to be not of standard quality, misbranded or spurious [counterfeit as per international regulations].

Bringing export within the ambit of the Drugs and Cosmetics Act/Rules will create additional burden on the exporters since they become answerable to both the importing country regulator and the CLA for quality of the products. Since, the standards applicable for products for export are based on the registered specifications with the importing countries, the procedure to be adopted for declaring products for export as not of standard quality will be very complex.

Suggestion: the corresponding amendments to Section 18, 27 be made and insertion of new Section requiring additional license, permission or certificate from the Central Licensing Authority may be dropped.

3. ***Clause 24 (Section 18 D)***

Section 18D provides that no drug or cosmetic or medical device shall be exported except in accordance with the conditions of a permission or license or certificate as the case may be issued by the Central Licensing Authority in such manner as may be prescribed.

In view of the proposed Section 18D, the manufacturers will be required to obtain additional license or permission or certificate for the purpose of export from the Central Licensing Authority. This will be in addition to the license already granted by the State Licensing Authority or Central Licensing Authority in respect of drugs.

For the purpose of export, the exporter has to comply with the regulatory requirement of the importing country and most of the countries now have a system of registration which involve elaborate procedure and submission of exhaustive documents to establish quality, safety and efficacy of the drugs. It is well recognized under Rule 94 of the Drugs and Cosmetics Rules 1945.

In India, in addition to the product permission granted by the Licensing Authority, the exporter has to ensure that the factory complies with the Good Manufacturing Practices guidelines issued by the World Health Organization and has also to obtain Certificate Of Pharmaceutical Product for every product intended to be exported.

In the circumstances, the requirement of obtaining additional license from the Central Licensing Authority would be an hassle for the manufacturer and will cause unnecessary delay in export. It is apprehended by the industry that such additional requirement resulting in delay will adversely affect export of drugs.

Suggestion: In view of the stringent quality monitoring system in place, it may not be necessary to provide for requirement of obtaining additional permission, license or certificate from the Central Licensing Authority and the proposed Section 18D be omitted.

4. ***Status of Drugs included in Indian Pharmacopoeia:***

As per present provisions, drugs included in the Indian Pharmacopoeia are exempted from seeking approval as 'New drug'. This provision is being removed and exporters having export orders for such drugs will now require to take NOC from DCGI for getting manufacturing licenses from State Drugs Controllers.

Suggestion: **Retention of the existing provisions will help export manufacturers**.

5. ***Additional requirement to take license from Central Drugs Authority also by exporters:***

The exporters are required to take separate license from Central Drugs authority in addition to the license taken from State drug controllers. This is likely to cause substantial delays and increases transaction costs. SME sector is likely to face hurdles.

6. ***Penal provisions for export of quality defective products:***

As per new provisions, Govt. can take penal action including prosecution in cases of export of quality defective/ not of standard quality drugs. Industry is of the opinion that since exporter is conforming to the GMP and quality standards prescribed by the importing country Government, imposition of penalties in the exporting country is not justified, except for any malafide/careless manufacture that may be established.

7. ***Additions/Changes in explanations***:

(a) Clause 6 of the Bill: under definition of "bioavailability study" the words .. 'the rate and extent to which' may be read as 'the rate and extent **at which'**.

(b) In clause 6 of the Bill under the definitions of "bioavailability study" and bioequivalence study" the phrase *'active drug'* may be replaced as ' *active Ingredient'* since there is no definition of an Active Drug.

(c) In clause 6 of the Bill, under the definition of "clinical trials" {new clause (af) } "new cosmetics" need to be defined under the Act as there is no definition available as of now in the Act and Rules. The absence of a definition may cause hardship to the manufacturers.

(d) In clause 6, under the explanation I to new clause (v) under Section 3, the explanation given for "new drug" the words..... "significant extent'".... needs to be clearly explained. Many litigations are pending in the Courts where this word has played an

important role for interpretation. To avoid further complications, this word may be properly explained.

