

**PARLIAMENT OF INDIA**  
**RAJYA SABHA**

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

**ON**

**THE DRUGS AND COSMETICS (AMENDMENT) BILL-2005**

**(PRESENTED TO THE RAJYA SABHA ON -21<sup>st</sup> DECEMBER, 2005)**

**(LAID ON THE TABLE OF LOK SABHA ON-21<sup>st</sup> DECEMBER, 2005)**

RAJYA SABHA SECRETARIAT

NEW DELHI

DECEMBER, 2005/ AGRAHAYANA, 1927 (SAKA)

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**COMPOSITION OF THE COMMITTEE**

1. Shri Amar Singh  $\frac{3}{4}$  *Chairman*

**MEMBERS**

**RAJYA SABHA**

2. Shrimati Sukhbuns Kaur
3. Shri Yusuf Sarwar Khan *alias* Dilip Kumar
4. Prof. P.J. Kurian
5. Dr. A.K. Patel
6. Shrimati Maya Singh
7. Dr. M.A.M. Ramaswamy
8. Shri R. Sarath Kumar
9. Shri Lalhming Liana
- \*10. Shri Digvijay Singh

**LOK SABHA**

11. Shri D.K. Adikesavulu
12. Shri M. Ambareesh
13. Smt. B. Sushila Devi Laxman
14. Dr. Babu Rao Mediyam

15. Dr. Ram Chandra Dome
16. Smt. Maneka Gandhi
17. Smt. Bhavana Pundlikrao Gawali
18. Shri S. Mallikarjunaiah
19. Dr. Chinta Mohan
20. Shri Rasheed Masood
21. Smt. Archana Nayak
22. Shri D.B. Patil
23. Shri Nakul Das Rai
24. Shri Rajendra Kumar
25. Smt. K. Rani
26. Dr. Mohd. Shahabuddin

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\* Member nominated w.e.f. 13<sup>th</sup> of December, 2005

27. Dr. Arvind Kumar Sharma
28. Shri Uday Singh
29. Smt. V. Radhika Selvi
30. Shri Kailash Nath Yadav
31. Dr. Karan Singh Yadav

#### **SECRETARIAT**

Shri N.C. Joshi, Additional Secretary  
 Smt. Vandana Garg, Joint Secretary  
 Shri P.R. Guharoy, Director  
 Shri Momraj Singh, Under Secretary  
 Shri S.C. Dixit, Committee Officer

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#### **PREFACE**

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this Twelfth Report of the Committee on the Drugs

Bill-2005. \*

2 In pursuance of Rule 270 of the Rules and Procedure and Conduct of Business in the Council of States, relating to the Department-related Parliamentary Standing Committees, the Hon'ble Chairman, Rajya Sabha, referred\*\* the Drugs and Cosmetics (Amendment) Bill, 2005 (Annexure-I) as introduced in the Rajya Sabha on the 10<sup>th</sup> May 2005 and pending therein, to the Committee on the 18<sup>th</sup> May 2005 for examination and report.

3. A Press Release inviting suggestions/comments from general public was issued in June, 2005. In response, a number of memoranda were received.

4. The Committee considered the Bill in its meetings held on the 14<sup>th</sup> July, 9<sup>th</sup> September, 17<sup>th</sup> November and 15<sup>th</sup> December, 2005.

5. The Committee held wide ranging discussions with all the stake-holders on the various provisions of the Bill. Divergent views were expressed by representatives of associations of drug manufacturers, chemists, stockists etc. NGOs highlighting concerns of consumers also appeared before the Committee (Annexure-II). The Committee also had the opportunity to interact with the Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare and the Drug Controller General of India. The Committee sought clarifications not only on the various view points put forth before it on the Bill but also shared its apprehensions on the present drug control scenario in the country. The Committee, thereafter, considered the draft Report in its meeting held on 15<sup>th</sup> December, 2005 and adopted the same.

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

- (i) Background Note on the Bill received from the Department of Health and Family Welfare;
- (ii) Presentation and clarification by the Secretary of the Department of Health and Family Welfare and Drug Controller General of India;

\* Published in Gazette of India Extraordinary Part II Section 2, dated 10<sup>th</sup> May, 2005.

\*\* Rajya Sabha Parliamentary Bulletin Part II, No 42207, dated 19<sup>th</sup> May 2005

- (iii) Memoranda received on the Bill from various associations, NGOs and experts;
- (iv) Replies to the Questionnaire on the Bill; and
- (v) Oral evidence on the Bill.

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

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

NEW DELHI;

AMAR SINGH

15<sup>th</sup> December, 2005 24, *Agrahayana, 1927*  
(Saka)

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

### Report

No country is reported to be immune from the problem of adulterated or spurious drugs and India is no exception. While counterfeiting of consumer goods is a general problem, the issue of adulterated or spurious drugs acquires a much more serious dimension because it involves medicinal use. Spurious or adulterated drugs can cause serious or even fatal injury, if they do not contain the required active ingredients or contain harmful substances. Reported large-scale production and trading of spurious drugs in India is a cause of concern not only to the consumers within the country but is also affecting the credibility of drug products from India.

