

PARLIAMENT OF INDIA

RAJYA SABHA

**DEPARTMENT-RELATED PARLIAMENTARY
STANDING COMMITTEE
ON
HEALTH AND FAMILY WELFARE**

THIRTY-SECOND REPORT

ON

**THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION)
BILL, 2007**

**(PRESENTED TO THE RAJYA SABHA ON 24TH OCTOBER, 2008)
(LAID ON THE TABLE OF THE LOK SABHA ON 24TH OCTOBER,
2008)**

RAJYA SABHA SECRETARIAT

NEW DELHI

OCTOBER, 2008/KARTIKA, 1930 (SAKA)

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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

SECRETARIAT

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

- (*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)

COMPOSITION OF THE COMMITTEE (2008-09)

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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29. Shri Uday Singh
30. Dr. Karan Singh Yadav
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SECRETARIAT

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

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

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

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 Thirty-second Report of the Committee on “The Clinical Establishments (Registration and Regulation) 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 Clinical Establishments (Registration and Regulation) Bill, 2007’ (Annexure-I), as introduced in the Lok Sabha on the 30th August 2007 and pending therein, to the Committee on the 28th September 2007 for examination and report.

3. A Press Release inviting suggestions/comments from general public as well as stakeholders/experts was issued in October, 2007. In response thereto, a number of memoranda were received.

4. The Committee considered the Bill in its meetings held on the 31st October 2007, 25th January 2008, 27th May 2008 and 9th June 2008. The Committee also 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 to have first-hand interaction with various stakeholders. Study Notes on the same were also prepared. (Annexure-II)

5. The Committee held wide ranging discussions with all the stakeholders on various provisions of the Bill. Divergent views were expressed by the representatives of the associations of various private healthcare establishments, Government Medical Institutes, organizations, experts, individuals, consumer fora, NGOs and State Governments. The Committee also interacted with the officers of the Department of Health and Family Welfare, Ministry of Health and Family Welfare, Medical Council of India, Indian Medical Association, Dental Council of India, Bureau of Indian Standards and the Quality Council of India. The Committee sought clarifications from the above entities on the various viewpoints put forth before it on the Bill.

*Published in Gazette of India Extraordinary Part II Section 2, dated the 30th August 2007

** Rajya Sabha Parliamentary Bulletin Part II, No 44503, dated the 1st October 2007

6. The Committee, thereafter, discussed and adopted its draft Report on the Bill in its meeting held on the 23rd October 2008.

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

- (i) Background Note on the Bill, Feedbacks received from various State Governments and some existing State Acts covering clinics/healthcare establishments received from the Department of Health and Family Welfare;
- (ii) Presentation and clarification by the Secretary and other officers of the Department of Health and Family Welfare;
- (iii) Memoranda received on the Bill from various stakeholders;
- (iv) Replies of the Ministry to the Questionnaires on the Bill; and
- (v) Oral evidences on the Bill.

8. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who submitted their valuable suggestions on the subject matter of the Bill by way of memoranda or deposition before the Committee.

9. 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;

October 23, 2008

Kartika 1, 1930 (Saka)

AMAR SINGH

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

REPORT

1. The Clinical Establishments (Registration and Regulation) Bill, 2007 (hereinafter referred to as the Bill), was introduced in the Lok Sabha on the 30th August, 2007 and referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare on the 28th September, 2007 for examination and report thereon.
2. The objective of the Clinical Establishments (Registration and Regulation) Bill, 2007 is to bring out a Central Legislation for ensuring uniform standards of the facilities and services provided by the Clinical Establishments throughout the country. The proposed legislation will apply to all clinical establishments, which includes both private and public establishments, under all recognised systems of medicine including single doctor establishments. The Bill, *inter-alia*, provides for:-
 - (i) The constitution of a National Council to determine the standards for clinical establishments to classify the clinical establishments, to develop the minimum standards and periodic review thereof, to compile, maintain and update a national register of clinical establishments; and
 - (ii) Assigning the State Governments with the function of:-
 - (a) registration of clinical establishments and cancellation of registration;
 - (b) compilation and updation of the State Register of clinical establishments for the purpose of updation of the National Register of clinical establishments.

The Statement of Objects and Reasons appended to the Bill and reproduced below explains the reasons warranting the need for the Bill :-

“At present, the supervision and regulation of the quality of services provided by the health care delivery system to the people by both public and private sectors has largely remained a contentious and therefore, unresolved issue. The current structure of the health care delivery system does not provide enough incentives for improvement in efficiency. The private sector health care delivery system in India has remained largely unregulated and uncontrolled. Problems range from inadequate and inappropriate treatment, excessive use of higher technologies, and wasting of scarce resources to serious problems of medical malpractice and negligence.

2. Despite many State Legislatures having enacted laws for regulating health care providers, the general perception is that current regulatory process for health care providers in India is inadequate or not responsive to ensure health care services of acceptable quality and

prevent negligence. Concerns about how to improve health care quality have continued to be frequently raised by the general public and a wide variety of stakeholders, including Government, professional associations, private providers, agencies financing health care, National Human Rights Commission and also by judiciary.

3. Accordingly, a need has long been felt for a central legislation for ensuring uniform standards of facilities and services by the clinical establishments throughout the State where the Legislative Assemblies have passed resolutions under article 252 of the Constitution and the Union territories and the States which may adopt the legislation by such resolutions.

4. The salient features of the proposed legislation, *inter alia*, are as follows:—

(i) the proposed legislation provides for the constitution of a National Council consisting of representatives of the Dental Council of India, the Nursing Council of India, the Pharmacy Council of India, the Indian Medicines representing the Ayurveda, Siddha, Unani and Homoeopathy systems, the Indian Medical Associations, the Bureau of Indian Standards, the Zonal Councils set up under the States Reorganisation Act, 1956, the North Eastern Council, etc.;

(ii) the function of the National Council shall be to determine the standards for clinical establishments, classify the clinical establishment into different categories, develop the minimum standards and their periodic review, compile, maintain and update a national register of clinical establishments, perform any other function determined by the Central Government, from time to time;

(iii) the concerned State Government shall designate the Director of Health Services or any other officer subordinate to him as the Registrar of clinical establishments. The State Registrar of clinical establishments shall compile and update the State register of clinical establishments and further send the same in digital format for updating the national register;

(iv) the concerned State Government shall, by notification, designate the District Health Officer or the Chief Medical Officer as district registering authority for registration of clinical establishments;

(v) no person shall carry on a clinical establishment unless it has been registered in accordance with the provisions of the proposed Bill. The legislation would not apply to the clinical establishments of the Armed Forces;

(vi) it is proposed that clinical establishments already in existence may be allowed for provisional registration to carry out their business. There shall be no prior enquiry for provisional registration. But the Authority

shall have power to make enquiry in accordance with such rules as may be prescribed;

(vii) the clinical establishment having provisional registration shall fulfil the standards which may be notified for the purpose. The provisional certificate shall not be granted or renewed beyond a period of three years from the date of notification of standards;

(viii) any clinical establishment may apply for permanent registration in such

form and shall pay such fee as may be prescribed by the State Government. A detailed

procedure for permanent registration is being provided in the proposed legislation;

(ix) the authority shall have power to cancel the registration of the clinical establishment which fails to comply with the conditions prescribed by the Central Government. The authority shall have power to inspect a registered clinical establishment. Any person aggrieved by an order of the registering authority shall prefer an appeal to the State Government;

(x) there shall be register of clinical establishments at the district level, State level and the National level;

(xi) if any person contravenes any provisions of the proposed legislation or any rules made thereunder, he shall be punished with fine. The maximum penalty being provided is rupees five lakh.

5. Legislation in respect of "Public health and sanitation, hospitals and dispensaries" are relatable to Entry 6 of List II-State List in the Seventh Schedule to the Constitution and Parliament has no power to make a law in the State (apart from the provisions of articles 249, 250 and 252 of the Constitution) under article 252 of the Constitution where the legislatures of two or more States pass resolutions in pursuance of article 252 of the Constitution empowering Parliament to pass the necessary legislation on the subject, a Bill may be introduced in Parliament. The legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim have passed such resolutions. The Bill is intended to give effect to the resolutions passed by the legislatures of the aforesaid States and to make also provisions in respect to Union territories.

6. The Bill seeks to achieve the above objective. ”

3. Appearing before the Committee on the 31st October, 2007, representatives of the Ministry of Health and Family Welfare elaborated on the background and circumstances that led to the introduction of this Bill. Speaking of the global experience, the Joint Secretary of the Department

while giving a presentation before the Committee stated that one of the first challenges countries have faced in planning for regulation and accreditation systems is to gain consensus on the definitions of various forms of regulation and evaluation. The elements of any regulatory process include establishment of rules, its application to specific cases, detection or monitoring violations and imposition of penalties on violators. Elaborating on the issue, he stated that at present there are no uniform regulatory requirements for hospitals, nursing homes, diagnostic centres etc. in India. Though laws in some States do exist but they are more on paper. Some are archaic and in some cases implementation dates have not been notified. In some cases either rules or the minimum standards have not been notified. Some States have drafted the regulatory legislations but have not been able to get them tabled and considered by their respective Legislative Assemblies. He stated that there has been resistance from service providers. The existing laws do not have provisions to regulate functioning of laboratories and diagnostic centers of private healthcare service providers, despite the emergence of a considerable number of such facilities in India. Concerns have been raised frequently by general public and a wide variety of stakeholders including Government professional associations, private providers, agencies financing healthcare, National Human Rights Commission (NHRC) and even High Courts in various States. In a case of medical negligence in 1996, the NHRC directed the Government of India, Medical Council of India and the Delhi Government to examine - Registration of private hospitals after ensuring availability of minimum facilities; Monitoring to ensure availability of facilities; Framing of regulations; Violation to be made a cognizable offence and shifting of non-conforming hospitals that are health hazards from non-conforming areas.

4. The Committee was apprised that a need for a central legislation has often been raised in Parliament. The Joint Secretary further stated that the Ministry of Health & Family Welfare has faced several bottlenecks in bringing a central legislation since 1997. The subject of standards for clinical establishments is related to the State List under Seventh Schedule to the Constitution and only States are competent to frame laws in this respect. However, Parliament can make laws on a State subject if Rajya Sabha passes resolution in national interest (Article 249) or if legislatures of at least three States pass a resolution authorizing Parliament to legislate on a State subject. Further, Central law would apply only to those States that have passed the resolution and the Union Territories. In order to have a central legislation, the Ministry has been lobbying with the States to authorise Parliament to legislate on the subject.

5. The Sixth Conference of Central Council for Health & Family Welfare (CCH) held on 8-10 April 1999 resolved-

“The Central Government may frame norms and standards for ensuring proper healthcare for different categories of institutions in consultation with the State Government for private hospitals/nursing homes/clinical establishments to be followed by all States. These norms shall prescribe the minimum standards of staff and infrastructure for all such institutions”.

6. The legislatures of the States of Himachal Pradesh, Mizoram, Arunachal Pradesh and Sikkim have passed resolutions under Article 252 that the clinical establishments in these States should be regulated by Parliament by law. A Central Legislation on the subject can now be enacted for these States and all Union Territories and can later be adopted by other States. A model Bill was circulated to all States in 1999. Based on the comments received, a revised draft Bill was again prepared in 2000. This Bill provided for Regulation and accreditation; Regulatory Councils/ Boards at National and State level; inspection, raids, punishments etc.

7. The Ministry drafted a Bill, namely, the Clinical Establishments Registration and Regulation Bill, 2006 *inter-alia* covering several modifications like - making the proposed legislation user friendly and IT enabled; provision for covering the clinical establishments in Government sector; existing units to be registered on as-is-where-is basis and time to be allowed for complying with the norms; no harsh penal provisions and registration on the basis of self certification without inspection. This Bill was circulated to the Ministries of Home affairs, Panchayati Raj, Defence, Labour & Employment; Railway Board and to all the State Governments. Based on the feedbacks, the Ministry of Health & Family Welfare in consultation with the Legislative Department, Ministry of Law & Justice finalized the Clinical Establishments (Registration & Regulation) Bill, 2007 and the same was introduced in the Lok Sabha on 30th August, 2007.

8. In view of the objectives behind the proposed legislation and its far reaching implications on the healthcare delivery system in India, the Committee decided to acquaint itself with all shades of opinion on the Bill. Through a Press Release, the Committee gave wide publicity to the Bill and invited views/ suggestions from all the stakeholders and general public with respect to the various provisions of the Bill. The Committee received an overwhelming response in the form of a large number of memoranda containing views from various organizations/ experts/ individuals/ associations/consumer fora/NGOs etc. After going through the memoranda, it was decided to have first-hand information in the form of personal interaction with some of the stakeholders and some of the State Governments. Accordingly, the Committee undertook a study visit to Bangaluru, Thiruvananthapuram, Chennai and Hyderabad from 7th to 14th January, 2008 in the first phase and to Indore, Ahemdabad, Mumbai and

Goa from 12th to 19th February, 2008 in the second phase and interacted with various entities like representatives of Private/Government Healthcare Establishments, experts, NGOs, Consumer Fora and representatives of the State Governments etc.

9. The Committee would like to acknowledge the valuable and enriching contributions of various stakeholders which has proved to be of enormous help in formulating its views on the various provisions of the Bill.

10. The clauses where the amendments have been suggested by the Committee are given in the succeeding paragraphs:-

11. Clause-1

11.1 This clause provides for the short title of the proposed legislation, its extent and commencement. The proposed legislation shall first come into force at once in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim which have already passed resolutions under Article 252 of the Constitution and the Union Territories and also in any other State which may adopt the Act by a resolution as aforesaid. Different dates may be appointed for different categories of clinical establishments and for different recognized systems of medicine to come into force.

