



PARLIAMENT OF INDIA RAJYA SABHA

30

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

THIRTIETH REPORT

ON

DRUGS AND COSMETICS (AMENDMENT) BILL-2007

**(PRESENTED TO THE RAJYA SABHA ON 21st OCTOBER, 2008)
(LAID ON THE TABLE OF LOK SABHA ON 21st OCTOBER, 2008)**

**RAJYA SABHA SECRETARIAT
NEW DELHI**

OCTOBER, 2008/ASVINA-KARTIKA, 1930 (SAKA)

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**COMPOSITION OF THE COMMITTEE
(2007-08)**

RAJYA SABHA

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|-------------------------------|----|-----------------|
| 1. Shri Amar Singh | -- | Chairman |
| 2. Prof. P.J. Kurien | | |
| 3. Shri Su. Thirunavukkarasar | | |
| 4. Shrimati Maya Singh | | |
| 5. Shri Digvijay Singh | | |
| 6. Dr. M.A.M. Ramaswamy | | |
| @7. Shri Lalhming Liana | | |
| 8. Shrimati Viplove Thakur | | |
| 9. Shrimati Kanimozhi | | |
| *10. Shri Rajeev Shukla | | |

LOK SABHA

11. Smt. Bhavana P. Gawli
12. Dr. Ram Chandra Dome
13. Smt. Maneka Gandhi
- \$14. Shri B. Vinod Kumar
15. Shri Rajendra Kumar
16. Smt. Susheela Bangaru Laxman
17. Shri S. Mallikarjuniah
18. Shri Rasheed Masood
19. Dr. Chinta Mohan
20. Shri Nihal Chand
21. Shri D.B. Patil
22. Smt. K. Rani
23. Shri Pannian Ravindran
24. Dr. R. Senthil
25. Dr. Mohd. Shahabuddin
26. Dr. Arvind Kumar Sharma
27. Shri Uday Singh
28. Dr. Karan Singh Yadav
29. Shri Vinod Khanna
30. Shri R.L.Jalappa
31. Smt. Yashodhara Raje Scindia

(*nominated w.e.f. 18th February, 2008)

(\$Ceased to be Member w.e.f. 3rd March, 2008)

(@Ceased to be Member w.e.f. 18th July, 2008)

SECRETARIAT

Smt. Vandana Garg,	Joint Secretary
Shri R.B.Gupta,	Director
Shrimati Arpana Mendiratta,	Deputy Director
Shri Dinesh Singh,	Committee Officer

**COMPOSITION OF THE COMMITTEE
(2008-09)**

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|----|-----------------|----|-----------------|
| 1. | Shri Amar Singh | -- | Chairman |
|----|-----------------|----|-----------------|

RAJYA SABHA

- | | | |
|------|----------------------------|--|
| 2. | Shrimati Viplove Thakur | |
| 3. | Prof. P.J. Kurien | |
| 4. | Shri Rajeev Shukla | |
| 5. | Shri Su. Thirunavukkarasar | |
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LOK SABHA

- | | | |
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| 11. | Dr. Ram Chandra Dome | |
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| 16. | Shri R.L.Jalappa | |
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| 20. | Dr. Chinta Mohan | |
| 21. | Shri Nihal Chand | |
| 22. | Shri D.B. Patil | |
| 23. | Smt. K. Rani | |
| 24. | Shri Pannian Ravindran | |
| 25. | Smt. Yashodhara Raje Scindia | |
| 26. | Dr. R. Senthil | |
| 27. | Dr. Mohd. Shahabuddin | |
| 28. | Dr. Arvind Kumar Sharma | |
| 29. | Shri Uday Singh | |
| 30. | Dr. Karan Singh Yadav | |
| # 31. | Shri B.Binod Kumar | |

(*nominated w.e.f. 12th August, 2008)

(#nominated w.e.f. 20th August, 2008)

SECRETARIAT

Smt. Vandana Garg,	Joint Secretary
Shri R.B.Gupta,	Director
Shrimati Arpana Mendiratta,	Deputy Director
Shri Dinesh Singh,	Assistant Director

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, after having been authorized by the Committee to present the Report on its behalf, present this Thirtieth Report of the Committee on the Drugs and Cosmetics (Amendment) Bill-2007. *

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 Hon'ble Chairman, Rajya Sabha, referred** the Drugs and Cosmetics (Amendment) Bill, 2007 (Annexure-I), as introduced in the Rajya Sabha on the 21st August 2007 and pending therein, to the Committee on the 23rd August 2007 for examination and report.

3. A Press Release inviting suggestions/comments from general public was issued in September, 2007. In response, thereto 40 numbers of memoranda were received.

4. The Committee considered the Bill in its meetings held on the 9th & 31st October, 2007, 25th January, 7th & 27th May, 9th & 29th July and 12th August, 2008. The Committee visited Karnataka (Bangalore), Kerala (Thiruvanthapuram), Tamil Nadu (Chennai) and Andhra Pradesh (Hyderabad), from 7th to 14th January, 2008; Madhya Pradesh (Indore), Gujarat (Ahmedabad) Maharashtra (Mumbai) and Goa (Panajim) from 12th to 19th February 2008. These were the States with maximum (about 75%) concentration of the drugs manufacturing units.

5. The Committee held wide ranging discussions with all the stake-holders on various provisions of the Bill. Divergent views were expressed by the representatives of the associations of drug manufacturers, cosmetics industry, medical devices industry represented by CII and FICCI, pharmacists, experts, chemists, Drug Inspectors' associations, Drug Controllers' associations, State Governments etc, Besides, NGOs and Consumers' Fora highlighting concerns of the consumers also appeared before the Committee, and also Dr. R.A. Mashelkar, whose report the Bill is modeled. (Annexure-II). The Committee also interacted with the Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, the Drug Controller General of India representatives of DTABs & Pharmacy Council of India and also heard Dr. R.A. Mashelkar, on whose report the Bill is modeled. The Committee sought clarifications from the above entities not only on the various view points put forth before it on the Bill but also shared its apprehensions on the existing drug control scenario in the country.

6. The Committee, thereafter, took up clause-by-clause consideration of the Bill at its meeting held on the 12th August 2008. One or two members of the Committee expressed reservations on certain provisions of the Bill. At its meeting held on 20th August 2008, the Committee discussed and adopted the draft Report. However, Dr. R.C. Dome and Shri Pannian Ravindran put forth their "Note of Dissent" and stated that the same may be appended to the report (Appendices I & II).

6. The Committee has relied upon the following documents/information in finalizing its Report:

- (i) Background Note on the Bill received from the Department of Health and Family Welfare;

* Published in Gazette of India Extraordinary Part II Section 2, dated 21st August 2007

** Rajya Sabha Parliamentary Bulletin Part II, No 44391, dated 24th August 2007

- (ii) Presentation and clarification by the Secretary of the Department of Health and Family Welfare and Drug Controller General of India;
- (iii) Memoranda received on the Bill from various associations, NGOs and experts;
- (iv) Replies to the Questionnaires on the Bill; and
- (v) Oral evidence on the Bill.

7. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who deposed before the Committee and submitted their valuable suggestions on the subject matter of the Bill.

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

NEW DELHI;

AMAR SINGH

August 20, 2008

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

Asvina29, 1930 (Saka)

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5. The Committee held wide ranging discussions with all the stake-holders on various provisions of the Bill. Divergent views were expressed by the representatives of the associations of drug manufacturers, cosmetics industry, medical devices industry represented by CII and FICCI, pharmacists, experts, chemists, Drug Inspectors' associations, Drug Controllers' associations, State Governments etc, Besides, NGOs and Consumers' Fora highlighting concerns of the consumers also appeared before the Committee, and also Dr. R.A. Mashelkar, whose report the Bill is modeled. (Annexure-II). The Committee also interacted with the Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, the Drug Controller General of India representatives of DTABs & Pharmacy Council of India and also heard Dr. R.A. Mashelkar, on whose report the Bill is modeled. The Committee sought clarifications from the above entities not only on the various view points put forth before it on the Bill but also shared its apprehensions on the existing drug control scenario in the country.