2 The Statement of Objects and Reasons appended to the Bill is as under:-

*“The Drugs and Cosmetics Act, 1940 is a consumer protection legislation, which is mainly concerned with the standards and quality of drugs manufactured in this country and control of the import, manufacture, sale and distribution of drugs and cosmetics. There have been widespread reports regarding the easy movement and harmful consequences of adulterated and spurious drugs in the country and wide ranging national concern has been expressed on these reports. The issue of adulterated or spurious drugs has serious*

*dimensions because it involves medicinal use and can lead to serious and even fatal injury. There is also loss of revenue to the Government due to the manufacture and sale of adulterated or spurious drugs.*

2.1 *Drugs and Cosmetic Act, 1940 was amended in 1982 so as to impose more stringent penalties on the anti-social elements indulging in the manufacture or sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death or grievous hurt to the user. However, the penalties existing in the said Act are not found effective. One of the reasons for the existing penalties not being effective is that manufacture and sale of adulterated and spurious drugs is primarily clandestine activity which is showing increasing involvement of organized crime in recent years. Besides, offenders often obtain bail as the offences are non-cognizable and bailable under the existing provisions of the Act. The offenders remain on bail due to delay in disposal of cases for manufacture and sale of adulterated and spurious drugs. Many cases for violation are detected and investigated by the police who needs to be conferred upon the power to prosecute such cases promptly.*

2.2 *The Central Government constituted an Expert Committee under the chairmanship of Dr. R.A. Mashelkar, Director General of Council of Scientific and Industrial Research in January, 2003 to undertake a comprehensive examination of drugs regulatory issues, including the problem of spurious drugs, evaluate the extent of the problem of spurious or substandard drugs recommend measures required to deal with the problem effectively. The Committee, inter alia, recommended for enhancement of penalties, designation of Special Court for speedy trial of spurious drugs cases, making offences relating to spurious drugs cognizable and non-bailable, authorising the police to file prosecution for offences related to spurious drugs and compounding of offences, etc. A Bill to amend the Drugs and Cosmetics Act, 1940 broadly to give effect to the recommendations of the aforesaid Committee was introduced on the 22nd December, 2003 in Lok Sabha and the Bill lapsed due to dissolution of Lok Sabha.*

3. Committee's attention has been drawn by the very low rate of prosecution cases with regard to adulterated / spurious drugs and even lower rates of cases launched in the country. Following figures support the contention of the Committee: -

<b>Year</b>	<b>Cases launched</b>	<b>Cases decided</b>
2001-2002	538	171
2002-2003	449	105
2003-2004	570	166

3.1 On a specific query about the factors responsible for such a dismal scenario, the Committee was given to understand that different pattern of infrastructure and logistics for drugs quality control in states was primarily responsible. Prolonged procedure for settlement of court cases was another hindrance. The Committee notes that the Drugs and Cosmetics (Amendment) Bill, 2005 seeks to impose more stringent penalties on manufacture/sale of adulterated/spurious/sub-standard drugs. The Committee, however, does not foresee any significant improvement, keeping in view the existing manpower of 1040 Drug Inspectors and annual rate of 35,000 samples tested against total number of 11,000 Drug Manufacturers/ Loan Licensee and 3,50,000 sales premises. The Committee observes that after passage of the Bill, the Government proposes to have interactive discussions with state authorities including police authorities and have orientation programmes arranged for its effective implementation. The Committee, however, is of the view that such initiatives alone will not serve the purpose. What is required is strengthening of infrastructure / manpower for drug quality control in all the states/UTs and its constant monitoring.

4. The clauses in respect of which amendments have been suggested by the Committee, are discussed in the succeeding paragraphs.

#### **Clause 2.**

4.1 Clause 2 of the Bill proposes to amend Section 27 of the Drugs and Cosmetics Act-1940 regarding 'Penalty for manufacture, sale etc. of drugs'. As enumerated in the clause, penalties i.e. both term of imprisonment and amount of fine are proposed to be enhanced considerably for manufacture/sale/distribution/stocking/exhibiting/ by any person directly or any other person or adulterated/spurious/ not of standard quality drugs. The proposed amendment seeks to enhance the term of imprisonment which shall not be less than ten years but which may extend to imprisonment for life and also the amount of fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more.

4.2 *The Committee has been given to understand that the proposed amendment is broadly based on the recommendations made by the Mashelkar Committee. The Committee, however, finds that there is a major difference. The Expert Committee's recommendation for death penalty for the said offence has been replaced by imprisonment for life. The Committee was informed that this modification was made in pursuance of the directions from the Cabinet. All experts, representatives of associations and NGOs appearing before the Committee while welcoming the increase in fine were also not in favour of death penalty. The Committee also holds the same view.*

4.3 While interacting with various stake-holders, the Committee came across divergent views on the criteria for imposition of penalties. Apprehensions were voiced about there being no difference in the level of penalty for different categories of persons. As a result, manufacturer/distributor/stockist/ seller/ person exhibiting or offering for sale/distribution or his nominee are liable to undergo the same penalty. Another viewpoint was that penalties should be commensurate with the gravity of offence. Penalties should be highest for such acts which are done deliberately with the clear intention of making profit. Punishment should be more severe in case of life-saving drugs.

4.4 Response of the Ministry to these reservations was that the object of the Act is to deal strongly with the harmful consequences of spurious drugs. It was a matter of national concern to safeguard the health of society from the harmful consequences and ill effects of spurious drugs and hence, it becomes necessary to deal with the manufacturer and the dealer on the same footing with respect to spurious drugs in the larger interest of the society. The Committee is in agreement with the view point of the Ministry that the enhancement in penalty under Section 27 of the Act would act as a deterrent for offenders.

4.5 Committee's attention was also drawn to there being instances of patients suffering from prolonged illness primarily due to the use of spurious/adulterated drugs. However, such cases are not covered under section 27 (a) . It was suggested that besides death and grievous hurt, prolonged illness should also be made the criteria for imposition of fine/imprisonment. The Committee feels that prolonged illness might occur due to a variety of reasons. There may be cases where doctor inadvertently or deliberately may be responsible for delay in getting the patient cured. However, if it is due to use of adulterated or spurious drugs, then this aspect needs to be looked into. The Committee, accordingly, recommends that the Department may explore the possibility of bringing such cases under Section 27 (a).