11.2 Serious objections concerning the word “clinical” occurring in the title of the Bill, were put forth before the Committee. It was pointed out that the word ‘clinic’ is normally taken for a miniature hospital; normally run by a single Doctor. However, the definition of ‘clinical establishment’ as given in the Bill clearly indicates that all categories of clinical establishments from a single doctor establishment to multi-speciality hospital are proposed to be brought under it. Not only this, the Bill also includes all types of laboratories. The term ‘Clinical Establishment’ used in the title does not reflect the inclusion of all such establishments. Suggestions made were either replacing the word ‘Clinical’ with ‘Clinical Laboratories and Healthcare’ or adding the words ‘Diagnostic Laboratories’ in the title.

11.3 The Committee, after going through the objections and suggestions, observes that contrary to some of similar existing State laws, this is a comprehensive Central Legislation aimed at not only covering all categories of healthcare establishments but also practising all the recognized systems of medicine. Therefore, its title should be such which covers all the desired entities or reflects them through some common term. The word clinical, though it means related to medical, appears to be restrictive to allopathic clinics only.

11.4 In the opinion of the Committee, the word ‘healthcare’ takes care of most of the objections. Healthcare means related to health and it may be through any system of medicine and includes laboratory and diagnostic services also. Therefore, the Committee recommends that the

title of the Bill may suitably be changed as “The Healthcare Establishments (Registration and Regulation) Act, 2007” and the consequential changes be made in the Bill as well.

11.5 As per clause 1 (2), the proposed Act, at the first instance, is going to come into force in four States and the Union territories; other States can adopt it under Article 252(1) of the Constitution. On a specific query, the Committee was given to understand that at present ten States/ UTs have enacted their own laws regulating healthcare establishments. They, however, did not cover all the systems of medicine and the Public Health Institutions. Not only this, the effectiveness of their implementation continued to be under question. The Committee notes that the present Bill, in contrast, is a compact and comprehensive one. **The Committee, therefore, recommends that the Government should make all out efforts in persuading all the States to adopt the Central Legislation so that uniformity in health standards is maintained across the length and breadth of the country. For this, financial as well as other infrastructural support, as and when required, may also be provided to the States to motivate them in adopting the same.**

12. Clause 2

12.1 This clause seeks to define certain terms used in the Bill. Clause 2(c) gives a detailed definition of the term ‘clinical establishment’ enumerating all the categories of clinical establishments including laboratories, also giving a clear idea about the agencies owning/ controlling/ managing such establishments. The Committee notes that this term is the most crucial one as it gives a clear picture of the entity which is mandated to be registered and regulated through this enactment. The Committee is, however, surprised to find the maximum number of objections/ reservations being raised and suggestions being given in this regard by different stakeholders. The Committee takes note of the following main objections raised/ suggestions made -

- Dispensaries, clinics etc. without beds, i.e., those dealing only with out-patients, appear to be excluded.
- Clinical Establishment should also include Medical Research Establishment.
- The definition excludes status of establishments which offer only advice like Counseling Centres, dietician/ nutritionist clinics.
- Status of Establishments offering preventive care is not known.

- “biochemical, microbiological and clinical laboratory technological investigation” services should also be included, as these are the most widely performed services.
- “Single doctor establishment” may be removed from the purview of the Act.
- It was also argued that more vigil was required for registering single doctor establishments.
- Status of establishments established by partnership, run by societies (other than co-operative), Charity/ Missionary, mobile units is also not clear.
- The healthcare establishments owned, controlled or managed by the Armed Forces may be included.
- There are objections for and against inclusion of Public Health Institutions and autonomous institutions within the purview of the Act

12.2 A very glaring deficiency pointed out to the Committee by a number of witnesses was the lack of clarity in the definition of ‘clinical establishment’ as given in clause 2(c) (i). It appeared to be restricted to only those clinical establishments having the facilities of beds. The Committee agrees with these apprehensions. The Committee also takes note of the ‘Explanation’ given in clause 11 relating to ‘Registration for clinical establishments’. Clause 11 lays down that no person shall carry on a clinical establishment unless it has been duly registered. The expression ‘carry on’ has been specifically clarified as admitting patients in a clinical establishment for providing treatment, diagnosis or nursing care. Thus, definition of ‘clinical establishment’ when interpreted along with the explanation given in clause 11 seems to be applicable only with those clinical establishments attending to outdoor patients. The Ministry in reply to a specific question in this regard has claimed that the Act would also apply to establishments providing OPD services. **The Committee is, however, of the opinion that lack of categorical provision, further made ambiguous by another contradictory provision on this count does not substantiate the Ministry’s claim. The Committee would like to point out that the very purpose of the legislation would be diluted and defeated if the OPD services are not brought within its ambit. One must also not forget that with the significant advancements made in medical sciences and healthcare, even many surgical interventions do not require patient’s stay in the hospital/ nursing home. The Committee, therefore, is of the view that the definition of ‘clinical establishment’ under Clause 2(c)(i) and also the explanation given in clause 11 need to be suitably modified to remove the ambiguity.**

12.3 Committee observes that many Healthcare Establishments are now a days also involved in independent Research & Development activities specially in the context of research in new drugs/ drug combinations followed by their clinical trial on patients. The Bill in its present form does not categorically provide for inclusion of these establishments under the definition of clinical establishments. The Committee strongly feels that their exclusion would be detrimental to the rights of the patients who form part of the experiments/research studies undertaken by such establishments. In view of this, the Committee recommends inclusion of R&D establishments in the definition of Healthcare Establishments.

12.4 Very strong reservations were expressed by various associations/ organizations representing medical fraternity on the inclusion of ‘single doctor establishment’ as indicated in clause 2(c)(5) under the definition of the term ‘clinical establishment’. The main arguments put forth were unnecessary harassment, paperwork and escalation in cost of treatment. It was also pointed out that doctors were already registered as mandated by the IMC Act, 1956. Clinics being run by doctors from their residences cannot be, strictly speaking, considered as clinical establishments. The Committee is, however, not convinced by this line of thinking. Ground realities existing in our country in the context of health care facilities for general public need to be taken into account. A very high percentage of our population is dependent on the services provided by ‘single doctor establishments’ whether run from residences or other places. The implication of not bringing such establishments under the proposed legislation will prove to be detrimental to the interest of common man, the most vulnerable segment of our society. The registration is a one time activity and it will be renewable after a sufficient gap. The Committee would also like to point out that such a move would also prove beneficial in the context of collecting vital and complete data regarding health scenario in the country and the statistics could be utilized in National level Planning. The Committee, therefore, is of the firm opinion that single doctor establishments need to be covered under this Act.

12.5 The Committee also finds no valid reasons for keeping establishments set up by partnerships, run by societies (other than co-operative), Charity/ Missionary, mobile units out of the ambit of the Bill. The Committee, therefore, recommends that such establishments may also be included in the definition of ‘Healthcare Establishments’.

12.6 The Committee finds that under Clause 2(d) “National Council” is a very general nomenclature for the proposed Council and does not reflect the entire spectrum of the issues covered under the Bill. In

consonance with its suggestions regarding the title in Clause 1, the Committee recommends that the National Council referred to in clause 2(d) and subsequently in other provisions, be changed as “National Council for Healthcare Establishments”.

12.7 As regards appropriateness or otherwise of the applicability of the Bill to Defence Forces Establishments, the Committee respects the security concerns arising out of their inclusion under the ambit of the Bill. The Committee fully understands that parting with the details related to Army Health Establishments could be detrimental to nation’s security. The Committee is also aware that military medical establishments and the medicare provided by them is subjected to internal checks and inspections by administrative and technical experts on a regular basis. The Committee, however, strongly feels that a feasible mechanism can be easily worked out whereunder all the armed forces medical establishments can be registered by maintaining secrecy/confidentiality aspect also. The Committee, therefore, recommends that the Act should invariably be applied to all the Army Health Establishments except those based in the forward/ combat areas.

12.8 Another view point strongly advocated by some of the stakeholders was exclusion of the Public Health Institutions (PHIs) from the purview of the Act. Reasons advanced were that they had been established under certain norms and were following Indian Public Health Standards. Further, they are also participating in National Health Programmes and provide services as per constitutional obligations without any discrimination to all sections of society free of cost or on very nominal rates. Similarly, representatives of an autonomous institute - Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMT), stated that the Bill proposed to include the establishments owned, controlled or managed by Government, Public trust or a corporation registered under the Central Act. It, however, did not specifically mention about the Institutes of national importance established by an Act of Parliament. Citing the example of exclusion of establishments under Armed Forces, they demanded that Institutes of the stature like Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMT), All India Institute of Medical Sciences (AIIMS) New Delhi and PGI Chandigarh may be exempted from the purview of this Act.

12.9 The Committee does not find any substance in exclusion of Government/Public Health Institutions/ Autonomous Institutions from the purview of the Act as put forth before it through some representations. The Committee has taken note of the fact that several of the existing laws in various States do not cover such institutions, thereby inviting criticisms for giving undue advantage to them. The Committee fully understands that the Public Health Institutions have

some social obligations. They are also doing commendable job by handling tremendous patient load under very demanding ground realities. It, however, does not favour their exclusion simply because such a move will lead to depriving the majority of the people having access to such establishments only, from the benefits of this Act to which they are rightfully entitled. The Committee would also like to emphasise that element of accountability which is not visible so far needs to be made applicable to all categories of medical establishments- whether Govt. or private. One must not forget that ultimate goal is 'Health for all'.

12.10 There is a drafting slippage in Clause 2(f) which may be modified as:-

“prescribed” means prescribed by rules made under this Act by the Central Government or, as the case may be, by the State Government;

12.11 Clause 2(g) gives the definition of 'recognised system of medicine'. It includes all the Indian systems of Medicine as well as Homeopathy and Naturopathy along with Allopathy. Inclusion of Yoga and Naturopathy not having a statutory council to regulate them was objected to by IMA and some of its State branches. They, accordingly, sought their exclusion from clause 2(g). **The Committee, however, is not convinced by this line of thinking. The Committee would like to point out that the mere fact of there being no statutory regulatory authority at present does not mean that a well-established system having a wide acceptability increasing day-by-day among the masses cannot be considered a recognized system of medicine. The Committee, accordingly, recommends that the definition of 'recognised system of medicine' may remain unchanged.**

13. Clause 3

13.1 This clause provides for establishment of a Council to be called the National Council consisting of the Director General of Health Services who shall be the chairperson and one representative duly elected by (i) Dental Council of India, (ii) Medical Council of India, (iii) Nursing Council of India, (iv) Pharmacy Council of India, (v) Ayurveda, (vi) Siddha, (vii) Unani, (viii) Homoeopathy, (ix) Indian Medical Association, (x) Bureau of the Indian Standards, (xi) Line of paramedical and two representatives each of the (i) Zonal Councils and (ii) North Eastern Council. A number of suggestions were received from various stakeholders about the composition of the National Council.

13.2 Clause 3(2) (a) - The Bill provides for the Director General of Health Services to be the *ex-officio* Chairperson of the proposed National Council.

The Committee notes that the National Council has to perform very crucial functions which include determination of standards of health care to be provided by the healthcare establishments and classification thereof. Not only this, the Council is also entrusted with the routine work of compilation, maintenance and updation of the national register of such establishments and collection of statistics likely to be used for future planning and corrective measures. The Committee strongly feels that the DGHS in his capacity as the Chairperson of the National Council would not be in a position to carry out its mandate. Reason being that as the Director General of Health Services, he has to take care of entire country in all the conceivable health related matters. The Committee is, accordingly, not in favour of a part-time Chairperson for the proposed National Council because the work relating to the National Council would be very demanding, especially at the initial stage of determining and developing minimum standards. The Committee is of the firm view that DGHS, who is already overburdened with official work, would not be able to do justice with this dual responsibility. Further, the Committee would also like to point out that such an arrangement is also likely to impinge upon the autonomy of the Council. Taking the above factors into consideration, the Committee recommends appointment of a full time Chairperson, who has the required experience specially of hospital administration and has the rank and qualification equivalent to that of DGHS.

13.3 Attention of the Committee was drawn to the fact that the National Council cannot be considered as a representative body in the real spirit. As this body is primarily meant for taking care of health care of general masses, there was a need for inclusion of their representatives also in the Council. **The Committee also feels that presence of representatives of reputed NGOs and consumer protection associations working in the health sector is very much required in such a body. The Committee, therefore, recommends that composition of the National Council may be modified accordingly.**

13.4 **Committee also takes note of the role of private sector in providing health care in the country. The Committee is well aware about the increasing involvement of hospitals/ institutions run by private management across the country. Nobody can deny the fact that with the limited resources available with the Govt., in the enormous task of providing health care to the general public, contribution of private sector is bound to become more visible with passage of time. In such a scenario, with all the stakeholders being part of the National Council, representation from eminent medical professionals from the private sector, preferably from the associations/ bodies of private**

hospitals/ nursing homes is very much required. The Committee, accordingly, recommends representation from the private sector.

13.5 The Committee was informed that the Quality Council of India (QCI) is mandated to carry out National Quality campaign to promote quality in all walks of life including health sector. Two of its Boards, i.e. National Accreditation Board for Hospitals and Healthcare Providers (NABH) and National Accreditation Board for Testing and Calibration Laboratories (NABL) put together provide accreditation to the Hospitals, Nursing Homes, Diagnostic Centres and Medical Laboratories. The Committee feels that the National Council can draw useful inputs from QCI as it has a number of health professionals including assessors and experts on developing standards. Therefore, the QCI deserves to be represented in the proposed Council. Composition of the National Council may be modified so as to include one representative from the Quality Council of India.

13.6 Clause 3(2)(e) -The Committee notes that the sub-clause suffers from a factual deficiency under clause 3 which specifies the representation from the Central Council of the Indian Medical Association constituted under MCI Act, 1956. As is well known, IMA is a private association of allopathic doctors and not a statutory body created by legislation. The Committee, therefore, recommends that the sub-clause may, accordingly, be modified. The Committee would also recommend inclusion of at least one representative from similar Association representing Indian systems of medicine on a rotational basis.