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NEW DELHI;

AMAR SINGH

August 20, 2008

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

Asvina29, 1930 (Saka)

Report

The Drugs and Cosmetics Act 1940 is a consumer protection legislation which is mainly concerned with the standards and quality of drugs and regulates the import, manufacture, sale and distribution of drugs and cosmetics. During its more than half a century of being in force, the Act has undergone modifications at twelve occasions, the last being carried out in 1995. However, efforts made by Government through these amendment legislations to make the Drugs and Cosmetics Act adaptive to the fast changing scenario, both in the country and at the global level, have not proved to be very effective.

2. The Drugs and Cosmetics (Amendment) Bill 2007, (**hereinafter to be referred in the Report as 'Bill'**) is the latest initiative of the Government which seeks to address the problems of the drugs regulatory system in the country. The Main features of the Bill are as follows:-

- (a) substitution of the “Drugs Technical Advisory Board” as well as the “Drugs Technical Advisory Board for Ayurvedic, Siddha and Unani Drugs” by the “Central Drugs Authority”;
- (b) insertion of a new Chapter 1A in the Act with a view to providing for the constitution of the Central Drugs Authority and other connected or incidental matters; thereto.
- (c) insertion of a new Chapter 1B in the Act, providing for grant of permission for clinical trials, punishment for conducting clinical trial without permission, trial of offences, etc.; and
- (d) expansion of the compositions of the Drugs Consultative Committees.

The statement of Objects and Reasons appended to the Bill states as under:-

“The Central Government had constituted an Expert Committee under the chairmanship of Dr. R.A. Mashelker, Director General of the Council of Scientific and Industrial Research in January 2003 to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs and to suggest measures to improve the drug administration in the country. The Committee, inter alia, recommended setting up of a Central Drugs Authority reporting directly to the Ministry of Health and Family Welfare and a system of centralised licensing. The Central Government considered the recommendations of the Committee and proposes to make amendments in the Act, in order to facilitate setting up of a Central Drugs Authority and introduction of Centralised licensing for manufacture of drugs in pursuance of the said recommendations.”

3. The Additional Secretary, Department of Health and Family Welfare, during the course of his evidence before the Committee on the 9th October 2007, gave an idea about the remarkable achievement made by the Indian Pharmaceutical industry in the production of drugs and pharmaceuticals in the Indian market as well as export market in the last few decades. The country was rated as the fourth largest producer of drugs in the world. In addition to industry's growth, the service sector of pharmaceutical industry was also attracting global pharmaceutical industry. Not only this, India has become a favourite destination for drugs related research. Its capability was acknowledged by the fact that the largest number of USFDA approved sites outside the United States were in our country. The Committee was given to understand that this encouraging scenario was hampered by the weak and ineffective drug regulatory system in different States of the country. Although the Drugs and Cosmetics Act, 1940 has been in force for more than half a century, the implementation of this Act had been less than satisfactory. The main reasons for the uneven levels of enforcement across the States, as cited by him are, non-uniformity in the interpretation of the provisions of law and their implementation, varying levels of competence of the regulatory officials and the lack of a comprehensive and effective Centralised regulatory system in the nature of a Central Drugs Authority, as available in most of the countries of the world. He explained that the problems in the drugs regulatory system in the country are further compounded by shortage of drug inspectors, inadequate and weak drugs control infrastructure at the State and Central levels, inadequate testing facilities, lack of specially trained cadres for specific regulatory areas, non-existence of data banks, non-availability of accurate information, etc. thereby resulting in a steady deterioration of the regulatory system. The existing weak and fragmented drugs regulatory system had failed to deal effectively with the changing scenario in the drugs sector.

4. Keeping in view, the wide-ranging national concern about the quality and efficacy of drugs and pharmaceuticals and an urgent need for a world-class drugs regulatory system in the country, the Ministry of Health and Family Welfare constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director-General, CSIR in 2003 to suggest further measures to improve the control and management of drugs administration in the country. The Committee examined the broader issues by looking at the recommendations of earlier Committees (Hathi Committee Report of 1975, the Pharmaceutical Research and Development Committee Report of 1999) as well as relevant policies (Drugs Policy, 1986, Drugs Policy, 1994, Pharmaceutical Policy, 2002, Health Policy, 2002). The

Committee also examined the drugs regulatory systems prevailing in large number of countries around the world. Part 'A' of the Mashelkar Committee Report submitted in November, 2003, contained recommendations related to amendments for improvement in the drugs regulatory infrastructure in the country including setting up of a Central Drugs Authority and a system of centralized licensing. The Committee was given to understand that the Drugs and Cosmetics (Amendment) Bill, 2007 has been brought forward pursuant to the aforesaid recommendations of the Mashelker Committee.

5. Due to the far-reaching implications of the Bill, the Committee decided to issue a Press Release seeking the views from all the stakeholders as well as public at large. In response, the Committee had received a large number of memoranda. After scrutinizing them, the Committee felt that for an in-depth examination of all conceivable aspects connected with the Bill, it was necessary to interact with all the stakeholders. The Committee, accordingly, visited Karnataka (Bangalore), Kerala (Thiruvanthapuram), Tamil Nadu (Chennai) and Andhra Pradesh (Hyderabad), from 7th to 14th January, 2008; Madhya Pradesh (Indore), Gujarat (Ahmedabad) Maharashtra (Mumbai) and Goa (Panajim) from 12th to 19th February 2008. These were the States with maximum (about 75%) concentration of the drugs manufacturing units.

6. During these study visits, the Committee had the opportunity to interact with all the stakeholders directly, right from the representatives of the small and medium pharmaceutical companies, representatives of associations of drug manufacturers, cosmetics industry, medical devices industry, pharmacists, chemists, Drug Inspectors' associations, Drug Controllers' associations, NGOs and Consumers' fora and representatives of State Governments. Besides, the Committee also held a series of meetings in Delhi where quite a few witnesses representing different government agencies involved in the implementation of the Act appeared before it. Finally, the Committee also heard Dr. R.A. Mashelker, whose Report has been projected as the very basis of the Bill. These interactions enabled the Committee to understand the complexities and problems prevailing in the existing regulatory system, and also the lack of co-ordination between the Central and the State Governments in the context of carrying out its various functions. The Committee also sought the views of the Department on the various issues/apprehensions raised by the stakeholders through detailed questionnaire as well as direct discussion with the Health Secretary and his team of officers. It would not be wrong to conclude that this exercise re-confirmed the Committee's observations and recommendations contained in the Report. The Committee would like to emphasize that during this prolonged exercise, Committee's endeavor was

to make an objective assessment of the Drugs and Cosmetics (Amendment) Bill 2007 and report thereon.

7. The clauses where amendments have been suggested by the Committee are discussed in the succeeding paragraphs.

8. CLAUSE-2

8.1 Section 3 of the Drugs and Cosmetics Act, 1940 deals with 'definitions'.

Clause 2(i) seeks to insert the definition of the term 'clinical trial' as follows : -

“(aaii) “clinical trial” means systematic study of any drug or cosmetic 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 or the cosmetic;”

An objective analysis of the definition of 'clinical trial' indicates that allopathic drugs as well as Ayurvedic, Siddha and Unani (ASU) drugs, **medical devices and its associated products and cosmetics** will be brought under its purview.

8.2 During the course of its interactions with representatives of a number of Ayurvedic, Unani and Siddha (ASU) drug manufacturers' associations, emphatic objections were raised on the proposed inclusion of ASU drugs under the ambit of Clinical Trials. Main reason cited was that ASU medicines being not formulated on the lines of modern medicines, it required different approach for assessing their efficacy and utility. Their exclusion from the scope of clinical trial was, accordingly, advocated by them. The Committee had the opportunity to ascertain the views of representatives of ASU Drug Technical Advisory Board on various provisions of the Bill. On a specific query about clinical trial of ASU drugs being envisaged, in the Bill, it was clarified to the Committee that clinical trial of ASU drugs needed to be based on different parameters and restricted only to new drugs. The Committee was given to understand that in the case of ASU drugs, clinical trial was only validation of the claims mentioned in the classical literature and pharmacopeias without any change being made in the ingredients and method of preparation. Clinical trials were also being carried out for the same formulation but for a different disease without changing the composition. It was, accordingly, suggested that definition of 'clinical trial' in the context of ASU drugs should be specifically in accordance with their traditional concepts and classical scriptures.