4.6 Another suggestion made before the Committee was that 'not of standard quality drugs' should be taken out from the ambit of Section 27. It was emphasized that 'not of standard quality drugs' should neither

be confused with spurious or adulterated drugs nor construed as spurious or adulterated drugs. It was pointed out that quality parameters as were provided under Section 16 for such drugs cannot be treated at par with adulterated/spurious drugs and hence deserve comparatively lesser penalties. The Committee is, however, not inclined to agree with this view-point. The Committee notes that Section 16 and second schedule specifies the standard of quality to be maintained by drugs. In the case of patent or proprietary medicines, the list of ingredients is to be displayed in the prescribed manner on the label or container. In the case of vaccines, sera, toxins, toxoids, antitoxins, antigens and biological products of like nature, standards are to be maintained by the labs recognized by WHO from time to time. The Committee is of the view that any deviation in the prescribed standards of medicines is equally serious when compared with adulterated and spurious drugs and needs to be treated at the same footing.

4.7 Clause 2 (B) of the Bill seeks to insert two provisos under Section 27 (a) whereby the victim or in the case of his death his relative is liable to be paid the amount of fine as compensation. The Committee notes that by way of explanation an exhaustive list of 'relatives' has been given, which indicates that dependence on the deceased person's earning is the sole criteria for making a relative eligible for compensation. The only exception is the spouse of the deceased person, minor legitimate son and unmarried legitimate daughter and a widowed mother. The Committee has strong reservations in this regard as in its opinion dependence on the deceased person should not be the only criteria as loss of loved one can never be compensated. It can be the criteria to increase the amount of compensation.

4.8 A suggestion made to the Committee was that divorced/deserted sister or daughter-in law should also be covered under 'relatives'. Reservation was also expressed about including only widowed mother. It was felt that mother needed to be included. The Committee also observes that parents of infant child victim are not covered under the proposed definition. On a specific query in this regard, the Department has submitted "that the joint and harmonious reading of the second proviso and the Explanation (ii) of the term 'relative' makes it clear that a minor legitimate son/daughter as well as an infant, as the case may be, is a relative and hence covered under the said section". The Committee is not convinced with the reply and feels that the Department, perhaps, has not addressed the issue appropriately. Apprehensions were also voiced about the chance of conflict in the event of there being more than one claimant being covered by the term 'relative'. There was thus a need for categorizing the same.

4.9 The Committee, accordingly, recommends that parents of infant victim should be covered under the definition of "relative" very explicitly so that the parents in case of such an eventuality are not deprived of their right of compensation.

4.10 Definition should also include deserted/divorced sister/daughter-in law and mother instead of only widowed mother. The Committee is convinced by the clarification of the Department that it should be left to the court of law to decide the bona fide recipient and the quantum of compensation to be paid to him/ her.

#### Clause 2 (ii), 3 and 4

4.11 These clauses propose to enhance the penalty under Section 27 (b), (c) and (d), 28 and 28A of the Act. The Committee is in agreement with these amendments and, accordingly, adopts these clauses.

#### Clause-5

5.1 Clause 5 seeks to increase the penalty for subsequent offences by proposing amendments in clause (a) and (b) of Section 30. The Committee, however, notes that clause (c) of Section 30 which deals with penalty for subsequent offences committed under Section 27 (d) is proposed to be deleted. Clause (c) provided that any person if again convicted of an offence under clause (d) of Section 27 shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than five thousand rupees or with both.

5.2 The Committee notes that Section 27 (d) provides for penalty, i.e. imprisonment for a term which

shall not be less than one year but which may extend to two years and fine for sale/manufacture etc of any drug not covered by Clause (a), (b) and (c) of Section 27, in contravention of any provision under chapter IV of the Act or any rule making power thereunder. It also gives the court discretionary powers to reduce the imprisonment term. **The** Committee fails to understand the rationale for deletion of this clause, especially whereas all other penalties under the other provisions under Chapter IV are proposed to be enhanced. Chapter IV deals with manufacture, sale and distribution of drugs. Section-33 under this Chapter relates to the rules making power of the Central Government which include very vital subjects, for example, establishment of labs, methods of test/ analysis of drugs, qualification/duties of Govt. Analysts/ Inspectors, proof stocking/exhibition for sale/ distribution of drugs after the expiry date/specification of offence regarding which order of confiscation is required to be made etc. As per Section 30 (c), penalty for subsequent offence was more stringent when compared with penalty for first offence under Section 27 (d). The Committee, therefore, is of the view that Section 30 (c) should not be deleted and penalty for subsequent offence in Section 30 (c) should be suitably enhanced.

5.3 The Committee notes that Clause 5 also proposes deletion of Sub-Section (2) of Section 30. This Sub-Section relates to penalty for subsequent offence of use of Govt. Analysts report for advertising. Penalty for subsequent offence was higher than the penalty for the first offence i.e. against a fine for Rs. 500/- penalty for subsequent offence is maximum imprisonment of ten years or with fine or withboth. No justification has been given by the Department for deletion of this Sub-section. The Committee, therefore, recommends that the Department should review this amendment.

#### **Clause-6**

6.1 Clause 6 of the Bill proposes to substitute Sub-Section 1 and 2 of Section 32 relating to cognizance of offences. The Committee notes that this amendment is based on the Mashelkar Committee recommendations which suggested that in addition to the Drugs Inspectors, police authorities may also be authorized at an early stage to file prosecutions for spurious drugs offences. The Committee notes that a police officer not below the rank of Sub- Inspector has, accordingly, been given the power to prosecute in the Bill. The Committee, however, observes that prosecution power is also proposed for Central/ State Govt. officers. On a specific query in this regard, the Department submitted that due to there being a large number of vacancies of State Drug Inspectors remaining unfilled, it was thought that to prevent delays and to expedite the process of prosecution, officers of the Central or State Government may also be authorized.