13.7 Clause 3(2)(i)- This sub-clause provides for one representative from the line of paramedical systems. In view of one representative each from Nursing Council of India and Pharmacy Council of India given representation *vide* clause 3(2)(b), it should be suitably modified to exclude representation from these two paramedical fields. The Committee is also surprised to note that with all categories of laboratories being covered under the proposed legislation, their representative not finding a place in the National Council cannot be considered a justifiable move. The Committee can only emphasise that instead of there being a general provision, specific nomination from medical lab fraternity may be included under clause 3(2)(j).

13.8 Clause 3(2)(j)- The Committee notes that under Clause 2(g) Yoga and Naturopathy have been recognized as systems of medicine. However, there is no specific clause providing for their representation in the National Council under Clause 3. Keeping in view the fact that Yoga and Naturopathy providing efficacious, promotive, preventive and curative interventions are getting wider popularity among all classes of

the society, the Committee finds absence of any clear mention of their representation in the proposed National Council untenable. The Committee, therefore, recommends that Clause 3(j) be amended to categorically mention that out of the three representatives proposed, one each from Yoga and Naturopathy shall find place in the Council.

13.9 Clause 3(3) &(4)- As per clause 3(3) and (4), the nominated members have been provided a term of one year against a three year term for elected members. The Committee is not in agreement with providing a shorter term of one year for the nominated members as against three years for elected members. The Committee is of the view that there should be uniform term for both the categories of members so as to enable them to have greater co-ordination and also to give adequate time to the nominated members to understand the nitty-gritty of the working of the Council and make meaningful contribution. The Committee, therefore, recommends a term of three years for the nominated members as well.

13.10 Clause 3(6)- The Committee favours giving full functional autonomy to the National Council. The Committee, therefore, recommends deletion of the words “subject to the previous approval of the Central Government” from this clause. The Committee also feels that quorum for the meetings of the National Council should be spelt out in unambiguous terms in the Act itself to strengthen the autonomy of the proposed Council. The Committee, therefore, recommends Clause 3(6) be amended to incorporate the quorum required for the meetings of the Council.

14. Clause 5

14.1 The Committee notes that the two main functions of the Council are to determine the standards for ensuring proper healthcare by the clinical establishments and also to develop the minimum standards and their periodic review. The Committee also takes note of the fact that minimum standards of the facilities and services are to be prescribed for registration and continuation of clinical establishments. The Committee is, however, surprised to note the absence of any time-span for accomplishment of this crucial mandate in the Bill. The Committee can well imagine the situation emerging after the enactment of this Bill. The Committee can only conclude that fulfillment of the mandate of this Bill will continue to remain on paper for quite some time. The Committee would have appreciated if some basic minimum standards have been specified in the Bill itself which would have evolved and expanded as per the demand of the time. The Committee understands that some of the State Acts have such a provision of minimum standards. The Committee fails to understand the reason for not adopting the same.

The Committee can only emphasise that this was very much required in such a legislation which was expected to be adopted by other State Govts also. The Committee would also like to draw the attention of the Ministry to the pioneering work accomplished by the two Boards of the Quality Council of India and the Bureau of Indian Standards. Norms and guidelines prescribed for health care by these bodies can easily become the base for laying down of minimum standards for health care. The Committee, accordingly, recommends that the Department may take necessary action in this regard by prescribing the minimum standards for health care.

15. Clause 8

15.1 This clause provides that every State shall designate the Director of Health Services (by whatever name called) or any other officer subordinate to him as the Registrar of clinical establishments. The main objections/suggestions received in respect of this clause from various stakeholders are:-

- (i) There will be conflict of interest as the DHS or any other officer subordinate to him on being the registrar of clinical establishment.
- (ii) Some stakeholders have suggested an independent regulator/autonomous body.
- (iii) DHS is drawn from allopathic system of medicine and therefore it is not justifiable to put him in charge of other systems of medicine.

15.2 **The Committee fully agrees with the objections that appointing the DHS or an officer subordinate to him as the registrar will create a conflict of interest in view of the fact that Public Health Institutions are also required to be registered and regulated under the proposed legislation. This legislation is aimed at having far reaching consequences in the healthcare delivery system in India. A person can not be a judge of his own case. Therefore, there is justified apprehension that the Registrar might be biased while exercising his authority in respect of the Public Health Institutions. Further, it will not be proper to vest the sole power into a single member authority. The Committee, therefore, recommends constitution of a multi-member autonomous authority with a lean structure, consisting of representatives drawn from all recognized systems of medicine from the state services. This authority can be set up on the pattern of TRAI, Pollution Control Board and similar bodies. The authority may be headed by an officer of the rank and qualification of DHS drawn from any recognized system of medicine. Further, two representatives each of reputed state level consumer fora working in the field of healthcare for at least five years and registered association of private healthcare establishments may be included in the authority to have transparency. Such authority may be**

provided functional autonomy, staff and infrastructural requirement and can also be entrusted with appellate powers. The tenure of the members of the Authority may be for a period of five years.

16. Clause 10

16.1 This clause provides that every State shall designate the District Health Officer or the Chief Medical Officer (by whatever name called) as the District Registering Authority for each district for registration of clinical establishments.

16.2 Several entities have cited that the clause will lead to conflict of interest as cited in Clause 8. Further, representation has been sought for IMA and private practitioners. It has also been pointed out that such a provision indirectly may be somewhat unfavourable for other systems of medicine. Reason being that everywhere the District Health Officer or the Chief Medical Officer represents the allopathic system. The Committee is also inclined to agree with this contention. **The Committee, therefore, recommends replication of the model of Authority under clause 8 at the District level also.**

17. Clause 11

17.1 This clause provides that no person shall carry on a healthcare establishment unless it has been duly registered in accordance with the provisions of this Act. As per the Explanation to this clause, the term 'carry on' means to admit patients in a clinical establishment for providing treatment, diagnosis or nursing care.

17.2 Committee's attention was drawn to the inherent ambiguity in the clause due to the Explanation by a number of stakeholders. By virtue of this Explanation, only clinical establishments having the facility of indoor treatment seemed to be covered by the proposed Act. The main objection of various stakeholders under this clause is on the explanation appended to it. The explanation is resulting in ambiguity that only establishments with facility of admission are referred to here. On a specific query in this regard, the Ministry clarified that the legislation covered all the clinical establishments as defined under clause 2(c) including those providing OPD services only.

17.3 The Committee is of the opinion that clause 11 requires redrafting in the following manner

“No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.”

With the redrafted clause 11, there is no need for adding an Explanation to it which was resulting in unnecessary complications and apprehensions.

18. Clause 12

18.1 This clause provides that every clinical establishment shall fulfil the minimum standards of facilities and services; minimum qualifications for the personnel; provisions for maintenance of records and reporting and such other conditions as may be prescribed.

18.2 Apprehensions were expressed by quite a few stakeholders with regard to viability of fulfillment of minimum conditions by every clinical establishment as enumerated in clause 12. It was pointed out that non-availability of required qualified para-medical staff, specially in rural and remote areas will prove to be a great hurdle in the running of a large number of clinical establishments after the enactment of the Bill. It was, accordingly, suggested that some consideration needed to be there for such personnel. **The Committee accepts the need for adherence to the minimum standards by the clinical establishments as prescribed by the National Council. The main objective of the legislation is to have a regulatory body so as to make available quality health care to the people. The Committee would, however, like to point out that the task of prescribing minimum standards has to be accomplished in a time-bound manner. Secondly, the Committee fails to comprehend the need for prescribing the minimum qualifications for the personnel working in the clinical establishments. The Committee would like to point out that minimum qualifications for both medical and para-medical personnel are already duly prescribed by the concerned regulatory bodies and authorities. Clause 12 may be modified accordingly.**

19. Clause 13

19.1 This clause provides for classification of clinical establishments into different categories and provides that different standards may be prescribed to the establishments as per local conditions.

19.2 On a specific query regarding introduction of the concept of 'local conditions' under clause 13(2), the Department replied that this is an enabling provision and depending upon deliberations in the National Council, local conditions such as geographical conditions, availability of doctors/nurses etc. can be taken into consideration while finalizing minimum standards. **While accepting the need for taking care of local conditions while prescribing standards for clinical establishments, the Committee has a word of caution. The Committee strongly feels that this prerogative needs to be in the hands of the National Council only.**

Otherwise there is every chance of standards getting diluted, thus defeating the very objective of bringing this legislation. Once the initial action as enumerated in clause 5 has been completed by the National Council in a time-bound manner, the power for periodic review and resultant modifications should continue to be vested with the National Council. Element of any change in the context of local conditions should also be the responsibility of the National Council only.

20. Clause 14

20.1 Clause 14 lays down the procedure for giving of applications for provisional certificate of registration. Committee believes that the purpose of this provision is to provide sufficient time to the existing healthcare establishments, which may or may not be registered under other state legislations, to comply with the new standards under this new legislation. The Committee welcomes the same and suggests that the procedure/ application proforma should be made simple along with nominal fees in order to encourage/motivate healthcare establishments to get them registered.

20.2 The Committee also apprehends the misuse of the facility of provisional registration. Implementation of clause 16(1), would mean that no preliminary enquiry is required to be conducted by the authority for granting of provisional registration and thereby legally enabling an establishment to run without any check and accountability. Thus the offenders can take advantage of this by shifting their base after every three years and avoid a permanent registration altogether. Clause 16 when interpreted along with clause 17 regarding validity of provisional registrations and clause 23 relating to time-limit for provisional registration would literally mean that any clinical establishment can continue to function without any enquiry whatsoever on the basis of provisional registration for years together. The Committee can well imagine the time likely to be taken for the clinical standards to be notified. A clinical establishment continuing to function for three years after notification of standards without undergoing any kind of verification can not be considered justifiable from any quarter. The Committee is of the firm view that provisional registration should be a one time affair given for the minimum possible time, maximum for one year with no facility for further extension of time. Therefore, the Committee recommends that provisional registration should be allowed till the standards are made and once these standards are fixed; no provisional registration should be allowed. The facility of provisional registration should be aimed at/ confined to the existing establishments in order to enable them to adhere to the new standards. Any new

establishment that comes up subsequent to fixing and notification of standards should not be subjected to the process of provisional registration. Therefore, Clause 14(1) should categorically state that provisional registration is meant for establishments at the time of enactment of the legislation and till the standards are notified, whichever is later. Similar facility may be given to all the establishments of a State which adopts this legislation on a later date.

20.3 Several stakeholders advocated for a compulsory online procedure for registration, which, in the opinion of the Committee, is not practical due to ground realities like non-availability of infrastructural support etc. across the length and breadth of the country.

20.4 Some entities have called for a review of sub-clause 14(5) in view of some existing State laws which will lead to duplication. The Committee after carefully examining the matter concludes that the very purpose of legislation is to have uniform health standards throughout the country. Moreover, it is up to the State Governments to align with the proposed legislation. The Committee, accordingly, recommends no change in clause 14(5). However, the Committee has some reservations about clause 14(4) as per which any clinical establishment in existence at the time of the commencement of the Act, shall have to apply for registration within one year. The Committee strongly feels that giving of one year's time for simply filing an application is not justified. It would have been appropriate if it has been made mandatory for clinical establishment to apply for registration within the minimum required period; one month of commencement of the Act. The Committee, therefore, recommends that clause 14(4) may be modified accordingly.

21. Clause 20

21.1 Clause 20 lays down that certificate of registration shall be non-transferable and in the event of change of ownership/ change of category/ change of management/ ceasing to function as a clinical establishment, fresh application for grant of certificate of registration shall be required. Objections have been raised regarding the need for applying afresh in the event of change of ownership or management of a health care establishment due to unnecessary paperwork and procedural delays. The Committee is fully inclined to agree with the view that there should be no requirement for applying afresh in case of a mere change of ownership or management. However, there should be a provision whereunder prior intimation may be made mandatory for such a change. With regard to the change of category, location of clinical establishment or ceasing of its functioning, the matter has to be dealt with on a different footing. The Committee feels that such structural changes are required to be

looked into afresh. The Committee, accordingly, recommends that clause 20 may be modified so as to provide for surrender of the certificate of registration followed by grant of fresh certificate in case of change of category of clinical establishment or on its ceasing to function as such an establishment.

22. Clause 21

22.1 The Committee notes that the Clause provides for the publication of healthcare establishments whose registration would be expiring within the next forty-five days. **The Committee feels that the expression “within next 45 days” is difficult to comply with as it means the list would be updated on a daily basis and therefore complying with such a provision is not practicable unless the list is published on the Net through a computer programme. The Committee feels that the provision needs further elaboration for the sake of clarity.**

23. Clause 22 and 23

23.1 These clauses provide for application for renewal of certificate of provisional registration and procedure therefore and time-limit for provisional registration.

23.2 In view of Committee’s observations with regard to clauses 14, 16 and 17, Clauses 22 and 23 need to be deleted.

24. Clauses 25 and 26

24.1 Clause 25 prescribes for submission of evidence regarding compliance of prescribed minimum standards by the clinical establishments. Clause 26 provides for display of information as submitted by the clinical establishments for permanent registration for filing objections, if any, by the public, within a stipulated time. Following objections/suggestions were received by the Committee in respect of the same:

- Bill pushes onto the “public at large” the entire responsibility for verifying compliance with minimum standards while public authorities have no obligation to inspect the establishments.
- The provisions of this clause may be misused by business rivals or vested interests to raise false and fictitious objections and utilizing the same towards ‘bargaining and blackmailing’ purposes. Therefore this clause needs to be deleted.
- A penalty clause may be incorporated against those persons who file frivolous, motivated and baseless complaints.

24.2 The Committee, after wide range of deliberations with various stakeholders, has come to the conclusion that though some

objections/suggestions hold ground, the voice raised by various stakeholders for deletion of this clause entirely, is not convincing. The requirement is to have sufficient mechanism to prevent misuse. Further, the responsibility of the Authority regarding compulsory inspection needs to be framed. The issue of probable misuse of this clause by business rivals or vested interests was taken up with the Ministry which stated that the provision has been made to have transparency in the system. As inspection of the clinical establishments is not being made mandatory before grant of registration, it is felt that such objections from public will be a good idea to keep a check on the standards of the clinical establishments.