8.3 Representatives from the Cosmetic industry, who appeared before the Committee, stated that the definition of ‘clinical trial’ was too wide and not in line with the definition of ‘Cosmetics’ as given in the Act. It was pointed out that the impact of cosmetics on human body could not be equated with that of drugs since the physiological and therapeutic use of both were completely different. Agreeing to the fact that cosmetics and its related products also needed to be regulated, they were of the opinion that instead of clinical trial for cosmetics, the words **‘dermatological safety studies’** may be substituted in the Bill for ascertaining their safety and efficacy.

8.4 The Committee had the opportunity to interact with a number of representatives from the medical devices industry also. With the inclusion of the term ‘medical device’ under the definition of the term ‘drug’, definition of the term ‘clinical trial’ was also applicable on the medical devices. It was, however, pointed out that medical devices differed significantly from drugs. Accordingly, the definition of clinical trial of medical devices needed to be in accordance with their components and utility and formulated in such a manner that it was consistent with the international standards, i.e. the definition of Global Harmonization Task Force - the international body regulating medical devices.

8.5 In reply to a specific query regarding the appropriateness of clubbing the clinical trial of medical devices, a different class of product from drugs, under one umbrella definition of the terms ‘clinical trial’, the Ministry admitted that owing to the distinct nature and functions of medical devices, it would be appropriate to give a separate definition for their clinical trial.

8.6 The Committee, after analysing the opinion of the stakeholders, is of the view that even though ASU drugs are formulated by methods different from that used for modern allopathic drugs, the chances of harm that a drug – either modern or ASU, may likely cause are similar and cannot be ruled out. The Committee would also like to point out that definition of ‘drug’ as given in the Act is applicable to both allopathic and ASU drugs. The Committee, therefore, opines that Ayurvedic, Unani and Siddha drugs should not be excluded from the scope of definition of clinical trial of drugs.

8.7 The Committee is inclined to agree with the contention of representatives of the cosmetics industry that physiological and therapeutic impact of drugs and cosmetics on

human body is completely different. Therefore, there is a need to separate trials of cosmetics from drugs so far as the case of ascertaining their safety and efficacy is concerned. Such a study may be carried out on human volunteers under pre-defined test conditions as per standard industry protocol to ascertain the performance safety and efficacy of a cosmetic. The Committee's attention has also been drawn by ever-increasing number of cosmetic products including Ayurvedic and herbal products flooding the market-both domestic and international. Reports indicating harmful effects of some of such products on consumers also continue to be received. Main reason for such a situation is lack of any effective mechanism to check such products. The Committee, therefore, strongly feels that like clinical trial envisaged for drugs, similar provision should be there for regulating the dermatological safety studies for cosmetics. Necessary modification in the Bill may, accordingly, be made.

8.8 The Committee feels that the issue raised by the medical devices industry for having a separate definition of clinical trial for medical devices is very pertinent. It is convinced that owing to the distinct nature and functions of medical devices from that of the drugs, a separate definition of clinical trials for medical devices would be necessary. The Committee also takes note of the clarification given by the Ministry that medical devices are a separate and distinct category. Due to exigency, a few medical devices were being treated under the category of drugs. Now suitable amendment would be made to put these under the category of medical devices, to be defined separately in the Act. The Committee, accordingly, recommends that a separate definition of clinical trial for medical devices may be included in the Act. The Committee is also of the opinion that the definition of clinical trial for medical devices may be formulated in such a manner that it is consistent with the international standards which may read as follows:-

“Any systematic investigation or study in or on human subjects, undertaken to assess the safety and/or performance of a medical device”

8.9 Committee's attention was also drawn to another drawback in the definition of the term 'clinical trial' by a number of stakeholders. It was pointed out that the use of words 'any drug' in the definition implied that clinical trial of all types of drugs whether new or already in circulation could be conducted. The Committee also took note of the fact that already a definition of 'clinical trial' as given under rule 122 DAA of the Drugs and Cosmetics Rules, 1945, specifically mentions only 'new drug'. It was accordingly, suggested that the proposed definition of 'clinical trial' should relate only to new drugs. **The Committee is inclined to agree with the suggestion in view**

of the fact that all substances intended for use as components of a drug are included under the definition of ‘drug’ given in the Principal Act. Thus a product with a marketing authorization, when used or assembled in a different form, can be considered a new drug.

8.10 The Committee would also like to point out that the term ‘any drug’ gives rise to apprehensions about chances of clinical trial of drugs in circulation taking place due to unhealthy competition among pharmaceutical companies. **Therefore, the Committee recommends that the words “any drug” in Clause 2 (i) (aaii) be replaced with the words “any new drug”. The Committee also observes that with the definition of ‘clinical trial’ being included in the Act, there was no need of having the same in the Rules.**

8.11 Clause 2 (ii) of the Bill seeks to substitute the definition of ‘medical device’ as given in Section 3 (iv) of the Act by a more elaborate definition reproduced below:-

“drug” includes

“(iv) such medical device, medicated device, instrument, apparatus, appliance, material, software necessary for their application, intended for internal or external use in human beings or animals, whether used alone or in combination, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Central Drugs Authority, for the purpose of diagnosis, prevention, monitoring, treatment or mitigation of any disease or disorder; diagnosis, monitoring, treatment, alleviation of or compensation for, any injury or handicap; investigation, replacement or modification of anatomy or physiology; or control of conception, and which does not achieve its intended action primarily by any pharmacological or immunological or metabolic process, but is included in the pharmacopoeias mentioned in the Second Schedule;”;

8.12 It was strongly advocated by the representatives of the medical devices industry appearing before the Committee that instead of including medical devices under the definition of drugs, they needed to be treated as an independent entity, as both were two different classes of products so far as their manufacturing, use and outcomes were concerned. It was also clarified that medical devices comprised three categories of products, viz. Implantable Devices, In-Vitro Diagnostic Products and Medical Electronic Products. Implantable Devices were implanted within the human body ranging from syringes/needles to coronary stents . In-Vitro Diagnostic Products covered entire range of equipments, devices etc. for diagnosis of all types of diseases such as Diabetes, Cancer, T.B. etc. Medical Electronic Products were used in any hospital set up. It was, accordingly, suggested that the Global Harmonization Task Force (GHTF) definition of ‘medical

devices' should be inserted, being more comprehensive, covering intended uses not covered in the proposed definition and 'encompassing the broad and diverse range of medical devices in use today and in foreseeable future.

8.13 Another problem area highlighted was the industry's experience with regulation of the few categories of medical devices presently covered under the Act, although limited but being far from satisfactory. While agreeing to the fact that medical devices and its related products have remained improperly regulated over the past few decades, it was also pointed out that with the development of new advanced technology and rapidly increasing product range every year, it would become extremely difficult to conform to and get regulated by the existing regulations/standards. Another point raised was that while imported Medical Devices were being registered, for indigenous Medical Devices the process was yet to be implemented, thus putting the local industry at disadvantage so far as their export was concerned. An additional menace faced by the Medical Device industry was device re-use beyond the recommended usage cycles. Presently, there was no provision looking into the regulation of this crucial aspect. It was, accordingly, suggested that a separate chapter for Medical Devices offering a 'comprehensive legal framework' needed to be included in the Act.

8.14 The Committee finds logic in the views aired by the medical devices industry that the current system is inadequate in regulating certification, quality assurance and post marketing surveillance of both imported and locally made medical devices. Given the fact that use of medical devices in healthcare is increasing day by day and also the fact that the industry was at a growing stage, proper regulation is required to meet safety and efficacy norms as also to meet global standards and competitiveness of the medical devices products. The Committee also observes that the Mashelker Committee, in its Report, had dwelt at length on the issue of regulation of medical devices in the country. It was emphasized therein that the medical devices should be specifically defined and relevant rules and guidelines framed for their proper regulation. The other two major recommendations of the Committee were (i) the setting up of a specific Medical Devices Division for proper management of approval, certification and quality of medical devices and an appropriate regulatory mechanism for certification, quality assurance and post-marketing surveillance of both imported and indigenous medical devices. The Committee is, however, surprised to note that the only action proposed in the Bill was substitution of existing definition of medical device

by a more detailed definition. Another disturbing feature was continuance of medical devices under drugs. The Committee also feels that mere inclusion of medical devices in the pharmacopeias mentioned in the Second Schedule of the Act alongwith drugs will not serve the purpose.