6.2 One view which emerged before the Committee was that Drug Inspectors being conversant with drugs and its formulations, are most capable in assessing drug-related cases. Apprehensions were voiced about involvement of police personnel which may lead to unnecessary harassment of the license holder. It was, accordingly, suggested that involvement of police should only be made on written request from the Drugs Licensing Authority of the area.

6.3 The Committee also feels that a police officer or an officer of the Central Government or State Government do not have the required professional qualification to handle drug-related cases. Therefore, for the purpose of proper prosecution, involvement of Drug Licensing Authority is necessary. The Committee, therefore, recommends that in case of prosecution by the police inspector or Govt. Officer, prior permission of the Drug Licensing Authority of the concerned area should be made a precondition.

#### **Clause-7**

7. Clause 7 of the Bill proposes to insert a new section 32B after section 32 A which provides for compounding of offences. The Committee was given to understand that the power to compound the offence should not be made so simple or easy that it is left entirely to the discretion of the Govt. officer. The procedure should be made more transparent. To achieve these objectives there should be certain pre-requisites for compounding. Firstly, the aggrieved party's concurrence should be there. Secondly, the amount compounded should be adequate to compensate the aggrieved person. Thirdly, the cost of litigation should

also be included in the sum compounded. The Committee concurs with this view and recommends the Department to amend Section 32 B in the light of the above observation.

#### **Clause-10**

8.1 Clause 10 of the Bill proposes to insert a new Section 36 AB which mentions about designating one or more Courts of Sessions as special court for the trial of such offences.

8.2 The Committee would like to mention that the Expert Committee had recommended constitution of Special Courts and not the designation of some selected Courts as Special Courts for speedy trial of drug related offences. On a specific query, the Department has submitted that setting up of Special Courts by designating existing courts would save time. However, if new courts have to be set up as Special Courts, then this issue would have to be resolved in consultation with Ministry of Law. The Committee, however, is not inclined to believe that mere designation of one or more courts of Sessions as Special Court will help in expeditious disposal of cases as the Sessions Courts are already overburdened with a large number of cases. The Committee, therefore, recommends that new courts need to be set up for the purpose of trying offences under the Drugs & Cosmetics Act.

9 The Committee adopts the remaining clauses of the Bill, including enacting formula and the title without any amendment.

#### **General**

10 The Committee has taken note of the suggestion of the Expert Committee that a specific provision, on the lines of the Narcotics Drugs and Psychotropic Substances Act-1985, needs to be made in the Drugs and Cosmetics Act-1940 that will allow the person indulging in the spurious drug offences to be detained for a minimum period of three months. This would serve as an effective deterrent for such offenders. Explaining the reasons for not including this recommendation of the Committee, the Ministry submitted that the proposed Act envisages imprisonment for a term which shall be not less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times the value of the drugs confiscated, whichever is more, to all those persons indulging in offences pertaining to spurious drugs. The Committee has also been given to understand that these provisions will work as an effective deterrent and are far more stringent than NDPS Act. The Committee would, however, like to point out that interaction with various stake-holders indicates that persons accused of manufacturing or trading in spurious or adulterated drugs usually get bail very easily and thereafter either intimidate or influence the witnesses and try to win over them. They also manipulate the administrative and judicial system. In this manner they weaken the case of the prosecution and such cases thus drag on for years together. The conviction rate, due to the reasons mentioned above, is very low in drug related offences. The Committee, therefore, thinks that in order to realize the deterrent-effects of the proposed Bill, first of all a successful conviction in the court of law is necessary and for that to happen it should be ensured that the accused is prevented from manipulating the system to his advantage. The Committee also feels that peddling in spurious or adulterated drugs is no way less serious than peddling in narcotics. The Committee, therefore, recommends that the Department should incorporate similar provisions in the Bill, as exist in the **NDPS Act**.

11. The Committee is constrained to observe that there is no mechanism to make aware the consumers or public at large about the harmful effect of certain drugs or banned drugs. The Committee strongly feels that the Central Govt. needs to make efforts for publishing a list of banned drugs for the information of all concerned. The Committee was informed that a New Task Force on the subject is being set up which will review the existing procedure for drug verification to make it more user friendly. The Committee emphasizes that action to increase public awareness about harmful/banned drugs should be initiated at the earliest.

12. It is a well-known fact that a drug manufacturer in one state moves freely in interstate commerce as well as in export market. However, the infrastructure facilities, the number and quality of drug inspectors, testing



facilities support systems etc. continue to vary significantly from state to state. Not only this, a large number of states still do not have drug-testing labs. The Committee finds that out of the 17 drugs testing labs functioning in different states, only 7 are reported to have the capacity to test all categories of drugs. In view of such a situation, there is an urgent need for not only establishing viable testing facilities but also providing Intelligence Cells working in coordination with the different states. The Committee has been informed that under the World Bank assisted Capacity Building project for Food Safety and Quality Control of Drugs, up gradation/construction of at least one state of the art Drug Testing Laboratory in each State/UT and also some central labs is already in progress. Besides, in order to introduce further uniformity in the implementation of the Drugs and Cosmetics Act in the States, selected labs in the States are being provided with modern equipment and trainings are being provided to both the laboratory and drug regulatory personnel. Similarly, an IEC strategy is being developed for ensuring a better-informed and more aware consumer. The Committee hopes that with all these measures the situation would improve in the states.