24.3 The Committee is of the view that there is no harm in displaying the information pertaining to the healthcare establishments; on the contrary in this era of transparency and accountability, it is the need of the hour. The Committee, therefore, recommends that such information pertaining to the establishments should be displayed on a dedicated website. Further, after registration also, such details may be kept updated on net regarding all establishments for public display to ensure transparency.

24.4 The Committee, however, does not agree with the view of not having any obligation on the part of the Authority to conduct any inspection prior to grant of permanent registration. The Authority can not shy away from its responsibility. Further, in the opinion of the Committee, it may lead to corrupt practices. The Committee, accordingly, favours and strongly recommends that no permanent registration should be granted unless inspection has been carried out by the Authority. Moreover, the inspection report should be made public through net alongwith the details of the inspecting personnel. The status related to the follow up action should also be made available on net alongwith usual procedure. This would allay fears of the private medical practitioners that the inspection clause would lead to corruption and bias. It would further strengthen their accountability.

24.5 A point of view placed before the Committee to check frivolous, motivated and baseless complaints was to have a penalty clause against those who file such complaints. The Committee fully supports the apprehensions raised. However, the Committee is of the view that such cases might be covered under other provisions of IPC Act or Cr PC. The Committee, therefore, recommends the Department to take up the case with the Law Ministry and explore possibility of a penalty clause in the Act.

25. Clause 27

25.1 This clause provides for communication of objections received by the authority to the clinical establishments. **In this clause it has been stated that objections shall be communicated to the clinical establishment for response within a period, as may be prescribed. The Ministry is of the view that such period shall be provided in the rules. The Committee recommends that in order to have clarity and for leaving no scope for ambiguity or manipulation, such details should be provided for in the Act itself. Consequential changes in other clauses may be made accordingly.**

26. Clause 30

26.1 This clause provides for issuing certificate of permanent registration if the application for registration of clinical establishment is allowed.

26.2 The Committee recommends that as given under various clauses for provisional registration, clauses or sub-clauses on similar lines relating to validity of the permanent registration certificate, display of registration certificate, its non-transferability and publication of expiry of registration should be provided in the Act itself.

26.3 During its interaction with various stakeholders one unanimous view which emerged was that certificate of registration even being permanent has to be renewed, keeping in view the crucial aspect of healthcare of general masses involved. **The Committee also strongly feels that no registration can be for an indefinite period. Mechanism for renewal of certificate of registration has to be incorporated specially in the Act itself. On a specific query in this regard, the Ministry clarified that such a mechanism would be included in the Rules. The Committee is not inclined to agree with the view of the Ministry in this regard. The Committee is of the view that such a provisions should be part of the Act itself. The Committee, therefore, recommends that a provision regarding period of five years for renewal of the permanent registration certificate may be inserted at the relevant place in the Bill.**

27. Clause 32

27.1 This clause provides for issuing a show cause notice and subsequent cancellation of registration under certain conditions.

27.2 The Committee has received several representations regarding possible misuse of “reasonable opportunity” under clause 32(2) and have requested for its proper definition. **The Committee is of the view that no single time limit can be fixed for all types of cases where the establishments are required to respond to the show cause notice of the Authority, which can vary from 2-3 days to say a month. The Committee, accordingly, recommends insertion of suitable timeframe in**

the rules to be made in this regard alongwith safeguard from its possible misuse by the habitual offenders.

27.3 The Committee also finds an important omission in the clause. The present provision of the clause calls for action only after a due process is followed. There may be a situation when the situation demands immediate action on the part of the Authority even before following the due procedure. Therefore, some kind of enabling provision should be there for temporary suspension which can be applied under grave situations in Public Interest.

27.4 In view of the above, the Committee recommends inclusion of provisions for immediate temporary suspension which can be applied by the appropriate authority under grave situations in Public Interest, without following the due procedure.

28. Clause 33

28.1 This clause provides for inspection of registered clinical establishments by the registering authority or an officer authorised by it and intimating the inspection report to the clinical establishment.

28.2 Apprehensions were expressed by a number of stakeholders about vesting of power of inspection in an authority or officer, specially in view of the complex area of healthcare with its variety of specialties/ super-specialties. Even otherwise there were chances of misuse of this power entrusted to a single person. It was, accordingly, suggested that an inspection team instead of an individual authority may be involved in this exercise. The Department on a specific query in this regard clarified that the registering authority will be provided with sufficient staff and other infrastructure. Also in the long run, the system will become self-sustaining and all expenditure will be got recovered in the form of fees.

28.3 The Committee is of the opinion that instead of a single person/ authority, an inspection team comprising of experts well-versed with all aspects of healthcare needs to be involved in the task of inspection of clinical establishments. The Committee understands that for inspection of medical colleges, inspection teams are sent. Position must be the same in respect of other similar areas also. The Committee, therefore, recommends that clause 33(1) may be modified accordingly. If need be, appropriate provision in the rules may also be made.

28.4 The matter of absence of time-limits at various stages like communication of inspection report, follow-up action and final directions etc. was also taken up and it was stated that these details will be provided for in the rules to be framed under the legislation. Also the periodicity of inspection is not mentioned anywhere. **As the Act does not put liability on the Authority to carry out inspections, the Committee favours**

introduction of a sub-clause to incorporate a provision for some periodic inspection by the authority being made mandatory. This will help in keeping a check on the establishments. The Committee, accordingly, recommends inspection of all healthcare establishments prior to giving permanent registration and subsequently at least once in a period of two years.

28.5 Under clause 33(4), it is not mentioned that in what time-frame the establishment is required to comply with the directions of the Authority. Therefore at the end of this para of the sub-clause “within such time as indicated in the direction” may be added. This would remove any ambiguity in this regard.

29. Clause 34

29.1 This clause provides that the registering authority or an officer authorized by it may enter and search any clinical establishment suspecting of not being registered under the provisions of this Act.

29.2 The Committee has received several representations wherein it has been stated that no notice may be given for inspection. However, contrary views have also been received from various other stakeholders like this clause is undesirable and may be reconsidered and a notice period of at least two days may be given.

29.3 The Committee after careful deliberations is of the view that this clause is necessary to have a check on the establishments running without proper registration certificate. Therefore, the Authority needs to be provided with power to enter and search such establishments which are suspected to be running without registration. As regards provision of notice, it is necessary in order to allay fears among genuine healthcare establishments of any misuse of power by the Authority. The Committee also recommends to include the various powers like that of search, seizure etc. in the Act itself so as to make the powers comprehensive and effective and not subject to litigations and interpretations.

30. Clause 35

30.1 This clause provides for fees to be charged from the healthcare establishments by the registering authority and remittance of its two per cent to the National Council. The Committee has received several suggestions regarding the figure of two per cent remittance to the National Council to be on the lower side; fees could escalate the cost of treatment and there have been suggestions like variation in fees structure according to grading or classification of establishments on the basis of beds and facilities.

30.2 The Committee opines that it is for the National Council to examine the issue of classification of different healthcare establishments

with due care for the local conditions. However, the Committee is aware that the Department might have carefully arrived at the figure of two percent for remittance to the National Council. Therefore, there is no need to comment on its appropriateness. The Committee also feels that the issue of fees should be taken care of in the right earnest so that the cost of treatment does not escalate, especially in case of small establishments which are catering to the healthcare requirements of the masses in rural and remote areas. The Committee, accordingly, recommends that feasibility of suitable fee relaxation to be given to the establishments being set up by the charitable institutions, establishments providing free treatment to poor patients and establishments being run in rural and remote areas, may be examined by the Department and necessary modifications be carried out accordingly.

30.3 The Committee notes that under clause 35(3) it is written that “it shallon time.” The word “on time” means that fees should be remitted to the National Council on a specific day; the clause however aims at remittance of fees within due time. Therefore, the sub-clause may be modified as – “ Itthat the amount referred to in sub-section (2), is remitted to the National Council, in time.”

31. Clause 36

31.1 This clause provides for an appeal to the State Government by any person aggrieved by an order of the registering authority.

31.2 After a close scrutiny, the Committee finds that the clause needs drastic modifications. The Committee observes that there is no logic in making the State Government as the appellate authority when there is next higher authority in the form of State Registrar. Further, the important omission is timeline for preferring an appeal. Besides, the provision for appeal under clause 36(1) does not cover other powers of the authority like for enquiry, inspection etc and also does not cover any other entity like patients, NGOs etc. other than aggrieved by the order of Registering Authority. Moreover, Committee notes that no appeal mechanism in respect of these penalties arising out of the provisions from clause 40 to 46 has been provided.

31.3 The Committee strongly recommends that in view of its recommendation that the State Registrar should be a multi-member body having Appellate powers; all the appeals should be made to the State Registrar in place of the State Government. The Committee recommends that besides cases pertaining to persons aggrieved by the order of Registering Authority regarding refusal to grant or renewal or revoking of the certificate of registration, the clause should be suitably

modified to include provision of appeal from the NGOs/ Public/ Local residents etc. who have filed their objections under clause 26. The Committee would also like to point out that patients/ their care takers may also be allowed to have the right to appeal in case of medical negligence on the part of clinical establishment. Necessary modification in clause 36 may, accordingly, be made

31.4 The Committee also recommends that the procedure for appeal should also be available for penalties arising out of the provisions under clause 40 to 46. In order to have transparency in the system, the Committee also recommends that the period of preferring an appeal should be one month from the date of order of refusal to grant, renew or revoke certificate of registration to a healthcare establishment or, in case of patients or NGOs etc. the verdict of the Registering Authority. Further, the appeals filed with the State Registrar should be disposed of within a period of two months from the date of such filing.

32. Clause 38

32.1 This clause provides that every State shall maintain register of clinical establishments in digital or in such other form and supply of information to the Central Government.

32.2 Sub-clause 38(2) states that “Every State and shall inform the Central Government without delay of all additions to and other amendments in such register made, from time to time.” **In the opinion of the Committee ‘without delay’ leaves scope for personal interpretation. It should be specific. Therefore, the Committee recommends that the sub-clause should be modified suitably as under-**

“(2) Every State shall supply in digital format to the Central Government, a copy of the State register of healthcare establishments and shall inform the Central Government, all additions to and other amendments in such register made for a particular month, by the 15th day of the following month.

This will ensure timely updation of the National Register and proper compliance by the State Registrars.

33. Clause 39

33.1 This clause provides for maintenance of national register for clinical establishments in digital format by the Central Government.

33.2 The Committee recommends that the National Register of the entire healthcare establishments should be displayed on the dedicated website for the purpose, State-wise. This would enable the general public to have an idea about the genuine establishments in their area.

34. Clause 40

34.1 The clauses 40-46 deal with the penalties. These are dealt with under the chapter V- “Register of Clinical Establishments”. In the opinion of the Committee, penalties should be dealt with under a separate chapter.

34.2 Clause 40 provides for penalty for contravention of any of the provisions of this Act. The Committee received divergent views of stakeholders on the penalty provisions. Many stakeholders were of the view that the provisions need to have more teeth by having provision of imprisonment so as to have a deterrent effect on habitual offenders. Others were of the view that the penalties were exorbitant and the same would be out of reach of the paying capacity of the smaller establishments.

34.3 The Committee during its course of deliberations with various stakeholders had discussed the issue threadbare and has reached to the conclusion that the purpose of penalties should be to ensure strict compliance of various health standards along with other provisions of the Act. At the same time, the Committee also aligns with the apprehensions of various stakeholders that the penalties cannot be made applicable on a uniform basis in respect of all categories of clinical establishments. Accordingly, the Committee recommends that the Ministry while framing rules in regard to penalties, should come up with detailed provisions varying the monetary penalties according to size, type and local conditions of the area in which the healthcare establishments are situated.

34.4 The Committee is of the opinion that sufficient provisions have been incorporated under Clauses 32 and 33 for providing appropriate opportunity to the healthcare establishments to rectify their shortcomings. Therefore, the Committee recommends that the penalty provisions should be invoked only after giving them the appropriate opportunity to rectify in case of registered healthcare establishments.

34.5 On a specific query on not having penalty of imprisonment, the Department responded that this has been done to assure the medical fraternity that this Bill will not be having an Inspector-Raj and will not be an impediment to their functioning. However, in view of the aforesaid fact that the penalties would be applied only after giving sufficient opportunity for rectification, the Committee differs with the view of the Department. Suitable penalties are must in the form of imprisonment for habitual offenders in order to instill sense of adherence to the provision of the Act. Accordingly, the Committee recommends enhancement of penalty for second offence as “upto 1 Lakh rupees” and for the third offence “upto 3 Lakh rupees alongwith

imprisonment upto six months” and for subsequent offence, “upto Rs. 6 Lakh alongwith upto two years of imprisonment”.

35. Clause 41

35.1 Clause 41(1) is about penalty for non-registration. It provides that conviction for first offence would invite a fine up to fifty thousand rupees, for second offence with fine which may extend to two lakh rupees and for any subsequent offence with fine which may extend to five lakh rupees. Clause 41(2) provides that whoever knowingly serves in a establishment which is not duly registered under this Act, shall be punishable with fine which may extend to twenty-five thousand rupees.

35.2 **In the opinion of the Committee, the clause only provides for penalty that too monetary in nature. It does not have any provision so as to ensure registration subsequent to the detection of an unregistered establishment. The Committee accordingly recommends that alongwith penalty of fifty thousand rupees at first conviction, a time limit of one fortnight may be provided to the establishment to apply for registration under the Act. If the establishment does not apply for registration during the said period and still continues to function, it may be subjected to penalty for second offence which may include “upto two lakh rupees alongwith seizure of equipments and machinery etc. and upto six months of imprisonment” and for subsequent offence, “upto five lakh rupees alongwith seizure of equipments and machinery etc. and imprisonment upto two years”. The Committee’s recommendation under clause 40 regarding varying the monetary penalties according to size, type and local conditions of the area in which the healthcare establishments are situated and the imprisonment according to the gravity of the offence, may also be applied here.**

35.3 **In the opinion of the Committee clause 41 (2), in its present form, would also be applicable to the supporting staff like peons, sweepers and other staff providing non-technical services that are generally illiterate or comparatively less educated. Therefore, in order to save such staff from harassment, the Committee recommends exclusion of such staff from the purview of this sub-clause. Further, the amount of penalties may be varied according to the responsibility/position held by the staff in the healthcare establishment.**

36. Clause 46

36.1 This clause provides for recovery of fines imposed under the Act as an arrear of land revenue. **The Committee is of the opinion that recovery of fine as arrears of land revenue would be a long process. This would provide sufficient time to the establishment to shift its base to some other place and start its activities afresh, thereby defeating the purpose**

of immediate results. Accordingly, the Committee recommends that recovery may also include forfeiture of assets of such Healthcare Establishment.

