Legislative Brief

The Drugs and Cosmetics (Amendment) Bill, 2005 and 2007

The 2005 Bill was introduced in the Rajya Sabha on May 10, 2005. The Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh) submitted its report on December 21, 2005.

The 2007 Bill was introduced in the Rajya Sabha on August 21, 2007. The Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh) is scheduled to submit its report by the last day of the Budget Session, 2008.

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Highlights of the Bills

- The Drugs and Cosmetics (Amendment) Bill, 2005 seeks to amend the Drugs and Cosmetics Act, 1940. It enhances penalties for certain offences and provides for special courts to try offences related to spurious and adulterated drugs.
- The Drugs and Cosmetics (Amendment) Bill, 2007 seeks to replace the Drugs Technical Advisory Boards for allopathic and Indian systems of medicine with the Central Drugs Authority (CDA). Drug consultative committees may be established to advise the CDA and central and state governments.
- The CDA shall be the licensing authority for the manufacturing, distribution, sale, import and export of drugs and cosmetics. It shall also recommend to the central government standards for drugs and cosmetics, measures to regulate clinical trials, etc.
- The 2007 Bill expands the definition of "drugs" to include medical devices. It also defines "clinical trial", states that all clinical trials require the approval of the CDA, and prescribes penalties for any person violating this provision.

Key Issues and Analysis

- The Standing Committee has submitted its recommendations on the 2005 Bill. It recommended enhanced penalties for spurious and adulterated drugs that lead to prolonged illness. It also suggested separate courts for trying offences under the Act.
- The CDA shall be the licensing authority for the manufacture, sale or stocking of drugs and cosmetics. Currently, these functions are delegated to state governments.
- The 2007 Bill does not mandate medical and scientific experts in the CDA. A member can be any person with special knowledge of and a minimum of 15 years professional experience in the pharmaceutical industry, public administration, finance or law.
- The Mashelkar Committee made various recommendations with regard to strengthening the drug regulatory system and the problem of adulterated and spurious drugs. Whereas several of these recommendations are being implemented through these Bills, neither Bill addresses the recommendations related to strengthening drug regulation at the state level.

PART A: HIGHLIGHTS OF THE BILL[1]

Context

The pharmaceutical sector in India is regulated by a number of laws.[2] The Drugs and Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics.

Over the years, various government appointed committees and other institutions have suggested ways to improve the drug regulatory system in the country.[3] Some of the recommendations were incorporated in the Drug Policy, 1986 and 1994, and the Pharmaceutical Policy, 2002. In 2003, the central government constituted an expert committee under Dr. R.A. Mashelkar to review the drug regulatory infrastructure. The Committee recommended changes in drug regulation, a system of centralised licensing, enhancement of penalties, etc.[4] A Bill, based on these recommendations, was introduced in 2003 but it lapsed due to the dissolution of Lok Sabha.[5]

The Drugs and Cosmetics (Amendment) Bill, 2005 seeks to enhance penalties and include provision for speedy trials. The Standing Committee on Health and Family Welfare submitted its report on December 21, 2005.

The Drugs and Cosmetics (Amendment) Bill, 2007 seeks to implement some other recommendations of the Mashelkar Committee. These include establishment of the Central Drugs Authority and regulation of clinical trials.

Key Features of 2005 Bill

The 2005 Bill increases penalties significantly for certain offences in the Drugs and Cosmetics Act, 1940 (Principal Act). Some of them are listed in Table 1.

Table 1: Some offences and penalties in 2005 Bill

Nature of Offence	Penalty
Manufacturing or selling adulterated/spurious drugs leading to grievous harm or death.	Life imprisonment and min fine of Rs 10 lakh or 3 times value of the drugs confiscated. Fine to be paid as compensation to victim or relative of victim. (1940 Act: 5 years to life imprisonment and min fine of Rs 10,000).
Manufacturing or selling a drug which is adulterated or without a license.	3-5 years imprisonment and a min fine of Rs 1 lakh. (1940 Act: 1-3 years imprisonment and min fine of Rs 5,000. Court has discretion to impose lesser penalty).
Manufacturing or selling spurious drug.	7 years to life imprisonment and min fine of Rs 3 lakh or three times the value of the drug confiscated. (1940 Act: 3-5 years imprisonment and min fine of Rs 5,000. Court has discretion to impose lesser penalty).

The 2005 Bill also: (a) designates Session Courts as special courts to try offences related to adulterated and spurious drugs; (b) in addition to drug inspectors, allows police officers of a minimum rank of sub-inspectors and authorised officers of the central and state governments to prosecute offenders; and (c) makes offences related to adulterated or spurious drugs cognizable* and non-bailable in certain cases.

