



सत्यमेव जयते

REPORT NO.

79

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE
ON HEALTH AND FAMILY WELFARE

SEVENTY-NINTH REPORT

On

THE DRUGS AND COSMETICS (AMENDMENT) BILL,
2013

(Ministry of Health and Family Welfare)

(PRESENTED TO THE RAJYA SABHA ON 18th DECEMBER, 2013)

(LAID ON THE TABLE OF LOK SABHA ON 18th DECEMBER, 2013)



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



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COMPOSITION OF THE COMMITTEE (2013-14)

RAJYA SABHA

- | | | |
|-----------------------------|---|-----------------|
| 1. Shri Brajesh Pathak | - | Chairman |
| 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

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

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

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 08th 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 & 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.
- (iv) 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 & Family Welfare

* Published in Gazette of India Extraordinary Part II Section 2, dated 29th August, 2013

** Rajya Sabha Parliamentary Bulletin Part II, No.51252, dated 09th 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.

NEW DELHI;

BRAJESH PATHAK
Chairman,

17th December, 2013
Agrahayana 26, 1935 (Saka)

Department-related Parliamentary
Standing Committee on Health and Family Welfare

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 09th 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 & 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 & Cosmetics (Amendment) Bill, 2005 and the Drugs & 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 & Cosmetics (Amendment) Act, 2008. Salient features of the provisions in the Drugs & 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 & 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 & Justice (Legislative Department), therefore, suggested withdrawal of the 2007 Bill and introduction of a new Bill in its place.

The provisions in the Drugs & 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 & 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 & Cosmetics (Amendment) Bill, 2013 has been introduced in its place on 29.8.2013 in the Rajya Sabha. The Drugs & 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 Fertilisers, Department of Pharmaceuticals-- Member, ex officio;*
- (f) Secretary, Department of Health Research & 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 (betalactams 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 12th 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 12th Plan to initiate a Centrally Sponsored Scheme for the purpose. An outlay of Rs.1800 crores for CDSCO in the 12th 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 12th 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. Sh. Pawan Chaudhary, Chairman, Medical Equipment Division, CII during his deposition before the Committee 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 II A, 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 Committee 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 Bill 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 Committee 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 Committee 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 accreditation of all the three entities, engaged in clinical trials, i.e., accreditation 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 be 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 percent 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 betalactams 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 betalactams 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 & Technology

during his deposition before the Committee 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 selection 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-officio 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 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 Committee 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 Committee 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 framework 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 Committee 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 transparency 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 provision 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 Manufacturers 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 & monitoring safety & efficacy of the drug, whereas the

Regulatory mechanism under DCGI mainly relates to control of new drug approval based on data, manufacture, distribution & 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 & 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 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;'

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.

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.

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.*

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.*

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 Committee. 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 33 Q 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 33 R (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 (betalactams 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 IIIrd Schedule in General and especially 2 categories of Drugs namely Betalactams and Cephalosporins Antibiotics and Parenteral Preparations. The Committee recommends that in view of the concerns received from various stakeholders on the centralized licensing of Betalactams 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 Recommendation

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 & 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.