37. Clause 52

37.1 This clause empowers the Central Government to make rules for carrying out the provisions of the proposed legislation. The Committee observes that several state laws on healthcare subject were enacted but their relevant rules were framed after quite some time. The Committee, therefore, recommends to the Ministry to frame the requisite rules pertaining to the Act, within a period of six months from the date of its enactment.

37.2 The National Council is entrusted with the responsibility of determining the standards for healthcare establishments; classification of the establishments into different categories; develop the minimum standards and their periodic review; compile, maintain and update a national register of clinical establishments; collect the statistics in respect of clinical establishments and perform any other function determined by the Central Government, from time to time. In view of the role of the National Council, it is recommended that all the rules to be framed by the Government should be in consonance with the functions carried out by the National Council.

38. MISCELLANEOUS RECOMMENDATIONS MADE BY THE COMMITTEE

38.1 The Committee, during its interaction with various stakeholders has received a lot of positive feedbacks. After extensive deliberations, the Committee is of the view that the under mentioned provisions need to be examined in depth by the Department and wherever feasible, included in the Act and Rules thereunder:-

- A chapter on provision for patients' rights and duties of healthcare establishments should be there.**
- The information acquired in the course of enforcing this Act may be privileged and confidential. Hence, in order to protect the interests of the patients and the establishments, a confidentiality clause needs to be incorporated in the Act. Any information which has been obtained from any hospital, medical clinic, clinical laboratory or healthcare establishment in the course of carrying out any investigation or performing any duty or function under this Act should not be disclosed unless required to do so in case of**

- a prosecution for an offence under this Act or any regulations made there under.
- All the procedure with respect to application for registration, inspection and its follow-up, complaint mechanism and its follow-up, National Register etc. may be put on a dedicated website. This would make the entire process of registration, inspection and complaint transparent.
 - Committee notes that many tax exemptions are being provided to corporate and business entities that are setting up their business establishments under Special Economic Zones (SEZs). Similarly, in order to make health reach across the length and breadth of this vast country, motivation in the form of tax exemptions may be provided to healthcare establishments being opened in remote, backward and rural areas. The matter may, therefore be taken up with the Finance Ministry.
 - Maximum charges regarding the facilities available in the healthcare establishment alongwith contact details of the authority members to which any complaint may be made regarding non-adherence of the provisions of the Act, may be made mandatory to be displayed prominently at a conspicuous place preferably at the entrance of the establishment. Further, provision should be made to supply receipts of payments received alongwith the treatment/ diagnosis details to the patients.

RECOMMENDATIONS/OBSERVATIONS-AT A GLANCE

The clauses where the amendments have been suggested by the Committee are given in the succeeding paragraphs:- (Para10)

The Committee, after going through the objections and suggestions, observes that contrary to some of similar existing State laws, this is a comprehensive Central Legislation aimed at not only covering all categories of healthcare establishments but also practising all the recognized systems of medicine. Therefore, its title should be such which covers all the desired entities or reflects them through some common term. The word clinical, though it means related to medical, appears to be restrictive to allopathic clinics only.(Para 11.3)

In the opinion of the Committee, the word ‘healthcare’ takes care of most of the objections. Healthcare means related to health and it may be through any system of medicine and includes laboratory and diagnostic services also. Therefore, the Committee recommends that the title of the

Bill may suitably be changed as “The Healthcare Establishments (Registration and Regulation) Act, 2007” and the consequential changes be made in the Bill as well. (Para 11.4)

The Committee, therefore, recommends that the Government should make all out efforts in persuading all the States to adopt the Central Legislation so that uniformity in health standards is maintained across the length and breadth of the country. For this, financial as well as other infrastructural support, as and when required, may also be provided to the States to motivate them in adopting the same.(Para 11.5)

The Committee is, however, of the opinion that lack of categorical provision, further made ambiguous by another contradictory provision on this count does not substantiate the Ministry’s claim. The Committee would like to point out that the very purpose of the legislation would be diluted and defeated if the OPD services are not brought within its ambit. One must also not forget that with the significant advancements made in medical sciences and healthcare, even many surgical interventions do not require patient’s stay in the hospital/ nursing home. The Committee, therefore, is of the view that the definition of ‘clinical establishment’ under Clause 2(c)(i) and also the explanation given in clause 11 need to be suitably modified to remove the ambiguity.(Para 12.2)

Committee observes that many Healthcare Establishments are now a days also involved in independent Research & Development activities specially in the context of research in new drugs/ drug combinations followed by their clinical trial on patients. The Bill in its present form does not categorically provide for inclusion of these establishments under the definition of clinical establishments. The Committee strongly feels that their exclusion would be detrimental to the rights of the patients who form part of the experiments/research studies undertaken by such establishments. In view of this, the Committee recommends inclusion of R&D establishments in the definition of Healthcare Establishments. (Para 12.3)

The Committee is, however, not convinced by this line of thinking. Ground realities existing in our country in the context of health care facilities for general public need to be taken into account. A very high percentage of our population is dependent on the services provided by ‘single doctor establishments’ whether run from residences or other places. The implication of not bringing such establishments under the proposed legislation will prove to be detrimental to the interest of common man, the most vulnerable segment of our society. The registration is a one time activity and it will be renewable after a

sufficient gap. The Committee would also like to point out that such a move would also prove beneficial in the context of collecting vital and complete data regarding health scenario in the country and the statistics could be utilized in National level Planning. The Committee, therefore, is of the firm opinion that single doctor establishments need to be covered under this Act. (Para 12.4)

The Committee also finds no valid reasons for keeping establishments set up by partnerships, run by societies (other than co-operative), Charity/ Missionary, mobile units out of the ambit of the Bill. The Committee, therefore, recommends that such establishments may also be included in the definition of 'Healthcare Establishments'.(Para 12.5)

The Committee finds that under Clause 2(d) "National Council" is a very general nomenclature for the proposed Council and does not reflect the entire spectrum of the issues covered under the Bill. In consonance with its suggestions regarding the title in Clause 1, the Committee recommends that the National Council referred to in clause 2(d) and subsequently in other provisions, be changed as "National Council for Healthcare Establishments". (Para 12.6)

As regards appropriateness or otherwise of the applicability of the Bill to Defence Forces Establishments, the Committee respects the security concerns arising out of their inclusion under the ambit of the Bill. The Committee fully understands that parting with the details related to Army Health Establishments could be detrimental to nation's security. The Committee is also aware that military medical establishments and the medicare provided by them is subjected to internal checks and inspections by administrative and technical experts on a regular basis. The Committee, however, strongly feels that a feasible mechanism can be easily worked out whereunder all the armed forces medical establishments can be registered by maintaining secrecy/ confidentiality aspect also. The Committee, therefore, recommends that the Act should invariably be applied to all the Army Health Establishments except those based in the forward/ combat areas. (Para 12.7)

The Committee does not find any substance in exclusion of Government/Public Health Institutions/ Autonomous Institutions from the purview of the Act as put forth before it through some representations. The Committee has taken note of the fact that several of the existing laws in various States do not cover such institutions, thereby inviting criticisms for giving undue advantage to them. The Committee fully understands that the Public Health Institutions have some social obligations. They are also doing commendable job by

handling tremendous patient load under very demanding ground realities. It, however, does not favour their exclusion simply because such a move will lead to depriving the majority of the people having access to such establishments only, from the benefits of this Act to which they are rightfully entitled. The Committee would also like to emphasise that element of accountability which is not visible so far needs to be made applicable to all categories of medical establishments- whether Govt. or private. One must not forget that ultimate goal is 'Health for all'. (Para 12.9)

There is a drafting slippage in Clause 2(f) which may be modified as:-

“prescribed” means prescribed by rules made under this Act by the Central Government or, as the case may be, by the State Government; (Para 12.10)

The Committee, however, is not convinced by this line of thinking. The Committee would like to point out that the mere fact of there being no statutory regulatory authority at present does not mean that a well-established system having a wide acceptability increasing day-by-day among the masses cannot be considered a recognized system of medicine. The Committee, accordingly, recommends that the definition of 'recognised system of medicine' may remain unchanged. (Para 12.11)

The Committee notes that the National Council has to perform very crucial functions which include determination of standards of health care to be provided by the healthcare establishments and classification thereof. Not only this, the Council is also entrusted with the routine work of compilation, maintenance and updation of the national register of such establishments and collection of statistics likely to be used for future planning and corrective measures. The Committee strongly feels that the DGHS in his capacity as the Chairperson of the National Council would not be in a position to carry out its mandate. Reason being that as the Director General of Health Services, he has to take care of entire country in all the conceivable health related matters. The Committee is, accordingly, not in favour of a part-time Chairperson for the proposed National Council because the work relating to the National Council would be very demanding, especially at the initial stage of determining and developing minimum standards. The Committee is of the firm view that DGHS, who is already overburdened with official work, would not be able to do justice with this dual responsibility. Further, the Committee would also like to point out that such an arrangement is also likely to impinge upon the autonomy of the

Council. Taking the above factors into consideration, the Committee recommends appointment of a full time Chairperson, who has the required experience specially of hospital administration and has the rank and qualification equivalent to that of DGHS. (Para 13.2)

The Committee also feels that presence of representatives of reputed NGOs and consumer protection associations working in the health sector is very much required in such a body. The Committee, therefore, recommends that composition of the National Council may be modified accordingly. (Para 13.3)

Committee also takes note of the role of private sector in providing health care in the country. The Committee is well aware about the increasing involvement of hospitals/ institutions run by private management across the country. Nobody can deny the fact that with the limited resources available with the Govt., in the enormous task of providing health care to the general public, contribution of private sector is bound to become more visible with passage of time. In such a scenario, with all the stakeholders being part of the National Council, representation from eminent medical professionals from the private sector, preferably from the associations/ bodies of private hospitals/ nursing homes is very much required. The Committee, accordingly, recommends representation from the private sector. (Para 13.4)

The Committee feels that the National Council can draw useful inputs from QCI as it has a number of health professionals including assessors and experts on developing standards. Therefore, the QCI deserves to be represented in the proposed Council. Composition of the National Council may be modified so as to include one representative from the Quality Council of India. (Para 13.5)

Clause 3(2)(e) -The Committee notes that the sub-clause suffers from a factual deficiency under clause 3 which specifies the representation from the Central Council of the Indian Medical Association constituted under MCI Act, 1956. As is well known, IMA is a private association of allopathic doctors and not a statutory body created by legislation. The Committee, therefore, recommends that the sub-clause may, accordingly, be modified. The Committee would also recommend inclusion of at least one representative from similar Association representing Indian systems of medicine on a rotational basis. (Para 13.6)

In view of one representative each from Nursing Council of India and Pharmacy Council of India given representation *vide* clause 3(2)(b), it should be suitably modified to exclude representation from these two paramedical fields. The Committee is also surprised to note that with

all categories of laboratories being covered under the proposed legislation, their representative not finding a place in the National Council cannot be considered a justifiable move. The Committee can only emphasise that instead of there being a general provision, specific nomination from medical lab fraternity may be included under clause 3(2)(j). (Para 13.7)

Clause 3(2)(j)- The Committee notes that under Clause 2(g) Yoga and Naturopathy have been recognized as systems of medicine. However, there is no specific clause providing for their representation in the National Council under Clause 3. Keeping in view the fact that Yoga and Naturopathy providing efficacious, promotive, preventive and curative interventions are getting wider popularity among all classes of the society, the Committee finds absence of any clear mention of their representation in the proposed National Council untenable. The Committee, therefore, recommends that Clause 3(j) be amended to categorically mention that out of the three representatives proposed, one each from Yoga and Naturopathy shall find place in the Council. (Para 13.8)

The Committee is not in agreement with providing a shorter term of one year for the nominated members as against three years for elected members. The Committee is of the view that there should be uniform term for both the categories of members so as to enable them to have greater co-ordination and also to give adequate time to the nominated members to understand the nitty-gritty of the working of the Council and make meaningful contribution. The Committee, therefore, recommends a term of three years for the nominated members as well. (Para 13.9)

Clause 3(6)- The Committee favours giving full functional autonomy to the National Council. The Committee, therefore, recommends deletion of the words “subject to the previous approval of the Central Government” from this clause. The Committee also feels that quorum for the meetings of the National Council should be spelt out in unambiguous terms in the Act itself to strengthen the autonomy of the proposed Council. The Committee, therefore, recommends Clause 3(6) be amended to incorporate the quorum required for the meetings of the Council. (Para 13.10)

The Committee notes that the two main functions of the Council are to determine the standards for ensuring proper healthcare by the clinical establishments and also to develop the minimum standards and their periodic review. The Committee also takes note of the fact that minimum standards of the facilities and services are to be prescribed for registration and continuation of clinical establishments. The Committee

is, however, surprised to note the absence of any time-span for accomplishment of this crucial mandate in the Bill. The Committee can well imagine the situation emerging after the enactment of this Bill. The Committee can only conclude that fulfillment of the mandate of this Bill will continue to remain on paper for quite some time. The Committee would have appreciated if some basic minimum standards have been specified in the Bill itself which would have evolved and expanded as per the demand of the time. The Committee understands that some of the State Acts have such a provision of minimum standards. The Committee fails to understand the reason for not adopting the same. The Committee can only emphasise that this was very much required in such a legislation which was expected to be adopted by other State Govts also. The Committee would also like to draw the attention of the Ministry to the pioneering work accomplished by the two Boards of the Quality Council of India and the Bureau of Indian Standards. Norms and guidelines prescribed for health care by these bodies can easily become the base for laying down of minimum standards for health care. The Committee, accordingly, recommends that the Department may take necessary action in this regard by prescribing the minimum standards for health care. (Para 14.1)

The Committee fully agrees with the objections that appointing the DHS or an officer subordinate to him as the registrar will create a conflict of interest in view of the fact that Public Health Institutions are also required to be registered and regulated under the proposed legislation. This legislation is aimed at having far reaching consequences in the healthcare delivery system in India. A person can not be a judge of his own case. Therefore, there is justified apprehension that the Registrar might be biased while exercising his authority in respect of the Public Health Institutions. Further, it will not be proper to vest the sole power into a single member authority. The Committee, therefore, recommends constitution of a multi-member autonomous authority with a lean structure, consisting of representatives drawn from all recognized systems of medicine from the state services. This authority can be set up on the pattern of TRAI, Pollution Control Board and similar bodies. The authority may be headed by an officer of the rank and qualification of DHS drawn from any recognized system of medicine. Further, two representatives each of reputed state level consumer fora working in the field of healthcare for at least five years and registered association of private healthcare establishments may be included in the authority to have transparency. Such authority may be provided functional autonomy, staff and infrastructural requirement

and can also be entrusted with appellate powers. The tenure of the members of the Authority may be for a period of five years.(Para 15.2)

The Committee, therefore, recommends replication of the model of Authority under clause 8 at the District level also. (Para 16.2)

The Committee is of the opinion that clause 11 requires redrafting in the following manner

“No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.”