8.15 On being asked about the appropriateness of making separate provisions for the regulation, surveillance and monitoring of medical devices, the Ministry had replied in the affirmative. It was assured that keeping in view the distinct nature and functions of medical devices, the same would be defined separately with specific provisions for their regulation, surveillance and monitoring. The Committee, therefore, recommends that suitable modifications may be made in the Act with a separate chapter covering all the related aspects of regulation of medical devices. The Committee also strongly feels that a dedicated division as recommended by the Mashelkar Committee may be set up to deal with regulation, licensing, surveillance and monitoring of uniform implementation of the laws on medical devices in the country. The Committee also recommends that a comparative analysis of the GHTF definition of Medical devices and the proposed definition in the Bill may be made and should be followed by necessary modifications in the definition of ‘medical device’.

8.16 Committee’s attention was drawn towards another draft Medical Devices Regulation Bill floated in the public domain by the Department of Science and Technology. On being specifically asked about the implications of this development on the proposed legislation before the Committee, the Ministry clarified that as the present Bill included medical devices, the replication of it by the Department of Science and Technology appeared to be uncalled for. Views of the Ministry have already been conveyed to the Cabinet Secretariat. **The Committee fails to understand the circumstances leading to such an initiative by the Department of Science and Technology with the nodal Ministry obviously being taken unaware. The Committee can only hope that this issue is resolved at the earliest.**

9. CLAUSE-3

9.1 **Clause 3** of the Bill proposes to introduce a new Chapter 1A in the Act, relating to **CENTRAL DRUGS AUTHORITY**. **Section 5** under the new Chapter 1A provides for constitution of a Central Drugs Authority. Relevant provisions read as follows: -

“5. (1) The Central Government shall, by notification in the Official Gazette, constitute an Authority to be known as the Central Drugs Authority of India.

(3) The Central Drugs Authority shall consist of a Chairperson and not more than five but at the least three, Members to be appointed by the Central Government by notification in the Official Gazette.

5A. The Chairperson and Members of the Central Drugs Authority shall be appointed by the Central Government from amongst persons who have special knowledge of, and at the least fifteen years’ professional experience in pharmaceutical industry, research or teaching , or public administration, finance or law:

Provided that a person who is, or has been, in the service of Government shall not be appointed as a Chairperson or Member unless such person has held the post of Secretary and Additional Secretary to the Government of India or any equivalent post in the Central Government or a State Government or a public sector under taking.”

9.2 Statement of Objects and Reasons to the Bill mentions that the proposed constitution of Central Drugs Authority is based on the specific recommendation made by the Mashelker Committee in this regard. Status note submitted by the Ministry and subsequent interactions of the Committee with its representatives gave the genesis of this proposal. It was informed that the Drugs and Cosmetics Act, 1940 had been in force for more than half a century but the implementation of the Act has been less than satisfactory. The main reasons for this were uneven levels of enforcement across the states, non-uniformity in the interpretation of the provisions of law and their implementation, varying levels of competence of the regulatory officials and the lack of a comprehensive and effective centralized regulatory system in the nature of a Central Drugs Authority, as was available in many countries in the world. It was also explained that inspite of the Central Government’s repeated efforts to strengthen the State Drug Control Organizations and Central Drug Standard Control Organisation- through various schemes, like the Capacity Building Project implemented with the help of the World Bank, during the last four decades, the situation in many States has remained disheartening. The CDSCO had also been functioning with the limitation of being a branch of the Central Government.

9.3 Against this background, an Expert Committee under the chairmanship of Dr. R.A. Mashelker was constituted by the Government in 2003. The Committee examined the broader issues by looking at the recommendations of earlier Committees(Hathi Committee Report of 1975, the Pharmaceutical Research and Development Committee Report of 1999) as well as Drugs Policy, 1986, Drugs Policy, 1994, Pharmaceutical Policy, 2002 and Health Policy, 2002. The Committee also interacted with all the stakeholders. It was recommended by the Committee that

the most appropriate solution would be a strong, well equipped and professionally managed Central Drugs Authority reporting directly to the Ministry. The existing organisation for drugs regulation in the country at the central level, i.e. Central Drugs Standard and Control Organization (CDSCO) would be restructured into a Central Drugs Authority which apart from the traditional functions of CDSCO would address the new emerging fields pertaining to biotechnology products, medical devices, diagnostics, new drugs and clinical trials etc.

9.4 During its extensive interactions with different stakeholders, representing the entire spectrum of the pharmaceutical industry as well as the state authorities and central bodies, one view which was emphatically impressed upon constantly was that it would not be desirable to create a Central Drugs Authority, a small body having a wider mandate but lacking in representation of technically qualified/experienced experts. It was also pointed out that the position was further proposed to be made complicated and impractical by doing away with the two Drug Technical Advisory Boards representing technical expertise from allopathic and ASU drug sector.

9.5 While the existing DTABs are highly technical bodies comprising of experts from various fields, the Central Drugs Authority would comprise of a Chairperson and three to five members to be nominated by the Government from amongst eminent persons having special knowledge of, and at least 15 years' professional experience in pharmaceutical industry, research or teaching or public administration, finance or law. The proposed CDA was not considered to be a progressive reform-based step but actually a set-back with the absence of required technical expertise from different fields. It was also felt that the proposed CDA would simply create a resting ground for retired bureaucrats with technical experts having minimal chances of becoming its members. It was, accordingly, advocated by some stakeholders that CDA, if established, should be a more broad based organisation having representation of State Drug Control Organizations, pharmaceutical industry and professional and Consumer associations etc.

9.6 Committee's attention was also drawn, both during its study visits and meetings at Delhi, with all the witnesses representing different categories of stakeholders – be it small and big pharma industry associations, various State Governments, Drugs Controllers/Inspectors/ Associations/ bodies/associations from ASU sector - that recommendation of the Mashelker Committee was for a strong, well-equipped and professionally managed CDSCO, to be given the status of Central Drugs Administration and not creation of a Central Drugs Authority. After making a comparative analysis of

Mashelker Committee recommendations and the different provisions of the Bill, the Committee was surprised to note that the contention of various witnesses was justified. The Committee would like to point out the following specific recommendation made by the Mashelker Committee.

“The existing infrastructure at the Center and States was not adequate to perform the assigned functions efficiently and speedily. Creating another authority such as a National Drug authority (NDA) will not solve the problem at hand. It was essential to strengthen the existing organisations to enable them to undertake all the functions envisaged for NDA. A strong, well equipped, empowered, independent and professionally managed CDSCO, which could be given the status of Central Drug Administration (CDA), reporting directly to Ministry of Health would be the most appropriate solution.”

9.7 Feeling somewhat surprised by these conflicting reports, the Committee took up this matter with the Secretary, Ministry of Health and Family Welfare in its meeting held on the 29th July, 2008. Admitting some important departures in the Bill from the Mashelkar Committee recommendations, Secretary apprised the Committee that this deviation was reflected in the proposed legislation only after discussion by the then Health Secretary with Dr. Mashelkar, as given in the file notings. Realizing the complexity of the issue the Committee ascertained the views of Dr. Mashelkar also in its meeting held on the 12th August, 2008. The Committee was given to understand that in the light of considerable time gap between the Mashelkar Committee Report given in November, 2003 and proposed Bill coming up in 2007, ground realities have somewhat changed. A Central Drugs Authority in place of a restructured CDSCO has now become a viable option.