Key Features of 2007 Bill

Table 2: Amendments to the Principal Act Proposed by the Drugs and Cosmetics (Amendment) Bill, 2007

Drugs and Cosmetics Act, 1940	Drugs and Cosmetics (Amendment) Bill, 2007
Structure for Regulation of Drugs and Cosmetics	
The central government shall establish a Drugs Technical Advisory Board and an Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.	The central government shall establish a Central Drugs Authority (CDA) which replaces both Drug Technical Advisory Boards. It shall consist of a Chairperson and 3 to 5 members. The CDA shall appoint a Drugs Controller (India) who shall be the Chief Executive Officer and the legal representative of the CDA. The CDA shall recommend to the central government standards for drugs and cosmetics, the Central Drugs Laboratories for testing drugs and cosmetics, measures to regulate import, export, manufacture for sale, and distribution of drugs and cosmetics, measures to regulate clinical trials etc; and may appoint Government Analysts and Inspectors.
The central government may establish a Drugs Consultative Committee to advise the central and state government and the Drugs Technical Advisory Boards. The members shall be nominated by central and state governments.	The central government may establish a Drugs Consultative Committee and an Ayurvedic, Siddha and Unani Drugs Consultative Committee. These committees may advise the CDA as well as the central and state governments on matters related to uniformity in the administration of the law. Both Committees are to be composed of representatives of the central and state governments, industry, consumer groups, etc.
Licensing	
Central government to prescribe in the Rules the authority that would issue licenses. License for manufacture of drugs in Schedules C and C1 and imports, shall be issued by the Central License Approving Authority (Drug Controller, India). License for manufacture and sale of other drugs and manufacture of cosmetics shall be issued by Licensing Authorities appointed by state governments.	The CDA will be the sole licensing authority for manufacturing for sale, export, import distribution or stocking of certain drugs and cosmetics.

* A cognizable case is one in which a police officer may arrest a person without a warrant.

Definition	
The definition of "drug" includes, among other items, devices intended for internal or external use in the diagnosis or treatment of disease in human beings or animals, as may be specified by the central government.	The definition of "drug" expanded to include medical device, instrument, and software needed for their application, as may be specified by the central govt after consultation with the CDA. The device may be used for the purpose of diagnosis of any disease; diagnosis of or compensation for any injury or handicap or control of conception.
Creation of Fund	
No fund	The central government shall set up a Central Drugs Authority of India Fund. It shall include all grants and fees received by the CDA. It shall be used for salaries of the members and employees of the CDA and for the implementation of the Bill.
Regulation of Clinical Trials	
Clinical trial is not defined in the Act but is detailed in the Rules. Clinical trial means "a systematic study of *new drugs* in human subjects… with the objective of determining safety and/or efficacy of the new drug."	"Clinical trial" means systematic study of *any drug or cosmetic* [not just 'new' drugs].
Clinical trials shall be conducted only with the permission of the Drug Controller, (India) and an ethics committee of the testing institution. The ethics committee should have a Chairperson who is outside the institution and a mix of medical and non-medical persons.	Clinical trial can be conducted only with the permission of the CDA.
No penalty prescribed for violating this provision.	If a person contravenes this provision, he shall be punished with imprisonment for a maximum term of five years and a fine of up to Rs 10 lakh. On subsequent conviction for the same offence, the person shall be punished with imprisonment up to 10 years and a fine which may extend to Rs 20 lakh. A person can be prosecuted only on a complaint made in writing by an officer authorised by the CDA.

Sources: Drugs and Cosmetics Act, 1940 and Rules, 1945; Drugs and Cosmetics (Amendment) Bill, 2007; PRS

PART B: KEY ISSUES AND ANALYSIS

Standing Committee Recommendations

The key recommendations of the Parliamentary Standing Committee on Health and Family Welfare with regard to the provisions of the 2005 Bill are listed below. None of these recommendations are incorporated in the 2007 Bill.

Table 3: Key Recommendations of the Standing Committee on the Drugs and Cosmetics (Amendment) Bill, 2005

	2005 Bill	Standing Committee Recommendations
Penalty	Penalty enhanced for manufacturing or selling adulterated or spurious drugs, which is likely to cause death or grievous harm.	In addition to death and grievous harm, prolonged illness should be a criterion for imposition of this penalty.
Penalty for subsequent offences	Deletes provision of penalty for subsequent offences in case of manufacturing or selling any drug in contravention of the law (other than adulterated or spurious drugs) and in case of use of Government Analyst reports for advertising.	Provisions should not be deleted.
Cognizance of offences	In addition to drug inspectors, police officers and authorised officers of the central and state governments may prosecute offenders.	Prior permission of the Drug Licensing Authority of the concerned area should be made a pre-condition before involving police inspectors and government officers.
Compounding of offences	Allows authorised officers of the central and state governments to compound certain offences.	There should be certain pre-requisites for compounding such as aggrieved party's concurrence; the amount compounded should be adequate to compensate the aggrieved person; the cost of litigation should be included in the sum compounded.
Special Courts	Provides for special courts to try offences and designates Courts of Session as Special Courts.	New courts should be set up for the purpose of trying offences under the Drugs and Cosmetics Act, 1940.

Sources: The Drugs and Cosmetics (Amendment) Bill, 2005; the Parliamentary Standing Committee Report; PRS

Centralisation of Licensing

The Mashelkar Committee recommended that license for manufacture of drugs should be approved by the CDA. It cited that U.S.A., Australia, China, etc. have a centralized licensing authority. However, it did not discuss the issue of centralizing the licensing of sales and distribution of drugs.