With the redrafted clause 11, there is no need for adding an Explanation to it which was resulting in unnecessary complications and apprehensions. (Para 17.3)

The Committee accepts the need for adherence to the minimum standards by the clinical establishments as prescribed by the National Council. The main objective of the legislation is to have a regulatory body so as to make available quality health care to the people. The Committee would, however, like to point out that the task of prescribing minimum standards has to be accomplished in a time-bound manner. Secondly, the Committee fails to comprehend the need for prescribing the minimum qualifications for the personnel working in the clinical establishments. The Committee would like to point out that minimum qualifications for both medical and para-medical personnel are already duly prescribed by the concerned regulatory bodies and authorities. Clause 12 may be modified accordingly. (Para 18.2)

While accepting the need for taking care of local conditions while prescribing standards for clinical establishments, the Committee has a word of caution. The Committee strongly feels that this prerogative needs to be in the hands of the National Council only. Otherwise there is every chance of standards getting diluted, thus defeating the very objective of bringing this legislation. Once the initial action as enumerated in clause 5 has been completed by the National Council in a time-bound manner, the power for periodic review and resultant modifications should continue to be vested with the National Council. Element of any change in the context of local conditions should also be the responsibility of the National Council only. (para 19.2)

Committee believes that the purpose of this provision is to provide sufficient time to the existing healthcare establishments, which may or may not be registered under other state legislations, to comply with the new standards under this new legislation. The Committee welcomes the same and suggests that the procedure/ application proforma should be made simple along with nominal fees in order to encourage/motivate healthcare establishments to get them registered. (Para 20.1)

The Committee also apprehends the misuse of the facility of provisional registration. Implementation of clause 16(1), would mean that no preliminary enquiry is required to be conducted by the authority for granting of provisional registration and thereby legally enabling an establishment to run without any check and accountability. Thus the offenders can take advantage of this by shifting their base after every three years and avoid a permanent registration altogether. Clause 16 when interpreted along with clause 17 regarding validity of provisional registrations and clause 23 relating to time-limit for provisional registration would literally mean that any clinical establishment can continue to function without any enquiry whatsoever on the basis of provisional registration for years together. The Committee can well imagine the time likely to be taken for the clinical standards to be notified. A clinical establishment continuing to function for three years after notification of standards without undergoing any kind of verification can not be considered justifiable from any quarter. The Committee is of the firm view that provisional registration should be a one time affair given for the minimum possible time, maximum for one year with no facility for further extension of time. Therefore, the Committee recommends that provisional registration should be allowed till the standards are made and once these standards are fixed; no provisional registration should be allowed. The facility of provisional registration should be aimed at/ confined to the existing establishments in order to enable them to adhere to the new standards. Any new establishment that comes up subsequent to fixing and notification of standards should not be subjected to the process of provisional registration. Therefore, Clause 14(1) should categorically state that provisional registration is meant for establishments at the time of enactment of the legislation and till the standards are notified, whichever is later. Similar facility may be given to all the establishments of a State which adopts this legislation on a later date. (Para 20.2)

Several stakeholders advocated for a compulsory online procedure for registration, which, in the opinion of the Committee, is not practical due to ground realities like non-availability of infrastructural support etc. across the length and breadth of the country.(Para 20.3)

The Committee after carefully examining the matter concludes that the very purpose of legislation is to have uniform health standards throughout the country. Moreover, it is up to the State Governments to align with the proposed legislation. The Committee, accordingly, recommends no change in clause 14(5). However, the Committee has some reservations about clause 14(4) as per which any clinical establishment in existence at the time of the commencement of the Act, shall have to apply for registration within one year. The Committee strongly feels that giving of one year's time for simply filing an application is not justified. It would have been appropriate if it has been made mandatory for clinical establishment to apply for registration within the minimum required period; one month of commencement of the Act. The Committee, therefore, recommends that clause 14(4) may be modified accordingly.(Para 20.4)

The Committee is fully inclined to agree with the view that there should be no requirement for applying afresh in case of a mere change of ownership or management. However, there should be a provision whereunder prior intimation may be made mandatory for such a change. With regard to the change of category, location of clinical establishment or ceasing of its functioning, the matter has to be dealt with on a different footing. The Committee feels that such structural changes are required to be looked into afresh. The Committee, accordingly, recommends that clause 20 may be modified so as to provide for surrender of the certificate of registration followed by grant of fresh certificate in case of change of category of clinical establishment or on its ceasing to function as such an establishment. (Para 21.1)

The Committee feels that the expression “within next 45 days” is difficult to comply with as it means the list would be updated on a daily basis and therefore complying with such a provision is not practicable unless the list is published on the Net through a computer programme. The Committee feels that the provision needs further elaboration for the sake of clarity.(Para 22.1)

In view of Committee's observations with regard to clauses 14, 16 and 17, Clauses 22 and 23 need to be deleted. (Para 23.2)

The Committee is of the view that there is no harm in displaying the information pertaining to the healthcare establishments; on the contrary in this era of transparency and accountability, it is the need of the hour. The Committee, therefore, recommends that such

information pertaining to the establishments should be displayed on a dedicated website. Further, after registration also, such details may be kept updated on net regarding all establishments for public display to ensure transparency. (Para 24.3)

The Committee, however, does not agree with the view of not having any obligation on the part of the Authority to conduct any inspection prior to grant of permanent registration. The Authority can not shy away from its responsibility. Further, in the opinion of the Committee, it may lead to corrupt practices. The Committee, accordingly, favours and strongly recommends that no permanent registration should be granted unless inspection has been carried out by the Authority. Moreover, the inspection report should be made public through net alongwith the details of the inspecting personnel. The status related to the follow up action should also be made available on net alongwith usual procedure. This would allay fears of the private medical practitioners that the inspection clause would lead to corruption and bias. It would further strengthen their accountability. (Para 24.4)

A point of view placed before the Committee to check frivolous, motivated and baseless complaints was to have a penalty clause against those who file such complaints. The Committee fully supports the apprehensions raised. However, the Committee is of the view that such cases might be covered under other provisions of IPC Act or Cr PC. The Committee, therefore, recommends the Department to take up the case with the Law Ministry and explore possibility of a penalty clause in the Act. (Para 24.5)

In this clause it has been stated that objections shall be communicated to the clinical establishment for response within a period, as may be prescribed. The Ministry is of the view that such period shall be provided in the rules. The Committee recommends that in order to have clarity and for leaving no scope for ambiguity or manipulation, such details should be provided for in the Act itself. Consequential changes in other clauses may be made accordingly. (Para 25.1)

The Committee recommends that as given under various clauses for provisional registration, clauses or sub-clauses on similar lines relating to validity of the permanent registration certificate, display of registration certificate, its non-transferability and publication of expiry of registration should be provided in the Act itself. (Para 26.2)

The Committee also strongly feels that no registration can be for an indefinite period. Mechanism for renewal of certificate of registration has to be incorporated specially in the Act itself. On a specific query in this regard, the Ministry clarified that such a mechanism would be included in the Rules. The Committee is not inclined to agree with the view of the Ministry in this regard. The Committee is of the view that such a provisions should be part of the Act itself. The Committee, therefore, recommends that a provision regarding period of five years for renewal of the permanent registration certificate may be inserted at the relevant place in the Bill. (Para 26.3)

The Committee is of the view that no single time limit can be fixed for all types of cases where the establishments are required to respond to the show cause notice of the Authority, which can vary from 2-3 days to say a month. The Committee, accordingly, recommends insertion of suitable timeframe in the rules to be made in this regard alongwith safeguard from its possible misuse by the habitual offenders. (Para 27.2)

The Committee also finds an important omission in the clause. The present provision of the clause calls for action only after a due process is followed. There may be a situation when the situation demands immediate action on the part of the Authority even before following the due procedure. Therefore, some kind of enabling provision should be there for temporary suspension which can be applied under grave situations in Public Interest.(Para 27.3)

In view of the above, the Committee recommends inclusion of provisions for immediate temporary suspension which can be applied by the appropriate authority under grave situations in Public Interest, without following the due procedure. (Para 27.4)

The Committee is of the opinion that instead of a single person/ authority, an inspection team comprising of experts well-versed with all aspects of healthcare needs to be involved in the task of inspection of clinical establishments. The Committee understands that for inspection of medical colleges, inspection teams are sent. Position must be the same in respect of other similar areas also. The Committee, therefore, recommends that clause 33(1) may be modified accordingly. If need be, appropriate provision in the rules may also be made. (Para 28.3)

As the Act does not put liability on the Authority to carry out inspections, the Committee favours introduction of a sub-clause to incorporate a provision for some periodic inspection by the authority being made mandatory. This will help in keeping a check on the establishments. The Committee, accordingly, recommends inspection of

all healthcare establishments prior to giving permanent registration and subsequently at least once in a period of two years. (Para 28.4)

Under clause 33(4), it is not mentioned that in what time-frame the establishment is required to comply with the directions of the Authority. Therefore at the end of this para of the sub-clause “within such time as indicated in the direction” may be added. This would remove any ambiguity in this regard. (Para 28.5)

The Committee after careful deliberations is of the view that this clause is necessary to have a check on the establishments running without proper registration certificate. Therefore, the Authority needs to be provided with power to enter and search such establishments which are suspected to be running without registration. As regards provision of notice, it is necessary in order to allay fears among genuine healthcare establishments of any misuse of power by the Authority. The Committee also recommends to include the various powers like that of search, seizure etc. in the Act itself so as to make the powers comprehensive and effective and not subject to litigations and interpretations. (Para 29.3)

The Committee opines that it is for the National Council to examine the issue of classification of different healthcare establishments with due care for the local conditions. However, the Committee is aware that the Department might have carefully arrived at the figure of two percent for remittance to the National Council. Therefore, there is no need to comment on its appropriateness. The Committee also feels that the issue of fees should be taken care of in the right earnest so that the cost of treatment does not escalate, especially in case of small establishments which are catering to the healthcare requirements of the masses in rural and remote areas. The Committee, accordingly, recommends that feasibility of suitable fee relaxation to be given to the establishments being set up by the charitable institutions, establishments providing free treatment to poor patients and establishments being run in rural and remote areas, may be examined by the Department and necessary modifications be carried out accordingly. (Para 30.2)

The Committee notes that under clause 35(3) it is written that “it shallon time.” The word “on time” means that fees should be remitted to the National Council on a specific day; the clause however aims at remittance of fees within due time. Therefore, the sub-clause may be

modified as – “ Itthat the amount referred to in sub-section (2), is remitted to the National Council, in time.” (Para 30.3)

After a close scrutiny, the Committee finds that the clause needs drastic modifications. The Committee observes that there is no logic in making the State Government as the appellate authority when there is next higher authority in the form of State Registrar. Further, the important omission is timeline for preferring an appeal. Besides, the provision for appeal under clause 36(1) does not cover other powers of the authority like for enquiry, inspection etc and also does not cover any other entity like patients, NGOs etc. other than aggrieved by the order of Registering Authority. Moreover, Committee notes that no appeal mechanism in respect of these penalties arising out of the provisions from clause 40 to 46 has been provided. (Para 31.2)

The Committee strongly recommends that in view of its recommendation that the State Registrar should be a multi-member body having Appellate powers; all the appeals should be made to the State Registrar in place of the State Government. The Committee recommends that besides cases pertaining to persons aggrieved by the order of Registering Authority regarding refusal to grant or renewal or revoking of the certificate of registration, the clause should be suitably modified to include provision of appeal from the NGOs/ Public/ Local residents etc. who have filed their objections under clause 26. The Committee would also like to point out that patients/ their care takers may also be allowed to have the right to appeal in case of medical negligence on the part of clinical establishment. Necessary modification in clause 36 may, accordingly, be made. (Para 31.3)

The Committee also recommends that the procedure for appeal should also be available for penalties arising out of the provisions under clause 40 to 46. In order to have transparency in the system, the Committee also recommends that the period of preferring an appeal should be one month from the date of order of refusal to grant, renew or revoke certificate of registration to a healthcare establishment or, in case of patients or NGOs etc. the verdict of the Registering Authority. Further, the appeals filed with the State Registrar should be disposed of within a period of two months from the date of such filing. (Para 31.4)

In the opinion of the Committee ‘without delay’ leaves scope for personal interpretation. It should be specific. Therefore, the Committee recommends that the sub-clause should be modified suitably as under-

“(2) Every State shall supply in digital format to the Central Government, a copy of the State register of healthcare establishments and shall inform the Central Government, all additions to and other amendments in such register made for a particular month, by the 15th day of the following month.