13(i).

*Committee's attention has been drawn by another observation made by the Mashelkar Committee for there being a need for surveillance over distribution of drugs through medical practitioners. The Department also accepts this observation as distribution of drugs through medical practitioners is a major channel of distribution of spurious/ adulterated drugs.*

13(ii).

*Medical practitioners are exempted from the provisions of the Chapter IV of the Drugs and Cosmetics Act dealing with manufacture, sale and distribution of drugs and Rules made there under (Entry 5 of Schedule 'K' of the Rules). The Committee has, however, been given to understand that many registered medical practitioners dispensing drugs to their patients, do not always purchase their supplies from authorized sources. On a specific query about putting a check on such activities, the Committee was informed that provisions are already in existence to inspect the stock of drugs retained by the Registered Medical Practitioners and procurement of drugs in such cases should be made from authorized dealer with proper purchase voucher. In case of spurious drugs, the concerned Medical Practitioner should also be made an accused if the investigation so reveal. However, when asked about number of such cases of violation by medical practitioners registered so far, the Drug Controller General of India categorically admitted that not even a single case has been registered so far. The Committee finds it rather surprising. The Committee strongly feels that the Department has to take in the initiative in this matter. An effective monitoring mechanism needs to be set up to present such cases. At the same time, public should also be made aware of such provisions.*

14.

*The Committee observes that the definition of adulterated and spurious drugs – Allopathic, Ayurvedic, Unani and Siddha drugs is the same. However, similar provision for penalty for manufacture, sale etc. of AYUSH drugs is not there. As per media reports, Ayurvedic drugs containing metals and steroids are in circulation and sometimes cause grievous hurt to the users. On a specific query in this regard, Department clarified that presence of metals and steroids in Ayurvedic, Siddha and Unani medicines could be due to the contamination of raw material of natural origin i.e. soil-water contamination. Therefore, raw material testing to exclude the heavy metal presence above the permissible level is needed which requires good laboratories to undertake this testing at an affordable time. This will add to the cost of AYUSH medicine significantly. Phytosteroids are also present in plants naturally. Therefore, only adulteration of steroid should be penal offence. The Committee observes that Section 33(I) and (J) of the Drugs & Cosmetics Act provides penalty for manufacture, sale etc. of spurious and adulterated Ayurvedic, Siddha drugs and for subsequent offences respectively. The Committee however feels that more stringent penalties are required to be imposed in the case of spurious/adulterated/ not of standard quality Ayurvedic/Unani/Siddha drugs also. The Committee, therefore, is of the view that the penalty provision for AYUSH drug should be reviewed so as to make changes, if necessary. The Committee also emphasizes the need for strengthening the testing labs for AYUSH drugs, the present status of which cannot be considered satisfactory.*

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#### **OBSERVATION/RECOMMENDATIONS- AT A GLANCE**

The Committee also holds the same view. (para 4.2)

The Committee is in agreement with the view point of the Ministry that the enhancement in penalty under Section 27 of the Act would act as a deterrent for offenders. (para 4.3)

The Committee feels that prolonged illness might occur due to a variety of reasons. There may be cases where doctor inadvertently or deliberately may be responsible for delay in getting the patient cured. However, if it is due to use of adulterated or spurious drugs, then this aspect needs to be looked into. The Committee, accordingly, recommends that the Department may explore the possibility of bringing such cases under Section 27 (a). (para 4.5)

The Committee notes that Section 16 and second schedule specifics the standard of quality to be maintained by drugs. In the case of patent or proprietary medicines, the list of ingredients is to be displayed in

the prescribed manner on the label or container. In the case of vaccines, sera, toxins, toxoids, antitoxins, antigens and biological products of like nature, standards are to be maintained by the labs recognized by WHO from time to time. The Committee is of the view that any deviation in the prescribed standards of medicines is equally serious when compared with adulterated and spurious drugs and needs to be treated at the same footing. (para 4.6)

The Committee is not convinced with the reply and feels that the Department, perhaps, has not addressed the issue appropriately. Apprehensions were also voiced about the chance of conflict in the event of there being more than one claimant being covered by the term 'relative'. There was thus a need for categorizing the same.

(para 4.8)

The Committee, accordingly, recommends that parents of infant victim should be covered under the definition of "relative" very explicitly so that the parents in case of such an eventuality are not deprived of their right of compensation. (para 4.9)

Definition should also include deserted/divorced sister/daughter-in law and mother instead of only widowed mother. The Committee is convinced by the clarification of the Department that it should be left to the court of law to decide the bona fide recipient and the quantum of compensation to be paid to him/ her. (para 4.10)

These clauses propose to enhance the penalty under Section 27 (b), (c) and (d), 28 and 28A of the Act. The Committee is in agreement with these amendments and, accordingly, adopts these (para 4.11)

The Committee fails to understand the rationale for deletion of this clause, especially whereas all other penalties under the other provisions under Chapter IV are proposed to be enhanced. Chapter IV deals with manufacture, sale and distribution of drugs. Section-33 under this Chapter relates to the rules making power of the Central Government which include very vital subjects, for example, establishment of labs, methods of test/ analysis of drugs, qualification/duties of Govt. Analysts/ Inspectors, prohibition of sale/ stocking/exhibition for sale/ distribution of drugs after the expiry date/specification of offence regarding which order of confiscation is required to be made etc. As per Section 30 (c), penalty for subsequent offence was more stringent when compared with penalty for first offence under Section 27 (d). The Committee, therefore, is of the view that Section 30 (c) should not be deleted and penalty for subsequent offence in Section 30 (c) should be suitably enhanced. (para 5.2)