(e) Similarly under the Explanation II of the same clause mentioned above, it is stated that "A New Drug shall continue to be a new drug for such periods as may be prescribed ……." The present D&C Rules limits this period to FOUR YEARS. Industry has recommended that the said period of four years may be accepted and taken in the proposed amendment in the best interest of all the stakeholders. In its absence, all the manufacturers have to approach the DCGI for clearance etc., of the drugs which were cleared by that office earlier irrespective of the time that has elapsed.

(f) Definition of Medical Device – Under clause 6 (xi) of the Bill, under definition of medical devices, the "Clause (E) Disinfection of Medical devices" does not seem to convey proper sense - since it is a process, such item falling under this clause may not be considered as a Medical Device.

Department of Commerce

Comments of DoC on the proposed amendments in the Drugs and Cosmetics (Amendment) Bill, 2013 through Chapter II A (clause 13 of the Bill)

At present the medical devices are covered under the Drug and Cosmetics Act (D&C Act), but there is no single comprehensive specific law regulating medical devices. As the devices are governed in line with drugs, the regulatory compliance becomes quite challenging. The lack of regulatory clarity in terms of market entry, capital infusion, approval processes, labeling and classification is not favouring the growth of the Indian Medical device industry.

The CDSCO/DCGI is the principal authority regulating medical devices under the Ministry of Health and Family Welfare. As per present provisions, the companies should register their products with DCGI before their products are introduced in the country. The Central License Approval Authority serves as a main body that classifies medical devices while the D&C Act regulates the import, manufacture, sale and distribution of the notified medical devices.

The mechanism of applying D&CA to medical devices leads to delays in the approvals of medical technologies. The Indian manufacturers face 6-12 months in obtaining the manufacturing license which follows a hierarchical approval process going through the State Drugs licensing authority, then to the CDSCO Zonal/Sub Zonal offices and finally to the DCGI. The manufacturer is required to take approval for each brand. (*In a country like China, the approval is taken for a generic product and not a brand thereby reducing the time window and making them more competitive*).

Provisions related to drugs can't be applicable entirely for medical devices and taking note of this fact, the Drugs and Cosmetics (Amendment) Bill, 2013 is making an attempt towards specifying provisions specific to medical devices. The medical device sector has been largely unregulated so far and functioning in absence of any standards for the devices used in the healthcare sector. Although the draft bill introduced aims at providing an impetus to the industry, it is felt by the industry that there are issues which need to be addressed specifically before finalizing the bill.

Specific comments *w.r.t.* exports

Global harmonization of standards : The Standards of Quality of Medical Devices are not clearly defined. It only talks about Misbranded, Adulterated and Spurious form of medical devices, whereas these terms are applicable for drugs. Instead, consistent and globally harmonized standards would offer significant benefits to patients and consumers and to Regulatory Authorities as well. The global standards for medical device sector should be aligned to Indian standards :

e.g. CE is the standard being used towards import of Medical equipment in Europe and FDA is the standard being used towards import of Medical equipment in USA. Indian standards like BIS and AERB are not considered in Europe as well as in USA when it comes to their regulatory requirement and such India face a challenge even in sector some standards are laid down.

The important global standards for medical device sector are ISO 13485:2003, IEC 60601, ISO 15223-1:2012 and ISO 14971.

There are provisions in the Bill (clause 7N under chapter II A) for making Rules for presenting standards for different classes of medical devices, procedures etc. Department of Commerce would

like such Rules to be specified at the earliest and the industry should be consulted extensively while doing so, as this is likely to affect exports.

Regulation process:

Medical devices should not be viewed through the same laws as that of drugs. The proposed amendment to existing D&C Act with inclusion of all medical technology under one law and extrapolating laws applicable to drugs to medical technology, if notified is likely to impact both local and global manufacturers as well as healthcare providers. Having had no clear laws till date, any introduction of regulation at this stage need to ensure that the needs of the industry are met. The demand of the industry is for having a separate set of laws for medical devices altogether. Given the vast diversity of technologies and varying risk profile of Medical Devices, Regulatory Controls could be shared and split. A study of evolving laws in developed countries could facilitate a better approach in so far as exports are concerned.