This will ensure timely updation of the National Register and proper compliance by the State Registrars. (Para 32.2)

The Committee recommends that the National Register of the entire healthcare establishments should be displayed on the dedicated website for the purpose, State-wise. This would enable the general public to have an idea about the genuine establishments in their area. (Para 33.2)

The clauses 40-46 deal with the penalties. These are dealt with under the chapter V- “Register of Clinical Establishments”. In the opinion of the Committee, penalties should be dealt with under a separate chapter. (Para 34.1)

The Committee during its course of deliberations with various stakeholders had discussed the issue threadbare and has reached to the conclusion that the purpose of penalties should be to ensure strict compliance of various health standards along with other provisions of the Act. At the same time, the Committee also aligns with the apprehensions of various stakeholders that the penalties cannot be made applicable on a uniform basis in respect of all categories of clinical establishments. Accordingly, the Committee recommends that the Ministry while framing rules in regard to penalties, should come up with detailed provisions varying the monetary penalties according to size, type and local conditions of the area in which the healthcare establishments are situated. (Para 34.3)

The Committee is of the opinion that sufficient provisions have been incorporated under Clauses 32 and 33 for providing appropriate opportunity to the healthcare establishments to rectify their shortcomings. Therefore, the Committee recommends that the penalty provisions should be invoked only after giving them the appropriate opportunity to rectify in case of registered healthcare establishments. (Para 34.4)

On a specific query on not having penalty of imprisonment, the Department responded that this has been done to assure the medical fraternity that this Bill will not be having an Inspector-Raj and will not be an impediment to their functioning. However, in view of the aforesaid fact that the penalties would be applied only after giving

sufficient opportunity for rectification, the Committee differs with the view of the Department. Suitable penalties are must in the form of imprisonment for habitual offenders in order to instill sense of adherence to the provision of the Act. Accordingly, the Committee recommends enhancement of penalty for second offence as “upto 1 Lakh rupees” and for the third offence “upto 3 Lakh rupees alongwith imprisonment upto six months” and for subsequent offence, “upto Rs. 6 Lakh alongwith upto two years of imprisonment”. (Para 34.5)

In the opinion of the Committee, the clause only provides for penalty that too monetary in nature. It does not have any provision so as to ensure registration subsequent to the detection of an unregistered establishment. The Committee accordingly recommends that alongwith penalty of fifty thousand rupees at first conviction, a time limit of one fortnight may be provided to the establishment to apply for registration under the Act. If the establishment does not apply for registration during the said period and still continues to function, it may be subjected to penalty for second offence which may include “upto two lakh rupees alongwith seizure of equipments and machinery etc. and upto six months of imprisonment” and for subsequent offence, “upto five lakh rupees alongwith seizure of equipments and machinery etc. and imprisonment upto two years”. The Committee’s recommendation under clause 40 regarding varying the monetary penalties according to size, type and local conditions of the area in which the healthcare establishments are situated and the imprisonment according to the gravity of the offence, may also be applied here. (Para 35.2)

In the opinion of the Committee clause 41 (2), in its present form, would also be applicable to the supporting staff like peons, sweepers and other staff providing non-technical services that are generally illiterate or comparatively less educated. Therefore, in order to save such staff from harassment, the Committee recommends exclusion of such staff from the purview of this sub-clause. Further, the amount of penalties may be varied according to the responsibility/position held by the staff in the healthcare establishment. (Para 35.3)

The Committee is of the opinion that recovery of fine as arrears of land revenue would be a long process. This would provide sufficient time to the establishment to shift its base to some other place and start its activities afresh, thereby defeating the purpose of immediate results. Accordingly, the Committee recommends that recovery may also include forfeiture of assets of such Healthcare Establishment. (Para 36.1)

The Committee observes that several state laws on healthcare subject were enacted but their relevant rules were framed after quite some time. The Committee, therefore, recommends to the Ministry to frame the requisite rules pertaining to the Act, within a period of six months from the date of its enactment. (Para 37.1)

In view of the role of the National Council, it is recommended that all the rules to be framed by the Government should be in consonance with the functions carried out by the National Council. (Para 37.2)

The Committee, during its interaction with various stakeholders has received a lot of positive feedbacks. After extensive deliberations, the Committee is of the view that the under mentioned provisions need to be examined in depth by the Department and wherever feasible, included in the Act and Rules thereunder:-

- A chapter on provision for patients' rights and duties of healthcare establishments should be there.**
- The information acquired in the course of enforcing this Act may be privileged and confidential. Hence, in order to protect the interests of the patients and the establishments, a confidentiality clause needs to be incorporated in the Act. Any information which has been obtained from any hospital, medical clinic, clinical laboratory or healthcare establishment in the course of carrying out any investigation or performing any duty or function under this Act should not be disclosed unless required to do so in case of a prosecution for an offence under this Act or any regulations made there under.**
- All the procedure with respect to application for registration, inspection and its follow-up, complaint mechanism and its follow-up, National Register etc. may be put on a dedicated website. This would make the entire process of registration, inspection and complaint transparent.**
- Committee notes that many tax exemptions are being provided to corporate and business entities that are setting up their business establishments under Special Economic Zones (SEZs). Similarly, in order to make health reach across the length and breadth of this vast country, motivation in the form of tax exemptions may be provided to healthcare establishments being opened in remote, backward and rural areas. The matter may, therefore be taken up with the Finance Ministry.**

- **Maximum charges regarding the facilities available in the healthcare establishment alongwith contact details of the authority members to which any complaint may be made regarding non-adherence of the provisions of the Act, may be made mandatory to be displayed prominently at a conspicuous place preferably at the entrance of the establishment. Further, provision should be made to supply receipts of payments received alongwith the treatment/ diagnosis details to the patients. (Para 38.1)**

III

THIRD MEETING

The Committee met at 3.00 *p.m.* on Wednesday, the 31st October, 2007 in Committee Room “E”, Basement, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

- | | | |
|----------------------|----|---------------------|
| 1. Prof. P.J. Kurien | -- | In the Chair |
| 2. Smt. Maya Singh | | |

LOK SABHA

3. Smt. Maneka Gandhi
4. Shri B. Vinod Kumar
5. Shri Rajendra Kumar
6. Smt. Susheela Bangaru Laxman
7. Shri S. Mallikarjuniah
8. Shri Rasheed Massod
9. Dr. Chinta Mohan
10. Shri Nihal Chand
11. Dr. R. Senthil
12. Dr. Arvind Kumar Sharma
13. Dr. Karan Singh Yadav
14. Shri R.L. Jalappa

SECRETARIAT

- | | |
|---------------------------|-------------------|
| 1. Smt. Vandana Garg | Joint Secretary |
| 2. Shri R.B.Gupta | Joint Director |
| 3. Smt. Arpana Mendiratta | Deputy Director |
| 4. Shri Dinesh Singh | Committee Officer |

WITNESSES

A. On the Clinical Establishments (Registration and Regulation) Bill-2007

- (i) Shri Naresh Dayal Secretary, Department of Health and Family Welfare
- (ii) Dr. R.K.Srivastava, Director- General, Health Services
- (iii) Shri Vineet Chawdhry, Joint Secretary, Department of Health and Family Welfare

B. On the Drugs and Cosmetics (Amendment) Bill-2007.

- (i) Dr. R.K.Srivastava, Director General, Health Services.
- (ii) Dr M. Venkateshwarlu, Drugs Controller General (India) represented Central Drugs Standard Control Organisation and Drugs Consultative Committee.
- (iii) Dr. K.R. Mani, Director, Central Research Institute, Kasuali (CRI), represented Drugs Technical Advisory Board for Allopathy.
- (iv) Dr. M.C. Sharma, Director, National Institute of Ayurveda (NIA), Jaipur represented Drugs Technical Advisory Board for AYUSH.
- (v) Dr. P.K. Guha, Director, Central Drugs Laboratory (CDL), Kolkata.
- (vi) Dr. Gopa Ghosh, Director-in-charge, Central Drugs Laboratory (CDL), Mumbai.

2. In the absence of Chairman of the Committee, Prof. P.J. Kurien presided over the meeting.

3. The Committee discussed its future programme. Given the wider ramifications of the two Bills i.e. the Drugs and Cosmetics (Amendment) Bill, 2007 and the Clinical Establishments (Registration and Regulation) Bill, 2007 under its consideration, the Committee was of the opinion that there was a need to interact with a number of stakeholders and State Governments and also undertake study visits before finalizing the Reports. The Committee, accordingly, approved an action plan for the purpose.

4. Report on the Drugs and Cosmetics (Amendment) Bill, 2007 was to be presented by 22nd November, 2007. However, the Committee had proposed interaction with quite a few stakeholders involving study visits. The Committee, therefore, decided to seek extension of time for six months i.e. upto 22nd May 2008 for presentation of its Report on the Drugs and Cosmetics (Amendment) Bill, 2007 and authorized Chairman of the Committee to approach Hon'ble Chairman for the purpose.

5. Thereafter, the Committee first heard the Secretary and other representatives of the Department of Health and Family Welfare on

Drugs and Cosmetics (Amendment) Bill, 2007. Initially, Joint Secretary of the Department made a brief presentation shedding light on various facets of the Bill. During the course of discussion that followed the presentation, the Chairman and Members raised several queries, particularly on the definition of Clinical Establishments and their registration, standards to be laid down for clinical establishments, powers of the “National Council,” penal provisions for non compliance etc. Some of the queries were replied to by the witnesses and in respect of the remaining queries, the Committee directed the Secretary of the Department to furnish the same at the earliest. The Committee also directed the Secretariat to send a set of questionnaire to the Secretary for furnishing detailed replies.

6. The Committee, then, heard the witnesses on the Drugs and Cosmetics (Amendment) Bill, 2007. The Drugs Controller General (India) made a brief presentation on the subject. The Chairman and Members raised queries on various aspects of the Bill, particularly the composition and autonomy of the proposed Central Drugs Authority, and functioning of the Drug Laboratories in the country. The witnesses replied some of the queries. The Committee directed the Secretariat to forward a set of questionnaire to the Secretary, Department of Health and Family Welfare for detailed replies at the earliest on the aforesaid Bill.

7. A verbatim record of the proceedings was kept.
8. The Committee then adjourned at 5.15 *p.m.*

V

FIFTH MEETING

The Committee met at 11.00 *a.m.* on Friday, the 25th January, 2008 in Committee Room “A”, Ground Floor, Parliament House Annexe, and New Delhi.

MEMBERS PRESENT RAJYA SABHA

1. Shri Digvijay Singh
2. Prof. P.J.Kurien
3. Smt. Maya Singh
4. Shri Lalhming Liana

-- **In the Chair**

LOK SABHA

5. Smt. Maneka Gandhi
6. Shri Vinod Kumar
7. Shri S. Mallikarjuniah

8. Shri Rasheed Masood
9. Shri Nihal Chand
10. Smt. K. Rani
11. Dr. Arvind Kumar Sharma
12. Dr. Karan Singh Yadav

SECRETARIAT

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

WITNESSES

The Drugs and Cosmetics (Amendment) Bill-2007.

A. *Representatives of Confederation of Indian Industry*

1. Shri Alok Mishra Area Manager International, South Asia, Johnson & Johnson
2. Shri Ajay Pitre Managing Director, Sushrut Surgical Pvt. Ltd
3. Shri Pavan Choudary CEO & MD, Vygon India Pvt. Ltd.
4. Shri Ajay Maggo Director, Finance & Accounts, Philips Electronic, India, Ltd.

B. *Representatives of SME Pharma Industries Confederation:-*

1. Mr. Lalit Kumar Jain Vice Chairman
2. Mr. Jagdeep Singh Secretary General
3. Mr. J. Mathew Representative, SME Pharma Industries
4. Mr. Ramesh Arora Confederation
5. Mr. B.K. Gupta

The Clinical Establishments (Registration and Regulation) Bill-2007.

A. *Representatives of Quality Council of India:-*

1. Mr. Girdhar J. Gyani Secretary General
2. Dr. Y. P. Bhatia Representative, Quality Council of India

B. *Representatives of Indian Medical Association (Regd.):-*

1. Dr. M. Abbas, National President, IMA
2. Dr. S.N. Misra, Hony. Secretary General, IMA

2. In the absence of Chairman, Shri Digvijay Singh, M.P. presided over the meeting. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far with regard to examination of the Drugs and Cosmetics (Amendment) Bill-2007 and the Clinical Establishment (Registration and Regulation) Bill-2007, including the study visit undertaken by the Committee from 7th to 14th January 2008 to Bangaluru, Thiruvananthapuram, Chennai and Hyderabad.
3. The Chairman also informed Members that the Paramedical and Physiotherapy Central Councils Bill-2007 had been referred to the Committee on 14th December 2007 for examination and report.
4. In view of the fact that the Committee was yet to interact with a large number of stakeholders including Drugs Manufacturers Associations concentrated in northern and western parts of the country, the Committee decided to seek further extension of time upto the last day of the Budget Session 2008 for the presentation of its Report on the Bill. The Committee reiterated its decision taken during its study visit referred to above for undertaking another study visit to Indore, Ahmedabad, Mumbai and Goa from 12th to 19th February 2008, on both the Bills. The Committee authorized its Chairman to seek necessary permission from Hon'ble Chairman Rajya Sabha in this regard.
5. Thereafter the Committee heard the representatives of the Confederation of Indian Industries and SME Pharma, on the Drugs and Cosmetics (Amendment) Bill-2007.
6. The representatives from Confederation of Indian Industries (CII), speaking on the Drugs and Cosmetics (Amendment) Bill-2007, *inter alia*, stated that there is a need for separate provisions for regulation of medical devices, instruments, apparatus, appliances, materials etc., since provisions relating to devices cannot be clubbed with the provisions relating to drugs and cosmetics in view of the completely different characteristics of devices and equipments as compared to drugs and cosmetics. They further stated that the Government is proposing to set up the Medical Devices Regulatory Authority of India (MDRA). The MDRA being a national certifying and regulatory agency in India for medical equipment and devices would be expected to formulate appropriate guidelines. They pointed out that it was very important to ensure that there was not regulatory overlapping for the medical devices industry. It was informed that the Draft Medical Device Regulation Bill 2006, and the proposed Medical Device Regulatory Authority (MDRA) in this bill was based on tenets of European Medical Device Directive, which was largely accepted even by the Global Harmonization Task Force (GHTF) recommendations. They stated that such an independent Act or such a separate comprehensive sub-section for medical devices within the Drugs Control Act and the Rules framed there

under are essential for appropriate and comprehensive regulation of medical devices and that just the existing Drugs Control Act and the Rules framed there under (without this special comprehensive sub-section for Medical Devices) should not be made applicable to medical devices.