The Committee notes that Clause 5 also proposes deletion of Sub-Section (2) of Section 30. This Sub-Section relates to penalty for subsequent offence of use of Govt. Analysts report for advertising. Penalty for subsequent offence was higher than the penalty for the first offence *i.e.* against a fine for Rs. 500/- penalty for subsequent offence is maximum imprisonment of ten years or with fine or with both. No justification has been given by the Department for deletion of this Sub-section. The Committee, therefore, recommends that the Department should review this amendment. (para 5.3)

The Committee also feels that a police officer or an officer of the Central Government or State Government do not have the required professional qualification to handle drug-related cases. Therefore, for the purpose of proper prosecution, involvement of Drug Licensing Authority is necessary. The Committee, therefore, recommends that in case of prosecution by the police inspector or Govt. Officer, prior permission of the Drug Licensing Authority of the concerned area should be made a precondition. (para 6.3)

The Committee concurs with this view and recommends the Department to amend Section 32 B in the

light of the above observation. (para 7.1)

The Committee, however, is not inclined to believe that mere designation of one or more courts of Sessions as Special Court will help in expeditious disposal of cases as the Sessions Courts are already overburdened with a large number of cases. The Committee, therefore, recommends that new courts need to be set up for the purpose of trying offences under the Drugs & Cosmetics Act. (para 8.2)

The Committee adopts the remaining clauses of the Bill, including enacting formula and the title without any amendment. (para 9)

The Committee, therefore, thinks that in order to realize the deterrent-effects of the proposed Bill, first of all a successful conviction in the court of law is necessary and for that to happen it should be ensured that the accused is prevented from manipulating the system to his advantage. The Committee also feels that peddling in spurious or adulterated drugs is no way less serious than peddling in narcotics. The Committee, therefore, recommends that the Department should incorporate similar provisions in the Bill, as exist in the NDPS Act. (para 10)

The Committee emphasizes that action to increase public awareness about harmful/banned drugs should be initiated at the earliest. (para 11)

*The Committee hopes that with all these measures the situation would improve in the states.*

(para 12)

*The Committee finds it rather surprising. The Committee strongly feels that the Department has to take the initiative in this matter. An effective monitoring mechanism needs to be set up to present such cases. At the same time, public should also be made aware of such provisions.* (para 13(ii))

*The Committee however feels that more stringent penalties are required to be imposed in the case of spurious/adulterated/ not of standard quality Ayurvedic/Unani/Siddha drugs also. The Committee, therefore, is of the view that the penalty provision for AYUSH drug should be reviewed so as to make changes, if necessary. The Committee also emphasizes the need for strengthening the testing labs for AYUSH drugs, the present status of which cannot be considered satisfactory.* (para 14)

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## MINUTES

### MINUTES OF THE MEETING OF DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH & FAMILY WELFARE XVII SEVENTEENTH MEETING

The Committee met at 3.00 p.m. on Thursday, the 14<sup>th</sup> July, 2005 in Room No. 63 First Floor, Parliament House, New Delhi.

#### MEMBERS PRESENT

#### RAJYA SABHA

1. Shri Amar Singh ¾ *Chairman*
2. Shrimati Sukhbans Kaur
3. Dr. A.K. Patel

## 4. Shrimati Maya Singh

## LOK SABHA

5. Shri D.K. Adikesavulu
6. Smt. B. Sushila Devi Laxman
7. Dr. M. Baburao
8. Dr. R.C. Dome
9. Shri S. Mallikarjunaiah
10. Md. Shahabuddin
11. Dr. Arvind Kumar Sharma
12. Shri Uday Singh
13. Smt. V. Radhika Selvi
14. Shri Kailash Nath Singh Yadav
15. Dr. Karan Singh Yadav

## SECRETARIAT

Smt Vandana Garg, Joint Secretary  
 Shri P.R. Guha Roy, Director  
 Shri Mom Raj Singh, Under Secretary  
 Shri S.C. Dixit, Committee Officer

## REPRESENTATIVES OF THE DEPARTMENT OF HEALTH

- |    |                       |                                   |
|----|-----------------------|-----------------------------------|
| 1. | Shri S.Y. Quraishi    | Special Secretary & D.G. (NACO)   |
| 2. | Dr. S.P. Agarwal      | Director General (Health Service) |
| 3. | Dr. Ashwani Kumar     | Drug Controller General of India  |
| 4. | Smt. Rita Teaotia     | Joint Secretary                   |
| 5. | Shri Rajesh Bhushan   | Director                          |
| 6. | Dr. N.S. Dharamshakhu | Addl. Project Director (NACO)     |

2. At the outset, the Chairman welcomed the members of the Committee. The Special Secretary, Department of Health then gave a brief presentation on the Drugs and Cosmetics (Amendment) Bill-2005. The members raised certain issues in respect of the Bill to which the Spl. Secretary assured to submit written reply later.

3. The Committee then took up for consideration the Tenth and Eleventh Draft Reports of the Committee on the Homoeopathy Central Council (Amendment) Bill-2005 and the Indian Medicine Central Council (Amendment) Bill-2005 respectively. The Committee adopted both the Draft Reports without any change.

4. The Committee decided that the Reports may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha in the ensuing Monsoon Session of the Parliament. The Committee authorized the Chairman and in his absence Smt. Maya Singh to present the Reports in the Rajya Sabha and Shri Uday Singh and in his absence Shri R.C. Dome for laying the Reports on the Table of Lok Sabha.

4A. A verbatim record of the proceedings was kept.