9.8 The Committee observes that the Mashelkar Committee was an Expert Committee constituted by the Government in 2003 to examine all the aspects relating to quality control of drugs and their regulatory mechanism. The Committee also notes that the aforesaid conclusive recommendation made by the Mashelkar Committee has been arrived at after very intensive consultations with all the stakeholders. Not only this, in the Questionnaire sent to all the State Drug Controllers by the Mashelkar Committee, one of the questions asked was if CDSCO was to be strengthened, then would there be still a need for a National Drug Authority. In response, 19 out of 31 States (with 4 no comments) stated that there was a definite need to strengthen the Central Administration and if CDSCO could perform the statutory functions efficiently, there was certainly no need of NDA. The Committee also

takes note of the fact that out of the 19 States which responded, five were Andhra Pradesh, Goa, Gujarat, Maharashtra and Tamil Nadu which belonged to the seven States having more than 75 percent drug manufacturing units in the country.

9.9 In order to have a first-hand information at the ground level, the Committee had undertaken study visits of all the States having 75 percent of drug manufacturing units in the country. The only exception was West Bengal. This exercise of the Committee was supplemented by extensive discussions in a series of meetings held at Delhi and also feedback received in response to the press release. It would not be wrong to conclude that Committee's experience has also matched with the Mashelker Committee's findings. In view of the above assessment, the Committee is not inclined to accept the reasoning offered by the Secretary, Ministry of Health and Family Welfare for making such a major departure from the recommendations made by an Expert Committee

9.10 The Committee would also like to draw attention to the following statement made in the Pharmaceutical Policy, 2002:-

“The Ministry of Health and Family Welfare would set up a world class Central Drugs Standard Control Organisation (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcements administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals.”

9.11 The Committee fails to understand as to why, instead of implementing the recommendations of the Mashelkar Committee for strengthening, modernizing, restructuring and reforming the existing Central Drugs Standard Control Organisation (CDSCO) into a world class system, the Government has entered into a rigmarole of setting up a new Authority. Central Drugs Authority, a small body primarily having members with administrative background taking the place of the two Drug Technical Advisory Boards having technical expertise from allopathic and ASU drug sector, is simply not acceptable to the Committee. The Committee, accordingly, recommends the setting up of a “Central Drug Administration” as an independent body under the Ministry of Health and Family Welfare with its headquarters at Delhi, with its Zonal and Sub-Zonal offices at State level, by strengthening, modernizing and restructuring the CDSCO.

9.12 The Ministry, while informing the Committee on the manner in which it planned to restructure the CDA, elaborated that in the proposed CDA, the CDSCO with its Headquarters, Zonal Offices, Sub-Zonal Offices, Port Offices, Laboratories and Training Center, would be absorbed into it. Thereafter, the CDA would become functional with 10 Divisions at the Headquarters. In addition to new Zonal Offices and Sub-Zonal Offices, new Laboratories would be created and some of the existing Sub-Zonal Offices would be up-graded to Zonal Offices and the Laboratories would be strengthened, restructured and reoriented. The proposed CDA would have ten distinct divisions to handle all the areas. These ten divisions would be:-

- (1) Division for Regulatory Affairs, Enforcement, Legal & Consumer Affairs,
- (2) Division for New Drugs and Clinical Trials,
- (3) Division for Biological & Biotechnology Products,
- (4) Division for Pharmacovigilance / Drugs Safety,
- (5) Division for Medical Devices and Diagnostics,
- (6) Division for Imports,
- (7) Division for Organisational Services & Finance,
- (8) Division for Quality Control Affairs,
- (9) Division for Indian System of Medicine and Homeopathy,
- (10) Division for Training and International Cooperation.

9.13 The Committee observes that broadly –speaking, the proposed set up under the Central Drugs Authority is based on the set-up of Central Drug Administration proposed by the Mashelkar Committee. Ten Divisions are proposed under both the set-ups, the only difference being a separate division of Indian System of Medicine and Homoeopathy under the Ministry set-up. Another major difference between the two set-ups is that the Central Drugs Authority would be replacing the two drugs Technical Advisory Boards and performing their functions and also advising the Drug Controller General (I), who will be the Member-Secretary of CDA on all matters relating to drugs and cosmetics. Since the Committee is not in favour of creation of a separate “Central Drugs Authority”, and has recommended the restructuring of CDSCO as “Central Drug Administration” - an independent body under the Ministry of Health and Family Welfare, the Central Drug Administration as suggested by the Mashelker Committee may be brought into effect as early as possible.

9.14 Representatives of the organisations from AYUSH-sector strongly advocated the need for having an Additional Drug Controller (AYUSH), keeping in view the ever increasing acceptance of AYUSH drugs. The Committee is inclined to agree with this view point. The

Committee finds that the Ministry, while elaborating the proposed plan of expansion of the offices and the necessary expansion in the number of senior-level officers and supporting staff that would be required for its efficient functioning under the CDA , has stated that the post of Drug Controller (India) would be raised from the present level of the grade of Joint Secretary to Government of India to that of the grade of Additional Secretary to Government of India. It was also proposed to revive One post of Additional Drugs Controller (AYUSH) to assist DC (I) in the quality control and regulation of ASU products, and along with it, one more post of Additional Drugs Controller (India) was proposed to be created for assisting DC(I) in all other matters.

9.15 The Committee observes that in view of the wider mandate of a “Central Drug Administration” necessary expansion in the number of senior-level officers and supporting staff would be required for its efficient functioning. The Committee has been informed that an elaborate plan of expansion has been approved and being brought into shape. A special drive to fill up all the vacant posts in the CDSCO and the Drug Labs was already underway. 62 new posts of Drug Inspectors and 10 posts of Technical officers have already been created for strengthening of CDSCO and mitigating the problem of shortage of Drug Inspections to some extent. The Committee observes this as a welcome measure.

9.16 Under new chapter 1A, Section 5B speaks of the term of office of Chairperson and Members, of Central Drugs Authority; Section 5C relates to salaries, allowances, pensions and other conditions of service of Members, Section 5 D is regarding vacancies, etc. not to invalidate proceedings and Section 5 E refers to staff of the Central Drugs Authority.

In view of the Committee’s disagreement with the Ministry’s proposal for creating a separate Central Drugs Authority, Section 5B, 5C, 5D, and 5E under stand void.

9.17. Section 5F under new chapter 1A deals with the Powers and Functions of Central Drugs Authority.

Sub-clause (1) of Clause states as under: -

“5F. (1) The Central Drugs Authority may issue licences under clause (c) of section 10, clause (c) of section 18 and clause (c) of section 33EEC, and collect fees therefor.”

9.18 The Committee notes that the Drugs and Cosmetics Act, 1940, is a central legislation and is implemented by the Central and State Governments together. Under the Act, the following are the responsibilities of the Central Government-

1. Clearance (Market approval) of new drugs;
2. Laying down of standards;
3. Control over import of drugs and cosmetics;
4. Enacting of legislation; and
5. Licensing under the Central Licensing Approving Authority (CLAA) schemes.

The responsibilities of State Government are as follows:-

1. Licensing of manufacture of drugs;
2. Licensing for sale of drugs; and
3. Post Marketing Surveillance.

9.19 The Ministry has informed that one of the major problems faced in enforcement of the rules and regulations under the Drugs and Cosmetics Act was the non-uniformity of licensing process among the Centre and States. In spite of repeated pleas made by the National Human Rights Commission, Hathi Committee, Estimates Committee (7th Lok Sabha) for the Central Govt. to assume the responsibility for granting manufacturing licenses, the same could not be implemented for one reason or the other. Therefore, the Bill proposes to streamline the licensing activity by shifting the drug manufacturing license issuing power from the States to the Center. States will be, thus, responsible only for granting licenses for stock, distribution and sale of drugs and to carry out Post Marketing Surveillance on the quality of drugs moving in the market. The Ministry stated that it will give the needed focus and uniformity to the work of licensing and manufacturing on the one hand, while allowing the States to pay greater attention to the distribution aspect, which appears currently somewhat neglected. The regulatory system, therefore, would become more effective. It was also stated that the bringing in of a Central Drugs Authority with licensing functions will also help in the creation of data banks, especially with respect to manufacture and licensing of drugs.