7. The representatives from SME Pharma were of opinion that centralizing the licensing system would lead to concentration of powers with the Central Government and would not be effective in tackling the moot problem of spurious drugs and fake drugs. They were also of the opinion that creation of zonal offices catering to four to five states would not go in the interest of the SSI and the said Bill was designed to decimate SSI by large scale Pharma industries and MNCs functioning in Pharma sector. They further contended that with the creation of Central Drug Authority, there would be problems and difficulties in investigation of cases of sub-standard/spurious drugs as State Drug Control Officers may not have jurisdiction to inspect the manufacturing establishments leading to difficulties in answering questions in the State Assemblies owing to its responsibility in providing quality manufacturing of medicines within the States.

7. Thereafter, the Committee took oral evidence of the representatives of the Indian Medical Association (IMA) and Quality Council of India on the Clinical Establishment (Registration and Regulation) Bill-2007.

8. Representatives from the Indian Medical Association (IMA), *inter alia*, stated that the said Bill was an unwarranted, undesirable and impracticable solution to the problem of Health. They were also of the opinion that the proposed Bill will pave way for Inspector Raj and promote corruption. They further stated that all the doctors and Clinical Establishments like Hospitals, Nursing Homes were registered by different governments and statutory bodies like Medical Council of India, State Medical Councils and Health Departments of the State through its different agencies and that was why this Bill would lead to duplication or triplication of the registration and add to the cost of treatment to the common man.

9. Representatives from the Quality Council of India (QCI), *inter alia*, pleaded for its inclusion as one of the Members to the National Council proposed in the Bill, as the Quality Council of India (QCI) has on its Committee a number of health professionals including assessors and experts on developing health standards. They were also of the opinion that the role of the Government should be limited to enacting laws, policy making etc. Independent regulators should be appointed to oversee compliance of the Act.

10. A verbatim record of the proceedings was kept.

11. The Committee then adjourned at 1.00 *p.m.*

**RECORD OF DISCUSSION OF THE MEETING OF THE
DEPARTMENT-RELATED PARLIAMENTARY STANDING
COMMITTEE ON HEALTH & FAMILY WELFARE**

The Committee met at 3.00 *p.m.* on Tuesday, the 27th May, 2008 in Committee Room No. 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

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|------------------------|----|-----------------|
| 1. Shri Amar Singh | -- | Chairman |
| 2. Shrimati Maya Singh | | |
| 3. Shri Digvijay Singh | | |
| 4. Shri Rajeew Shukla | | |

LOK SABHA

5. Shri Rajendra Kumar
6. Shrimati Susheela Bangaru Laxman
7. Shri S. Mallikarjuniah
8. Dr. Chinta Mohan
9. Shri Pannian Ravindran
10. Dr. Karan Singh Yadav

SECRETARIAT

- | | |
|-----------------------|-----------------|
| Shrimati Vandana Garg | Joint Secretary |
| Shri R. B. Gupta | Director |

WITNESSES

I Representatives of the Medical Council of India

1. Lt. Col. (Retd.) Dr. A.R.N. Setalvad Secretary, MCI
2. Dr. Ved Prakash Mishra Member, Executive Committee, MCI

II Representatives of Ayurveda, Siddha and Unani Drug Technical Advisory Board (ASUDTAB) :-

1. Dr. S.K. Sharma Advisor (Ayurveda), Department of AYUSH
2. Dr. S.S. Handa Former Director, RRL (CSIR). Jammu
3. Dr. P. Jaya Rtd. Principal, Siddha Medical College, Chennai.
Prakash Naraynan

4. Prof. M.C. Sharma Director, N.I.A, Jaipur
5. Dr. V.R. Seshadri Secretary, IMP, Co-op. Pharmacy & Stores Ltd. Chennai.
6. Dr. Asad Mueed Director (R&D), Hamdard Wakf Laboratories, New Delhi
7. Prof. Shakir Jamil Dean, Jamia Hamdard, New Delhi
8. Prof. Anis Ansari Dean, Alligarh Muslim University, Alligarh

III Representatives of the Physiotherapists' Forum of AIIMS:-

1. Dr. G.K. Meena, (PT)
2. Dr. Harpreet Singh, (PT)
3. Dr. Neeru Goel, (PT)
4. Dr. Aravind. K (PT)
5. Dr. Deepti Wardhan, (PT)

IV Representatives of the Indian Association of Physiotherapists (Delhi Branch):-

1. Dr. Dheerendra Kumar,(PT)
2. Dr. Sanjeev Jha,(PT)
3. Dr. Prabhat Ranjan,(PT)
4. Dr. Poonam Mishra, (PT)
5. Dr. Pramod Kumar, (PT)

V Representatives of the All India Occupational Therapists' Association:-

1. Dr. R.K. Sharma, Convener, Council Act Committee, A.I.O.T.A, Safdarjung Hospital, N.D -29
2. Dr. Anil K. Srivastava President, A.I.O.T.A, Assistant Director (O.T.) Rehabilitation & Artificial Limb Centre, Lucknow, U.P.
3. Dr. Pankaj Bajpai, Executive Member, A.I.O.T.A, Associate Professor & H.O.D, Department of Occupational Therapy, N.I.O.H. Bon Hooghly, B.T. Road, Calcutta.
4. Dr. Paroomal Vaithi, Executive Member, A.I.O.T.A, Professor & Head, Department of Occupational Therapy,

VI Representatives of the Physiotherapy Forum for Physiotherapist:-

1. Dr. (Mrs) Neeraj Kalra
2. Dr. Sumit Sexena
3. Dr. Ajay Kumar
4. Dr. Rajeev Aggarwal

2. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far regarding the examination of the three Bills, viz., the Clinical Establishments (Registration and Regulation) Bill, 2007, the Drugs and Cosmetics (Amendment) Bill, 2007 and the Paramedical and Physiotherapy Central Councils Bill, 2007.

3. The Committee heard representatives of the Medical Council of India (MCI) on the Clinical Establishment (Registration and Regulation) Bill, 2007. The Secretary of MCI made a power-point presentation. Members sought clarifications which were replied to.

4. The Committee thereafter took oral evidence of the representatives of Ayurveda, Siddha and Unani Drug Technical Advisory Board (ASUDTAB) on the Drugs and Cosmetics (Amendment) Bill, 2007. Members sought clarifications on various provisions of the Bill which were replied to.

5. The Committee adjourned at 4.00 *p.m.* for tea and after the break, in the absence of the Chairman, Dr. Karan Singh Yadav, M.P. presided over the meeting.

6. The Committee then heard the views of the representatives of Physiotherapists' Forum of AIIMS, All India Occupational Therapists' Association, Indian Association of Physiotherapists (Delhi Branch) and the Physiotherapy Forum for Physiotherapist on the Paramedical and Physiotherapy Central Councils Bill, 2007. The representatives of the Associations/Fora also made a power-point presentation regarding their suggestions/views on the Bill. Members sought clarifications which were replied to.

7. A verbatim record of the proceedings was kept.

8. The Committee then adjourned at 5.03 *p.m.*

XII TWELFTH MEETING

The Committee met at 11.00 *a.m.* on Monday, the 9th June, 2008 in Committee Room No. 'C', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

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|-------------------------------|----|-----------------|
| 1. Shri Amar Singh | -- | Chairman |
| 2. Prof. P.J. Kurien | | |
| 3. Shri Su. Thirunavukkarasar | | |
| 4. Shrimati Viplove Thakur | | |
| 5. Shri Rajeev Shukla | | |

LOK SABHA

6. Smt. Maneka Gandhi
7. Shri Rajendra Kumar
8. Shrimati Susheela Bangaru Laxman
9. Shri S. Mallikarjuniah
10. Shri Pannian Ravindran
11. Dr. Karan Singh Yadav

SECRETARIAT

- | | |
|-----------------------|-------------------|
| Dr. V. K. Agnihotri | Secretary-General |
| Shrimati Vandana Garg | Joint Secretary |
| Shri R. B. Gupta | Director |

WITNESSES

I Representatives of Bureau of Indian Standards

- | | |
|----------------------|----------------------------|
| 1. Shri Tilak Raj, | Director Legal |
| 2. Shri Rahul Kumar | Scientist 'F' & Head (MHD) |
| 3. Shri C.P. Puri | Scientist 'E' (MHD) |
| 4. Shri Sanjay Arora | S.O24-25 legal |

II Representatives of Dental Council of India

1. Maj. Gen. (Retd.) Secretary, Dental Council of India
Dr. P.N.Awasthi
2. Prof.Anmol Kalha Head PG studies IDST,Modi Nagar

III Representatives of Pharmacy Council of India

1. Shri P.P Sharma
2. Chairman, Law Committee, PCI, Ex. Dy Drugs Controller
Mrs. Archana Mudgal
Registrar-cum-Secretary, Pharmacy Council of India

IV Representatives of Indraprastha Association of Rehabilitation Medicine

1. Dr. Shiv Lal Yadav Addl. Professor, Dept of PMR, AIIMS
2. Col S.N. Bhaduri Specialist, Dept. of PMR, R.R, Hospital, New Delhi
3. Dr. Ajay Gupta Specialist PMR, Dr. R.M.L Hospital, New Delhi
4. Dr. Mallikarjuna Nallegowda Specialist PMR, Kalawati Saran Hospital, New Delhi
5. Dr. B.Ramachandran Ex. CMO, Central Health Services and Secretary of IPARM

2. At the outset, the Chairman welcomed Members to the meeting and apprised them about the progress made so far regarding the examination of the three Bills, viz., the Clinical Establishments (Registration and Regulation) Bill, 2007, the Drugs and Cosmetics (Amendment) Bill, 2007 and the Paramedical and Physiotherapy Central Councils Bill, 2007.

3. The Committee heard representatives of the Bureau of Indian Standards (BIS) and the Dental Council of India (DCI) on the Clinical Establishments (Registration and Regulation) Bill, 2007. Members sought clarifications which were replied to.

4. The Committee thereafter took oral evidence of the representatives of the Pharmacy Council of India on the Drugs and Cosmetics (Amendment) Bill, 2007. Members sought clarifications on various provisions of the Bill which were replied to.

5. The Committee then heard the views of the representatives of Indraprastha Association of Rehabilitation Medicine on the Paramedical and Physiotherapy Central Councils Bill, 2007. Members sought clarifications which were replied to.

6. A verbatim record of the proceedings was kept.

7. The Committee then adjourned at 12.55 *p.m.*

VII SEVENTH MEETING

The Committee met at 4.30 p.m. on Thursday, the 23rd October, 2008 in Committee Room No.63, First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

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|-------------------------------|----|-----------------|
| 1. Shri Amar Singh | -- | Chairman |
| 2. Shrimati Viplove Thakur | | |
| 3. Shri Su. Thirunavukkarasar | | |

LOK SABHA

4. Dr. Ram Chandra Dome
5. Shri R.L. Jalappa
6. Shri S. Mallikarjuniah
7. Dr. Chinta Mohan
8. Smt. K. Rani
9. Shri Pannian Ravindran
10. Dr. R. Senthil
11. Dr. Arvind Kumar Sharma
12. Shri Uday Singh
13. Dr. Karan Singh Yadav

SECRETARIAT

Shri R. B. Gupta	Director
Shrimati Arpana Mendiratta	Deputy Director
Shri Dinesh Singh	Assistant Director

2. At the outset, the Chairman welcomed Members of the Committee. The Committee then considered the draft Report on the Clinical Establishments (Registration and Regulation) Bill, 2007. After some discussion, the Committee adopted the Report.

3. The Committee, thereafter, decided that the Report may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Friday, the 24th October, 2008. The Committee authorized the Chairman of the Committee and in his absence Smt. Viplove Thakur and in her absence Shri Digvijay Singh to present the Report in Rajya Sabha, and, Dr. Karan Singh Yadav, and in his absence Dr. Ram Chandra Dome to lay the Report on the Table of the Lok Sabha.

4. The Committee then adjourned at 5.10 *p.m.*

ANNEXURE-II

**LIST OF WITNESSES WHO APPEARED BEFORE THE
COMMITTEE**

AT NEW DELHI

Date of hearing- 31st October, 2007

1. Shri Naresh Dayal Secretary, Department of Health and Family Welfare
2. Dr. R.K. Srivastava Director- General, Health Services
3. Shri Vineet Chawdhry Joint Secretary, Department of Health & Family Welfare

Date of hearing- 25th January, 2008

REPRESENTATIVES OF QUALITY COUNCIL OF INDIA

4. Mr. Girdhar J.Gyani Secretary-General
 5. Dr. Y. P. Bhatia Representative, QCI
- REPRESENTATIVES OF INDIAN MEDICAL ASSOCIATION (REGD.)***

6. Dr. M. Abbas, National President, IMA
7. Dr. S.N. Misra, Hony. Secretary General, IMA

Date of hearing- 27th May, 2008

REPRESENTATIVES OF MEDICAL COUNCIL OF INDIA (MCI)

8. Col. (Retd.) Dr. A.R.N. Setalvad, Secretary, MCI
9. Dr. Ved Prakash Mishra, Member, Executive Committee, MCI

Date of hearing- 9th June, 2008

BUREAU OF INDIAN STANDARDS

10. Shri Tilak Raj, Director Legal