**5. The Committee then adjourned at 4:00 p.m.**

NEW DELHI

MOM RAJ SINGH

14<sup>th</sup> July, 2005

UNDERSECRETARY

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

**I  
FIRST MEETING**

The Committee met at 11.00 a.m. on Friday, the 9<sup>th</sup> September, 2005 in Room No. 139 First Floor, Parliament House Annexe, New Delhi.

**MEMBERS PRESENT**

**RAJYA SABHA**

- |                        |   |                 |
|------------------------|---|-----------------|
| 1. Shri Amar Singh     | ¾ | <i>Chairman</i> |
| 2. Prof. P. J. Kurian  |   |                 |
| 3. Dr. A.K. Patel      |   |                 |
| 4. Shrimati Maya Singh |   |                 |
| 5. Shri Lalhming Liana |   |                 |

**LOK SABHA**

6. Dr. Ram Chandra Dome
7. Shri Rajendra Kumar
8. Smt. Sushila Bangaru Laxman
9. Shri S. Mallikarjuniah
10. Dr. Babu Rao Mediyam
11. Dr. Chinta Mohan
12. Shri D.B. Patil
13. Shri Nakul Das Rai
14. Dr. Arvind Kumar Sharma
15. Shri Uday Singh
16. Dr. Karan Singh Yadav

**SECRETARIAT**

Smt Vandana Garg, Joint Secretary  
Shri P.R. Guha Roy, Director  
Shri Mom Raj Singh, Under Secretary  
Shri S.C. Dixit, Committee Officer

**WITNESSES**

**(A) REPRESENTATIVES OF INDIAN DRUG MANUFACTURERS ASSOCIATION, MUMBAI**

- |                    |                    |
|--------------------|--------------------|
| 1. Shri G.Wakankar | Executive Director |
| 2. Shri S.K Arya   | Joint Director     |

**(B) REPRESENTATIVES OF THE ALL INDIA ORGANISATION OF CHEMISTS & DRUGGISTS, MUMBAI**

- |                   |                  |
|-------------------|------------------|
| 1. Shri R.B. Puri | President, AIOCD |
|-------------------|------------------|

2. Shri J.S. Shinde Hon. Gen. Secretary, AIOCD

(C) REPRESENTATIVES OF INDIAN PHARMACEUTICAL ALLIANCE, MUMBAI

1. Shri D.G.Shah Secretary General  
2. Shri Raghu Cidambi Dr. Reddy`s

(D) REPRESENTATIVES OF CONFEDERATION OF INDIAN PHARMACEUTICAL INDUSTRY (SMALL SCALE), DELHI

1. Shri P.K.Gupta **Co-Chairman**  
2. Shri Subhash Malhotra  
3. Shri Sudesh Kumar

(E) REPRESENTATIVES OF VOICE, DELHI

1. Dr. Sri Ram Khana Managing Trustee  
2. Shri H.W. Awasthi Manager Legal

(F) REPRESENTATIVES OF VHAI, DELHI

1. Dr. Mira Shiva Director, WHD & Rational Drug Policy  
2. Dr. C.M. Gulati Editor, Monthly Index of Medical Specialties

2. At the outset, the Chairman welcomed the members of the re-constituted Committee to its first meeting. Members were informed that two Bills, namely, the Indian Medical Council (Amendment) Bill-2005 & the Indian Medicine and Homoeopathy Pharmacy Bill-2005 have been referred to the Committee for examination and report within three months.

3. The Chairman apprised the Committee that a detailed questionnaire on the Drugs and Cosmetics (Amendment) Bill, 2005 has been prepared by the Secretariat and forwarded to the Department of Health & Family Welfare for their comments. The Committee thereafter heard a number of witnesses representing various organizations and also NGOs on the Drugs and Cosmetics (Amendment) Bill, 2005. The members raised queries on certain provisions of the Bill to which the witnesses gave their reply.

4. The Committee then dwelt upon the low satisfaction level of beneficiaries of CGHS, with regard to various services provided under the scheme. The attention of the Committee was drawn to the observations of Planning Commission on the CGHS in its mid term appraisal of the 10<sup>th</sup> Five Year Plan and also some media reports in this regard. The Committee proposed to take up this subject for examination and directed the Secretariat to obtain the comments of the Department concerned on the matter.

4A. A verbatim record of the proceedings was kept.

5. The Committee then adjourned at 2:15 *p.m.* to meet again on Monday the 26<sup>th</sup> September, 2005 at 11.00 a.m.

**NEW DELHI**

**MOM RAJ SINGH**  
**UNDER SECRETARY**

9<sup>th</sup> September, 2005

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**MINUTES OF THE MEETING OF DEPARTMENT-RELATED PARLIAMENTARY  
STANDING COMMITTEE ON HEALTH & FAMILY WELFARE  
IV  
FOURTH MEETING**

The Committee met at 3.00 *p.m.* on Thursday, the 17<sup>th</sup> November, 2005 in Committee Room "A" Ground Floor, Parliament House Annexe, New Delhi.