9.20 During the Committee's interactions with the stakeholders – drug manufacturers' associations, State Drug Controllers' associations, experts and also State Govts., strong apprehensions were expressed by majority of them on the proposed switching over to centralized licensing of drug manufacturing activities in the country. Undue delays in grant and renewal of licenses, difficulties in filing of appeal by manufacturing units located far from Delhi and lack of incentives for the industry to set-up their units in backward areas were the main reservations expressed. It was also argued that the existing system is superior to the proposed central licensing on the grounds that it offers better control of the drug manufacturing units as the authority has to control one State only. It was also pointed out by many State Governments and the State Drug

Controllers that the fee for grant of licenses, product permission and various certificates being the only source of revenue for State Drug Departments, centralized licensing would cause loss of revenue to the State Governments. One centralised agency like CDA dealing with the issue of licensing for manufacture, distribution and sale of drugs across the country that too without the assistance of DTAB and ASUDTAB was not considered a practical proposition.

9.21 The Committee found that it was a general perception among majority of the stakeholders that with the Centralized licensing coming into effect, every activity including procedural formalities would be centered in Delhi leading to number of hurdles being faced by the drug manufacturing units, specially small units. The Committee, however, observes that the apprehension stands suitably addressed, keeping in view the fact that CDA through its network of Zonal and Sub-Zonal offices and port offices would have its presence in most of the States where there is significant concentration of drug manufacturing activity. This would also facilitate Centralized licensing and Good Manufacturing Practices (GMP) Certification. Besides, these offices would also take care of concerns regarding inordinate delays in issuance of licenses etc. raised by the stakeholders subsequent to centralized licensing coming into force. The Committee is of the view that in this age of IT advancement, the restructured CDSCO with its ten divisions having a well-defined jurisdiction and network of subordinate offices spread across the country, apprehension about delay factor do not seem to be genuine. The notion of the States that the existing system is superior to the proposed central licensing on the grounds that it offers better control by the States pre-supposes the existence of an efficient infrastructure and quality of enforcements in every State. The Committee observes that this assumption is far removed from the ground realities in majority of the States.

9.22 In this regard, the Committee takes note of the specific recommendation for licensing of drug manufacturing units by the Central Drug Administration made by the Mashelkar Committee after a detailed analysis of ground realities, recommendations of earlier expert Committees and views of all the stakeholders. Issue of non-uniformity of enforcement at the State level with regard to quality control of drugs was the main factor behind such a recommendation made by all the bodies like NRHC, Hathi Committee, Estimates Committee (Seventh Lok Sabha) and Mashelkar Committee. Committee's attention has been drawn by

the guiding principle driving this suggestion, aptly summarized in para 33 of the Hathi Committee Report quoted below:-

“quality control of products manufactured anywhere in India was not solely the responsibility of the state in which the manufacturing unit is located, since the product is sold all over the country. If a unit in one state was allowed to manufacture and market a product of substandard quality, this would nullify the measures taken by other States. It was essential that the Central Government should assume responsibility for ensuring statutory enforcement and control over the manufacture of drugs all over the country.”

9.23 The Committee agrees with the assessment made by all the earlier Committees that there was an urgent need for having a world class drug regulatory system in the country which can effectively handle the health concerns of one sixth of humanity. The Committee can only reiterate that wherever the health and safety of life of the people is concerned, cutting across regional/State specific interests/issues, the emphasis should be protecting the same.

9.24 On being asked as to how the Ministry proposes to centralise the licensing activity, the Secretary, while deposing before the Committee at its meeting held on 29th July 2008, stated that progressive central licensing through reforming and expanding the existing Central Licensing Approving Authority (CLAA) system, rather than by the State by State method, was a more feasible proposition. He clarified that in order to avoid the resultant ambiguity of jurisdiction by the Centre as well as the States; it was thought best that by including more and more health products under the existing CLAA system, it would result in a progressive increase in the number of centrally licensed items leading to a gradual shift of the licensing activity from State to Centre.

9.25 The Committee notes that presently, under the CLAA system, following items are being licensed concurrently by the State and Central licensing authorities:

- Human blood and blood products.
- Seral vaccines.
- Large volume parenterals.
- Medical devices except needle, syringes and perfusion sets.

The representatives from quite a number of drug manufacturing organisations pointed out that a lot of bottlenecks were being faced by them under the CLAA system. It was stated that

undue delays in grant and renewal of licenses for the above categories of products were a constant source of discomfiture for them.

9.26 The Committee's attention has been drawn to the following specific excerpts from the Mashelkar Committee Report: -

"The matter of licensing of manufacturing units by Central Government has been considered on several occasions in the past. During 1988-89, the reports of poor quality of I V fluids and substandard blood made the Central Government focus on the issue of having a stricter control on these products. This resulted in the amendment of Rules to provide for dual licensing mechanism in December 1992, the Central authority being the License Approving Authority (CLAA) and the States being the license giving authorities. The idea was to improve the quality and implement uniform norms but the experience has not been encouraging. The change, however, has not made the desired level of impact."

"The National Human Rights Commission in their order of 1999 clearly stated that: the present dual system of control does not appear to have achieved desired effectiveness, therefore, Central Government must immediately take steps to examine the entire system of Licensing (including loan licensing), Certification and Complaint handling under effective Central Government control through CLAA or other suitable means"

9.27 The Committee observes that though the method of progressive increase in the number of items under CLAA seems to be a good measure aimed at smooth transition of the licensing activity from the States to the Center, it has its own apprehensions regarding the timely disposal of applications, effective co-ordination with the industry, interpretation of law under the CLAA system. The facts stated above by the witnesses and supported by the findings of the Mashelkar Committee all point out that the present mechanism under the CLAA system is far from satisfactory. The Committee was also given to understand that the number of units involved was very large, volume of records need to be handled was also enormous and every unit would have to be inspected after one year. Keeping in view the tremendous strain the above-mentioned exercise was likely to have on the Central Government; transition period from State licensing to centralized licensing may be spread over a period of ten years. On Committee's showing its concern on such a long time-span, Secretary, Health admitted that it was too long a period. He assumed that every effort would be made to switch over to centralized licensing in six to seven years.

9.28 The Committee was surprised to note that the proposed move was in direct contravention to the roadmap in three phases drawn by the Mashelkar Committee for implementation of centralized licensing. During Phase-I, the manpower was to be

strengthened and infrastructure of Central Drug Administration was to be in place. Expansion of zonal and sub-zonal offices, creation of additional infrastructure for new offices in States, creation of considerable number of additional senior level and supporting posts are the specific requirements for implementation of the above recommendation. During Phase-II, the licensing functions of States having minimum concentration of manufacturing units were to be shifted to the Centre, and during Phase- III, licensing in seven States having maximum concentration of drug manufacturing units (75 per cent) of licenses was to be taken over by the Central Drug Administration. All this exercise was to be completed within a span of three years.

9.29 On being asked about reasons for not accepting this specific recommendation of the Mashelkar Committee, the Secretary informed that this issue was also discussed with Dr. Mashelkar who has agreed to the progressive transfer from the State Licensing to the Central licensing rather than going State by State. The Committee has its own reservations on not going for the roadmap having a specific time frame drawn by the Expert Committee for switch-over to centralized licensing which was the outcome of extensive interactions with all concerned based on the ground-realities. The Committee would also like to point out that so far no plan of action having a specific time-limit has been drawn by the Ministry. As indicated by the representative of the Ministry, it can be anywhere from five to ten years. Apprehension of the Committee on this vital issue is strengthened by the fact that a reputed consultancy firm/consultant would be engaged by the Ministry for suggesting the roadmap based on the best practices available across the globe. The Committee can only conclude that against such a background, chances of things falling into place in the near future seem to be very dim. The Committee feels that the roadmaps drawn by the Mashelkar Committee is backed by sound logic and fully endorses the line of action pointed out by it for implementing the centralized licensing of drug manufacturing units. The Committee, therefore, strongly recommends that every effort should be made for implementing the same within the specified time-frame.