The punitive clauses under the Bill recommends penalty and flat punishment for all levels of non-conformance – Minor/Moderate/Major. Best practices across the globe have provisions of CAPA (Corrective and Preventive Action) and progressive penalties starting with commercials. The discretionary powers in determining contraventions of the Act compounded by punitive actions prescribed may be deterrent for the Industry. The Act (or the Rules to be framed under clause 7 N of Chapter II A) could have graded punitive clauses for different category of medical devices, depending on the damage that can be caused.

Investment *(not relevant directly to the provisions in the Bill*)

Increasing demand for better healthcare and growing medical tourism is stimulating growth in medical devices sector. The Indian medical devices market is estimated to be about USD 4-5 billion whereas global market is expected to increase to USD 400 billion by 2015. Since the sector involves high end technology and is capital intensive, nearly 65% requirements are met through imports. The present exports is of the order of USD 110-120 million only.

In the absence of suitable regulations and standards, investment scenario is uncertain. The investment regulations, particularly FDI in the sector, has to be liberal so as to attract leading global players to set up manufacturing bases in India, which will in the long term stimulate domestic manufacturing and bring along innovation and technology transfer. Due to the advantage of having pool of skilled persons and labor arbitrage, large MNCs are keen to set up manufacturing bases in India. So there is a strong need for the Bill to address the concerns of the export industry relating to formulating definite standards for medical devices and also a robust and globally acknowledged level of regulatory system to facilitate investment for growth.

LIST OF REPORTS PRESENTED EARLIER

Report No.	Subject
1	2
1.	Report on Demands for Grants 2004-05 of Department of Health (Ministry of Health and Family Welfare)
2.	Report on Demands for Grants 2004-05 of Department of Family Welfare (Ministry of Health and Family Welfare)
3.	Report on Demands for Grants 2004-05 of Department of AYUSH (Ministry of Health and Family Welfare)
4.	Report on Action Taken by the Department of Health on the Recommendations/ Observations contained in the First Report of the Committee on Demands-for-Grants (2004-05) of the Department of Health (Ministry of Health and Family Welfare)
5.	Report on Action Taken by the Department of Family Welfare on the Recommendations/Observations contained in the Second Report of the Committee on Demands-for-Grants (2004-05) of the Department of Family Welfare (Ministry of Health and Family Welfare)
6.	Report on Action Taken by the Department of AYUSH on the Recommendations/ Observations contained in the Third Report of the Committee on Demands-for-Grants (2004-05) of the Department of AYUSH (Ministry of Health and Family Welfare)
7.	Report on Demands for Grants 2005-06 of Department of Health and Family Welfare (Ministry of Health and Family Welfare)
8.	Report on Demands for Grants 2005-06 of Department of Family Welfare (Ministry of Health and Family Welfare)
9.	Report on Demands for Grants 2005-06 of Department of AYUSH (Ministry of Health and Family Welfare)
10.	Report on the Homoeopathy Central Council (Amendment) Bill, 2005
11.	Report on the Indian Medicine Central Council (Amendment) Bill, 2005
12.	Report on the Drugs and Cosmetics (Amendment) Bill, 2005
13.	Report on Action Taken by the Department of Family Welfare on the Recommendations/Observations contained in the Eighth Report of the Committee on Demands-for-Grants (2005-06) of the Department of Family Welfare (Ministry of Health and Family Welfare)