**RAJYA SABHA**

1. Shri Amar Singh ¾ *Chairman*
2. Shrimati Sukhbuns Kaur
3. Dr. A.K. Patel
4. Shrimati Maya Singh

**LOK SABHA**

5. Shri D.K. Audikesavulu
6. Smt. Maneka Gandhi
7. Shri Rajendra Kumar
8. Smt. Sushila Bangaru Laxman
9. Shri S. Mallikarjuniah
10. Dr. Babu Rao Mediyam
11. Dr. Chinta Mohan
12. Shri Uday Singh
13. Smt. V. Radhika Selvi
14. Dr. Karan Singh Yadav

**SECRETARIAT**

Smt Vandana Garg, Joint Secretary  
Shri P.R. Guha Roy, Director  
Shri Mom Raj Singh, Under Secretary  
Shri S.C. Dixit, Committee Officer

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**WITNESSES**

(a) Prof. (Dr.) Anil Kumar, MD, DM (Cardiology), Consultant Cardiologist, Bombay, Hospital & Medical Research Center, Bombay

(b) REPRESENTATIVES OF MINISTRY OF HEALTH & FAMILY WELFARE

1. Shri P.K. Hota, Secretary, Deptt. of Health & Family Welfare
2. Dr. Ashwini Kumar, Drug Controller General Of India
3. Dr. R.K. Srivastava, Director General of Health Services
4. Smt. Rita Teotia, Joint Secretary
5. Dr. S.K. Sharma, Advisor (Ayurveda)

(c) REPRESENTATIVES OF DELHI MEDICAL ASSOCIATION

1. Dr. K.K. Aggarwal, President
2. Dr. Girish Tyagi, Hony. State Secretary
3. Dr. Prem Aggarwal, Former Secretary General, I.M.A



## (d) REPRESENTATIVE OF DELHI MEDICAL COUNCIL

Dr. S.K. Khattri, Registrar

2. At the outset, the Chairman welcomed the members of the Committee. Then Prof. (Dr.) Anil Kumar made a brief presentation on the various provisions of the Indian Medical Council (Amendment) Bill, 2005. The members raised a number of queries and the witness replied thereto.
3. The Committee thereafter heard the Secretary, Department of Health and Family and the Drug Controller General Of India on various provisions relating to the Drugs and Cosmetics (Amendment) Bill, 2005. The members raised a number of queries and the witnesses replied thereto.
4. Resuming the discussion on the Indian Medical Council (Amendment) Bill 2005, the Committee heard the views of the representatives of Delhi Medical Association and Registrar, Delhi Medical Council on the subject. The witnesses replied to the queries raised by the members.
5. The Chairman informed the members that the Indian Medical Council (Amendment) Bill, 2005 and The Indian Medicine and Homoeopathy Pharmacy Bill, 2005 were referred to the Standing Committee on Health & Family welfare on 24<sup>th</sup> August, 2005 for examination and report within 3 months and the said period is going to lapse on 24<sup>th</sup> November, 2005. Another Bill, i.e. the Drugs and Cosmetics (Amendment) Bill, 2005 is already under the consideration of the committee. The Committee has not concluded its examination of the IMC (Amendment) Bill, 2005 as a number of witnesses are yet to be heard. The Committee could not, therefore, take up the Indian Medicine and Homoeopathy Pharmacy Bill, 2005. The Chairman proposed that the Hon'ble Chairman, Rajya Sabha may be requested to accord extension of three months time in respect of the Indian Medical Council (Amendment) Bill, 2005 and six months in respect of the Indian Medicine and Homoeopathy Pharmacy Bill, 2005. The Committee endorsed the proposal.
6. Verbatim record of the proceedings was kept.

**7. The Committee then adjourned at 6.15 p.m.**

NEW DELHI  
17<sup>th</sup> NOVEMBER, 2005

MOMRAJ SINGH  
UNDER SECRETARY

**MINUTES OF THE MEETING OF DEPARTMENT-RELATED PARLIAMENTARY**  
**STANDING COMMITTEE ON HEALTH & FAMILY WELFARE**  
**V**  
**FIFTH MEETING**

The Committee met at 2.00 p.m. on Thursday, the 15<sup>th</sup> December, 2005 in Committee Room 63, Parliament House, New Delhi.

**MEMBERS PRESENT**  
**RAJYA SABHA**

1. Shri Amar Singh ¾ *Chairman*
2. Prof. P.J. Kurian

**LOK SABHA**

3. Shri D.K. Adikesavulu
4. Dr. Ram Chandra Dome
5. Smt. Maneka Gandhi
6. Shri S. Mallikarjunaiah
7. Dr. Baburao Mediyam
8. Shri Nakul Das Rai
9. Shri Uday Singh
10. Smt. V. Radhika Selvi
11. Shri Kailash Nath Singh Yadav
12. Dr. Karan Singh Yadav

**SECRETARIAT**

Smt Vandana Garg, Joint Secretary  
 Shri P.R.Guha Roy, Director  
 Shri Momraj Singh, Under Secretary  
 Shri S.C. Dixit, Committee Officer

2. At the outset the Chairman welcomed the Members of the Committee. The Committee then considered and adopted the following Reports: -

- (i) 12th Report of the Committee on the Drugs and Cosmetics (Amendments) Bill-2005.
- (ii) 13th Report on the Action Taken by the Government on the recommendations/observations contained in the 8<sup>th</sup> Report on Demands for Grants (2005-06) relating to the Department of Family Welfare.
- (iii) 14th Report on the Action Taken by the Government on the recommendations/observations contained in the 9<sup>th</sup> Report on Demands for Grants (2005-06) relating to the Department of AYUSH.
- (iv) 15th Report on the Action Taken by the Government on the recommendations/observations contained in the 7<sup>th</sup> Report on Demands for Grants (2005-06) relating to the Department of Health.

2A. The Committee also decided that the 12<sup>th</sup>, 13<sup>th</sup>, 14<sup>th</sup> and 15<sup>th</sup> Reports may be presented in Rajya Sabha by the Chairman and in his absence, by Prof. P.J. Kurian and in his absence Smt. Maya Singh laid on the Table of Lok Sabha by Dr. Karan Singh Yadav and in his absence by Shri Uday Singh on the 21<sup>st</sup> December, 2005.

3. The Committee adjourned at 3.00 *p.m.*

**NEW DELHI**

15<sup>th</sup> December, 2005

**MOMRAJ SINGH**  
 UNDER SECRETARY