9.30 An important issue that was raised by several witnesses was that the Bill was silent about the grievance redressal mechanism. It was pointed out that whereas under the present system of licensing where licenses are issued by the State Licensing Authorities, an aggrieved party can file

the appeal with the State Government, the appeal shall lie with the Central Government, irrespective of the State where the unit filing the appeal is located if the licensing system is centralized. With the power to grant, renew, suspend or cancel the licenses being given to the proposed CDA, this would result in undue hardship, wastage of precious time and additional financial burden especially to small scale units located far away from the CDA. The licensee would have to file an appeal against the order of CDA before the Central Govt. and therefore, run to the Centre frequently for redressal.

9.31 In reply to a specific query on the issue, the Ministry has stated that the appeal would lie with the Government (Ministry of Health and Family Welfare) and the provisions in this regard will be accordingly incorporated in the proposed Bill which would read as under:-

“Any person aggrieved by a decision of the CDA(I) passed under section 5(F) may within ninety days of the date of such decision prefer an appeal to the Central Government and the Central Government, after giving the appellant an opportunity of being heard, shall pass a reasoned order”.

9.32 The Committee is inclined to agree to the view-point of the stakeholders that they would be at a serious disadvantage in terms of undue hardship, wastage of precious time and additional financial burden especially for small scale units located far away from Delhi. Since the Centre would be carrying out its licensing operations from its various zonal and sub zonal offices placed in each State/ UT, the Committee recommends that the appellate authority for grievance redressal of the aggrieved party should be placed in such offices, keeping in mind the comparative disadvantages that the small scale pharma units would otherwise face.

9.33 Section 5-I provides for creation of a **Fund** that would be called **Central Drugs Authority of India Fund**. which reads as follows: -

“**5-I.** (1) There shall be constituted a Fund to be called the Central Drugs Authority of India Fund and there shall be credited thereto—

(a) all grants, fees and charges received by the Central Drugs Authority under this Act; and

(b) all sums received by the Central Drugs Authority from such other sources as may be determined by the Central Government.

(2) The Fund shall be applied for meeting—

(a) the salaries, allowances and pensions payable to the Chairperson and other Members and the administrative expenses, including the salaries, allowances and pensions payable to or in respect of the Drugs Controller (India) and other officers and employees of the Central Drugs Authority; and

(b) the expenses to carry out the objects and purposes of this Act.”

9.34 The Ministry had informed the Committee that initially, the Central Govt. would provide grants for running of the CDA. It will have financial autonomy to the extent that it will retain the revenues earned by it to be utilised for its operational expenses. During the first 5 years, all the revenues of CDA will be met through license fee and other ancillary functions. Details about the proposed earnings of CDA as indicated by the Ministry are given as below:-

“Presently the CDSCO earns revenues through import registration fees, new drug registration, license fees etc. Once the CDA becomes functional, it is proposed to add new fees for GMP certification inspection and to increase the rate of present fees for import registration (started in 2002), new drug registration (started in 2002), license for manufacturing/ inspection/ products (revised in 2001) and clinical trials (started in 2002). It has been assumed that while there would not be any regular yearly appreciable increase in the category of new drug registration and license fees, the other fee categories would show an increase of 5% per annum. While expenditure of CDA would vary from Rs. 7.30 crore (in year 1) to Rs. 23.67 crore (in year 10), the revenue of the proposed Authority would vary from Rs. 21.31 crore (in year 1) to Rs. 32.94 crore (in year 10). Hence, the net inflows of CDA would vary from Rs. 14.07 crore (in year 1) to Rs. 9.27 crore (in year 10). Reason for downward trend in the cash flow is because it has been calculated on the assumption that the rate of various fees would remain constant over the 10 year period. If, however, the fees were to be enhanced at a 5 yearly interval then the cash flows would undergo a change.”

9.35 **The Committee notes that the proposed Fund for Central Drugs Authority will be receiving all grants, fees and charges levied for different purposes. Only initial funds are sought to be provided by the Central Govt. The Committee apprehends that this would be grossly inadequate. Given the fact that strengthening of the CDSCO as Central Drug Administration would require expanding the Zonal and Sub-zonal offices, creation of additional infrastructure for new offices in the States and manpower to match equally, for setting up a world class Central Drug Administration, substantive additional funds would be required for such activities. The Committee strongly feels that the Central Govt. will have to play a major role. In view of majority of the States facing funds constraints, the required funds will have to be provided by the Central Govt. It, therefore, suggests that like major social sector central/ centrally sponsored schemes, the task of setting up a world class Central Drug Administration may be taken up in a mission mode. Accordingly, a Central Fund meant for Central Drug Administration with major contribution from the Centre in the form of a Corpus Fund may be set up.**

9.36. **Section 5L** under new chapter 1A deals with **Power to make Rules**

It provides that the Central Government may, after consultation with, or on the recommendation of the Central Drugs Authority may make rules relating to the functioning of CDA.

In view of the Committee's disagreement with the proposal for creating a separate Central Drugs Authority, Clause 5L stands void.

10. Clause 3 of the Bill also introduces another Chapter 1B, after Chapter 1A, that deals with the regulation of Clinical Trials.

10.1 Section 5N under the new **Chapter 1B**, which speaks about conducting **Clinical Trial without Permission**, states that: -

“5N. No person shall conduct clinical trials in respect of any drug or cosmetic except under, and in accordance with, the permission granted by the Central Drugs Authority.”

10.2 It was argued by a number of witnesses that Clause 5N will bring all post marketing clinical trials and academic research to a complete halt. The surveillance studies generate useful data on local population for drugs that are not tested extensively before marketing in India. To avoid such situation, the word “**Any Drug**” used in the clause should be substituted by “**Any Investigational New Drug**”. Clinical trials should be necessary only on new drugs which were at investigational stage. It was also emphasized that the Confirmatory trials, Pilot trials, trials for submission to foreign regulatory authorities and contract research trials may be exempted from this provision.

10.3 In the light of observations made by the Committee with regard to the definition of the term ‘clinical trial’, permission for conducting clinical trials of only investigational new drugs and cosmetics and medical devices may be included. Secondly, under the proposed restructured CDSCO as envisaged by the Mashelkar Committee, out of the ten divisions which would be functioning at the Headquarters, there are two separate divisions one for New Drugs and Clinical Trials, and the other for Medical Devices and Diagnostics. The Committee, accordingly, recommends that these two Divisions may be entrusted with the responsibility for granting permission for conducting clinical trials for drugs and dermatological safety studies for cosmetics, and evaluation of safety and performance of medical devices and other allied issues.

10.4 Section 5O regarding Punishment for Conducting Clinical Trial without Permission, lays down that:-

“5O. (1) Whoever, himself or by any other person on his behalf, conducts clinical trials in contravention of section 5N shall be punished with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(2) Whoever having been convicted of an offence under subsection (1) is again convicted of an offence under that sub-section, shall be punished with Imprisonment for a term which may extend to ten years and with fine which may extend to twenty lakh rupees.”

10.5 Some of the stakeholders had pointed out that the punishment for conducting clinical trial without permission was very harsh and it was likely that the students conducting academic research in Government/ Private Institutions or for post graduate courses may face such serious consequences of harsh punishment merely due to not obtaining permission from the CDA out of ignorance. In such cases liability should be fixed on the concerned institutions. It was also suggested that a distinction was needed to be made between clinical trials conducted strictly in accordance with the Good Clinical Practices and in compliance with all ethical requirements but without obtaining permission and unauthorised clinical trials causing adverse impact or grievous hurt to the volunteers. Lesser punishment of only fine may be prescribed and in such cases they should be considered as compoundable offences.

10.6 The Committee, after carefully weighing the contention of the stakeholders as well as of the Department, is of the view that the provisions of punishment, for conducting Clinical trial without permission should be retained. Such a provision would act as a deterrent for violators of law. The Committee is disinclined to agree that academic research would be brought to a halt by such a provision. It contends that that if the punishment norms for academic research are relaxed, chances of drug manufacturing companies carrying out trials through private institutions by financially supporting them cannot be ruled out. The Committee suggests that in such cases the onus of proving themselves not guilty should be fixed on the Institutions where the students are conducting academic research.