1	2
14.	Report on Action Taken by the Department of AYUSH on the Recommendations/ Observations contained in the Ninth Report of the Committee on Demands-for-Grants (2005-06) of the Department of AYUSH (Ministry of Health and Family Welfare)
15.	Report on Action Taken by the Department of Health on the Recommendations/ Observations contained in the First Report of the Committee on Demands-for-Grants (2005-06) of the Department of Health (Ministry of Health and Family Welfare)
16.	Report on Demands for Grants 2006-07 of Department of Health and Family Welfare (Ministry of Health and Family Welfare)
17.	Report on Demands for Grants 2006-07 of Department of AYUSH (Ministry of Health and Family Welfare)
18.	Report on the Indian Medicine and Homoeopathy Pharmacy Bill, 2005
19.	Report on the Indian Medical Council (Amendment) Bill, 2005
20.	Report on Action Taken by the Department of Health and Family Welfare on the Recommendations/Observations contained in the Sixteenth Report of the Committee on Demands-for-Grants (2006-07) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
21.	Report on Action Taken by the Department of AYUSH on the Recommendations/ observations contained in the Seventeenth Report of the Committee on Demands-for-Grants (2006-07) of the Department of AYUSH (Ministry of Health and Family Welfare)
22.	Report on Demands for Grants 2007-08 of Department of Health and Family Welfare (Ministry of Health and Family Welfare)
23.	Report on Demands for Grants 2007-08 of Department of AYUSH (Ministry of Health and Family Welfare)
24.	Report on Jawaharlal Institute of Post-Graduate Medical Education and Research Puducherry, Bill, 2007
25.	Report on Action Taken by the Department of Health and Family Welfare on the Recommendations/Observations contained in the Twenty-second Report of the Committee on Demands-for-Grants (2007-08) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
26.	Report on Action Taken by the Department of AYUSH on the Recommendations/ Observations contained in the Twenty-third Report of the Committee on Demands-for-Grants (2007-08) of the Department of AYUSH (Ministry of Health and Family Welfare)
27.	Report on Demands for Grants 2008-09 of Department of Health and Family Welfare (Ministry of Health and Family Welfare)

1	2
28.	Report on Demands for Grants 2008-09 of Department of AYUSH (Ministry of Health and Family Welfare)
29.	Report on Demands for Grants 2008-09 of Department of Health Research (Ministry of Health and Family Welfare)
30.	Report on the Drugs and Cosmetics (Amendment) Bill, 2007
31.	Report on the Paramedical and Physiotherapy Central Councils Bill, 2007
32.	Report on the Clinical Establishments (Registration and Regulation) Bill, 2007
33.	Report on the Post-Graduate Institute of Medical Education and Research, Chandigarh (Amendment) Bill, 2008
34.	Report on the functioning of the three Vaccine Producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL), Chennai.
35.	Report on Action Taken by Government on the Recommendations/Observations contained in the Twenty Seventh Report on Demands for Grants 2008-09 of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
36.	Report on Action Taken by Government on the Recommendations/Observations contained in the Twenty eighth report on Demands for Grants 2008-09 of the Department of AYUSH (Ministry of Health and Family Welfare)
37.	Report on Action Taken by Government on the Recommendations/Observations contained in the Twenty ninth report on Demands for Grants 2008-09 of the Department of Health Research (Ministry of Health and Family Welfare)
38.	Report on Major Issues concerning the three vaccine producing PSUs, Namely the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL), Chennai.
39.	Report on Demands for Grants (2010-11) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare).
40.	Report on Demand for Grants 2010-11 of Department of AYUSH (Ministry of Health and Family Welfare).
41.	Report on Demands for Grants 2010-11 of Department of Health Research.
42.	Report on Demands for Grants 2010-11 of Department of AIDS Control (Ministry of Health and Family Welfare)
43.	Report on Action Taken by the Department of Health and Family Welfare on the Recommendations/Observations of the Committee contained in its Thirty-Eighth Report on major issues concerning the three vaccine producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL), Chennai

1	2
44.	Report on the Transplantation of Human Organs (Amendment) Bill, 2009
45.	Report on Issues Relating to Availability of Generic, Generic-branded and Branded Medicines, their Formulation and Therapeutic Efficacy and Effectiveness
46.	Report on the Indian Medicine Central Council (Amendment) Bill, 2010
47.	Report on the Jawaharlal Institute of Post-Graduate Medical Education and Research, Puducherry (Amendment) Bill, 2010
48.	Report on Action Taken by Government on the Recommendations/Observations contained in the Forty-First Report on Demands for Grants 2010-11 (Demand No. 48) of the Department of Health Research (Ministry of Health and Family Welfare)
49.	Report on Action Taken by Government on the Recommendations/Observations contained in the Forty-Second Report on Demands for Grants 2010-11 of the Department of AIDS Control (Ministry of Health and Family Welfare)
50.	Report on Action Taken by Government on the Recommendations/Observations contained in the Fortieth Report on Demands for Grants 2010-11 (Demand No. 47) of the Department of AYUSH (Ministry of Health and Family Welfare)
51.	Report on Action Taken by Government on the Recommendations/Observations contained in the Thirty-Ninth Report on Demands for Grants 2010-11 (Demand No. 46) of the Department of Health And Family Welfare
52.	Report on Action Taken by the Department of Health and Family Welfare on the Recommendations/Observations of the Committee contained in its 43rd Report on Action Taken by the Department of Health and Family Welfare on the Recommendations/Observations of the Committee contained in its 38th Report on major issues concerning the three Vaccine Producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL), Chennai
53.	Report on the National Institute of Mental Health and Neuro-Sciences, Bangalore Bill, 2010
54.	Report on Demand for Grants 2012-13 (Demand No. 46) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
55.	Report on Demands for Grants 2012-13 (Demand No. 47) of the Department of AYUSH (Ministry of Health and Family Welfare)
56.	Report on Demands for Grants 2012-13 (Demand No. 48) of the Department of Health Research (Ministry of Health and Family Welfare)
57.	Report on Demand for Grants 2012-13 (Demand No. 49) of the Department of AIDS Control (Ministry of Health and Family Welfare)