10.7 The Committee would also like to point out that a careful perusal of the clause reveals that the punishment would vary with the degree and nature of violation. Thus the question of this provision being very harsh does not arise. The Committee also feels that punishments for cases related to ‘drugs’ and those related to ‘cosmetics’ should be separate and clearly

defined. Similarly, those cases related to ‘medical devices’ should be dealt separately under a chapter concerning regulation of medical devices, as mentioned earlier.

11. CLAUSE-5

11.1 Clause 5 of the Bill seeks to omit Section 5 of the Principal Act, which relates to constitution of the Drug Technical Advisory Board.

11.2 When asked to justify the abolition of the Drugs Technical Advisory Boards, the Ministry clarified that under the existing provisions of the Drugs and Cosmetics Act, 1940, there are two separate Drugs Technical Advisory Boards (DTABs), for the allopathic and ASU drugs. The DTAB is a broad based body wherein, in addition to persons involved in regulatory system, representatives from IMA, pharmaceutical manufacturers, Indian Pharmaceutical Associations etc. are also included. It advises the Government on matters relating to implementation of provisions of D&C Act and Rules made thereunder as well as to make suitable amendments in the Rules and Regulations as per the requirements.

11.3 Clarifying a query regarding the justifiability of replacing the highly technical eighteen-member DTAB with a small body like Central Drugs Authority, the Ministry stated that the process of translating the recommendations of this advisory body into rules and regulations inevitably results in some delay because of the procedures involved. This was sought to be streamlined by empowering the CDA which would be replacing DTAB to formulate regulations based on the recommendations of the DCC and its own expertise and analysis. It was further clarified by the Ministry that the Drug Consultative Committee would be reconstituted to include all the stake holders who were members in the erstwhile DTAB.

11.4 During its interactions, one view which was strongly advocated by all the stakeholders was that the proposal to abolish the DTAB with CDA taking its role was unjustified. It was pointed out that such a move would inevitably lead to depriving the drug industry in the country from the advice and expertise of this highly technical Board. It was also mentioned that such a proposal was not there in the Mashelkar Committee Report.

11.5 The Committee is of the opinion that the DTAB is a highly technical body with representation of experts from various fields and whose main function is to advise the

Central Government and the State Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it under the Act.

Being the most important body under the Central Drug Administration, the Committee feels that DTAB should be retained. The issue has been dealt with earlier also in this Report. Hence, it recommends that Section 5 of the principal Act which deals with the Constitution and Composition of the Drugs Technical Advisory Board (DTAB) may be retained.

12. CLAUSE-6

12.1 **Clause 6** of the Bill speaks of **amending certain provisions of Section 6** of the Principal Act which deals with the Central Drugs Laboratory

“6. In the principal Act, in section 6,—

(a) for the word “ Laboratory”, wherever it occurs, the words “Laboratory or Laboratories” shall be substituted;

(b) in sub-section (2), for the word “Board”, the words “Central Drugs Authority” shall be substituted.”

12.2 The Ministry informed the Committee that the Bill proposes that all the Central Drug Laboratories be placed under the CDA as bringing all the drug laboratories under CDA will facilitate proper planning, utilization of the capacities of these laboratories by restructuring and reorienting their objectives and goals. For example, at present, almost all the laboratories are notified for analyzing all categories of drugs, but some of the laboratories can be assigned with specific jobs like testing of medical devices, testing of cosmetics etc. Based on the techniques of analysis, each laboratory can be given a focus on a specific technique like chromatography, microbiology, instructional biology etc. and such focus will facilitate creation of expertise and capacity of testing. This restructuring will strengthen the CDA in evaluation of the quality of the drugs.

12.3 The Committee would like to state here that the Mashelkar Committee Report had also pointed out serious deficiencies in the State and Central Government drug testing labs. The limitations in testing of drug samples in the Government labs are related to the absence or lack of sophisticated instruments, lack of trained analysts, lack of commitment, lack of reagents, non-validated methods, shortage of funds, inadequate number of staff and in many cases a combination of more than one of these constraints. The Committee has also been given to understand that efforts made by the Central Government for setting up/upgrading their testing facilities in States under various Five-year plans and through WHO funds, have been far from satisfactory.

12.4 The Committee observes that, keeping in view the need for quality control of drugs across the country, the proposed move of bringing all the Central Drug Laboratories under the control of one central agency is called for. However, in view of the Committee's recommendation for having Central Drug Administration in the form of re-structured CDSCO, all the Central Drug Laboratories may be placed under the Division of Quality Control Affairs under the Central Drug Administration.

13. CLAUSE-7

13.1 Clause 7 of the Bill seeks to amend Section 7 of the Act for substituting the words "Drugs Technical Advisory Board" with the words "Central Drugs Authority". It also provides for change in the composition of the Drugs Consultative Committee.

Sub clauses (b) (2) under the above clause states as follows: -

“(b) for sub-section (2), the following sub-section shall be substituted, namely:—
(2) the Drugs Consultative Committee shall consist of such number of representatives of the Central Government, industry, consumer associations, academic and research institutions, as may be prescribed and one representative of each State Government to be nominated by the State Government concerned.”;

13.2 Justifying the proposed changes in this section, the Ministry had stated that it was proposed to restructure the composition of the Drugs Consultative Committee (DCC) to make it more representative and broad-based. It would be an advisory Committee constituted by the Central Govt. to advise the Central Govt., State Govts. and the proposed CDA on any matters tending to secure uniformity throughout India or any other matter referred to it for the administration of the Drugs and Cosmetics Act. The DCC would be reconstituted to include all the stake-holders who were members in the erstwhile DTAB.

In view of the Committee's recommendations to retain DTAB at Clause 5, the proposed change at Section 7 (a) of the Act stands void. Drugs Consultative Committee as envisaged may continue.

14. CLAUSE-18

14.1 Clause 18 (b) (i) does away with the rule making powers of the Government to prescribe the qualifications and duties of the two important officials under the CDSCO - Government Analysts and Inspectors, provided under Section 33 of the Principal Act.

14.2 Witnesses were of the opinion that with the proposed Central Drugs Authority not being empowered to prescribe qualifications and duties of the Government Analyst and the qualification of Inspectors, any person without any professional qualifications would be entitled to be appointed as the Government Analyst and Drugs Inspector – by the licensing authority, a situation not desirable in the interest of effective implementation. Hence, Section 33(2) (b) and (n) should be retained.

On a specific query in this regard, the Ministry replied that the omission of clauses (b) and (n) of Section 33 (2) is an inadvertent error in typing which would be duly rectified.

15. CLAUS-19

15.1 Clause 19 of the Bill provides for omission of Section 33 of the Act dealing with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.

15.2 In view of the Committee's recommendation at Clause 5 to retain DTAB, the provision under Section 33C of the Principal Act for constitution of ASU DTAB may be retained. The proposed clause 19 of the Bill accordingly, stands void.

16. CLAUSE-20

16.1 Clause 20 of the Bill seeks to amend section 33D of the principal Act. which deals with the ASU Drugs Consultative Committee.

16.2 In view of the Committee's recommendation to retain Drug Consultative Committee as envisaged in Section 7 (2)(b) of the Principal Act, the proposed change in section 33 D (1) of the Act stands void.

17. In view of Committee not agreeing to the replacement of DTAB by the CDA, the consequential changes in the relevant Clauses stand void.

18. MISCELLANEOUS ISSUES

1. During the course of his deposition before the Committee the on 12th august 2008, Dr. Mashelkar was asked to apprise the Committee of the updated status of the 'Implementation Committee on Drug Regulatory Reform' supposedly set up by the Ministry of Health and Family Welfare under his chairmanship. Dr. Mashelkar expressed his ignorance on the existence of any such Committee. The Committee takes serious exception to the fact that though almost a year has passed since the Ministry has informed the Committee that the process for setting up of an

‘Implementation Committee on Drugs Regulatory Reform’ has been initiated, no progress seems to have been made on the issue. The Committee would like to state that the Ministry should apply caution in future and use all care and circumspection before furnishing such information to a Parliamentary Standing Committee.