1	2
58.	Report on Action taken by the Government on the Recommendations/Observations contained in the Forty-Fifth Report on issues relating to availability of Generic, Generic-Branded and Branded Medicines, their formulation and Therapeutic Efficacy and Effectiveness
59.	Report on the Functioning of the Central Drugs Standard Control Organisation (CDSCO)
60.	Report on the National Commission for Human Resources For Health Bill, 2011
61.	Report on Action Taken by Government on the Recommendations/Observations contained in the Fifty-Fifth Report on Demands for Grants 2012-13 (Demand No. 47) of the Department of AYUSH (Ministry of Health and Family Welfare)
62.	Report on Action Taken by Government on the Recommendations/Observations contained in the Fifty-Seventh Report on Demands for Grants 2012-13 (Demand No. 49) of the Department of AIDS Control (Ministry of Health and Family Welfare)
63.	Report on Action Taken by Government on the Recommendations/Observations contained in the Fifty-Sixth Report on Demands for Grants 2012-13 (Demand No. 48) of the Department of Health Research (Ministry of Health and Family Welfare)
64.	Report on Action taken by Government on the Recommendations/Observations contained in the Fifty-Fourth report on Demands for Grants 2012-13 (Demand No. 46) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
65.	Report on the Proposal to Introduce the Bachelor of Science (Community Health) Course
66.	Report on Action Taken by the Government on the Recommendations/Observations contained in the Fifty-Ninth Report on the functioning of Central Drugs Standards Control Organisation (CDSCO)
67.	Report on Demands For Grants 2013-14 (Demand No. 47) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)
68.	Report on Demands for Grants 2013-14 (Demand No. 48) of the Department of AYUSH (Ministry of Health and Family Welfare)
69.	Report on Demands for Grants 2013-14 (Demand No. 49) of the Department of Health Research (Ministry of Health and Family Welfare)
70.	Report on Demands for Grants 2013-14 (Demand No. 50) of the Department of AIDS Control (Ministry of Health and Family Welfare)
71.	Report on the Functioning of Central Government Health Scheme (CGHS)
72.	Alleged irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by Path in India

1	2
73.	Report on the Indian Medical Council (Amendment) Bill, 2013
74.	Report on the Mental Health Care Bill, 2013
75.	Report on Action Taken by Government on the Recommendations/Observations contained in the Sixty-Eighth Report on Demands For Grants 2013-14 (Demand No. 48) of the Department of AYUSH (Ministry of Health and Family Welfare)
76.	Report on Action taken by Government on the Recommendations/Observations contained in the Seventieth Report on Demands for Grants 2013-14 (Demand No. 50) of the Department of AIDS Control (Ministry of Health and Family Welfare)
77.	Report on Action taken by Government on the Recommendations/Observations contained in the Sixty-Nineth Report on Demands for Grants 2013-14 (Demand No. 49) of the Department of Health Research (Ministry of Health and Family Welfare)
78.	Report on Action taken by Government on the Recommendations/Observations contained in the Sixty-Seventh Report on Demands for Grants 2013-14 (Demand No. 47) of the Department of Health and Family Welfare (Ministry of Health and Family Welfare)

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