Clauses 5F(1), Financial Memorandum of 2007 Bill

The Bill proposes to establish the CDA as the licensing authority for manufacture, import, export, sale or stocking of drugs and cosmetics. Thus, the power to issue licenses to manufacturers, distributors and retailers shall be shifted from state governments to the CDA (headquartered in Delhi). This will have cost and time implications for license applicants. The CDA may establish offices at state and district level. However, the Financial Memorandum to the Bill does not provide for funding of such offices.

Recommendations of Mashelkar Committee Report

Table 4: Comparison of Key Recommendations of Mashelkar Committee Report and the 2005 and 2007 Bill

	Recommendations	
Drug Regulation at central level	▪ Transform the Central Drugs Standard Control Organisation into a well-equipped, independent and professionally managed body, with the status of CDA, under the Ministry of Health and Family Welfare ▪ Establish 10 main divisions within the CDA manned by adequately trained manpower ▪ Provide for funds for new structure and sourcing of external expertise and provide for technical manpower ▪ Allow CDA to grant manufacturing licenses to address issue of non-uniformity of enforcement	2007 Bill establishes CDA with provision for offices in other places; creates Fund for financing its activities; and centralises licensing
Drug Regulation at state level	▪ Strengthen state drug control organisations with additional manpower, infrastructure, technical capabilities and adequate budget ▪ Set up intelligence cum legal cell under the supervision of trained senior nodal officers, and enforce condition of licence for sale of drugs	2007 Bill has no provision
Medical Devices and Diagnostics	▪ Separately define medical devices and frame guidelines for their regulation ▪ Set up Medical Devices Division in the CDA ▪ CDA should set up regulatory mechanism for quality assurance and post-marketing surveillance of imported and locally made medical devices	2007 Bill expands definition of "drugs" to include certain devices
Clinical Research	▪ Share responsibility for safety of Indian subjects in clinical research by all stakeholders (investigators, sponsors, ethics committee and regulators) ▪ Institutionalise Good Clinical Practices to achieve credibility for data generated in India ▪ Require regulatory agency to develop adequate capacity to undertake routine inspections of clinical trial sites ▪ Consider expedited approvals for Phase II and III clinical trials on the basis of approvals accorded by International Conference on Harmonisation signatory countries ▪ A single window clearance mechanism for approval of applications related to drug research ▪ Rationalise policies related to animal experiments	2007 Bill provides for regulation of clinical trials for any drug or cosmetic
Spurious and Sub-standard Drugs	▪ Create effective interaction among stakeholders (regulators, consumers, industry, medical profession) ▪ Enhance penalties making offences cognisable and non-bailable ▪ Identify designated courts for speedy trials of spurious drug cases ▪ Discourage proliferation of drug distribution outlets ▪ Industry should create counterfeit drug strategies and surveillance systems ▪ Review system to tackle issue of non-uniformity in action taken on sub-standard drugs in different states ▪ Strengthen states with technical know-how and manpower to monitor quality of drugs manufactured and sold ▪ Improve testing laboratories by making Good Laboratory Practices norms a statutory requirement, accreditation with National Accreditation Board for Testing and Calibration Laboratories mandatory, etc	2005 Bill provides for enhanced penalties for certain offences, makes offences cognisable and non-bailable, and designates Sessions Courts for trying cases

Sources: The Mashelkar Committee Report, 2003; PRS

Composition of Central Drugs Authority

Clause 5(3), 5A

The 2007 Bill states that the central government shall appoint the Chairperson and members of the CDA with special knowledge of and at least 15 years of professional experience in the pharmaceutical industry, research or teaching, or public administration, finance or law. It is possible to constitute the CDA without any medical and scientific experts since the proportion of members from each field has not been specified. The Drugs and Cosmetics Rules of the Principal Act prescribe minimum qualifications of a Licensing Authority which include at least a graduation degree in Pharmacy or Pharmaceutical Chemistry or Medicine with specialisation in clinical pharmacology and microbiology.

Notes

1. This Brief has been developed on the basis of The Drugs and Cosmetics (Amendment) Bill, 2005 and 2007. The 2005 Bill was introduced in Rajya Sabha on May 10, 2005. The Standing Committee on Health and Family Welfare (Chairperson: Shri Amar Singh) submitted its report on December 21, 2005. The 2007 Bill was introduced in Rajya Sabha on August 21, 2007. The Bill was referred to the Standing Committee on Health and Family Welfare (Chairperson: Shri Arjun Singh), which is scheduled to submit its report by the last day of the Budget Session, 2008.
2. The Drugs and Cosmetics Act, 1940; The Pharmacy Act, 1948; The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; The Narcotic Drugs and Psychotropic Substances Act, 1985; The Medicinal and Toilet Preparations (Excise Duties) Act, 1956; and The Drugs (Prices Control) Order 1995 (under the Essential Commodities Act).
3. Committees include the Hathi Committee (1975); Task Force on strengthening drug regulatory system in the centre and the states (1982); the Estimates Committee of Lok Sabha (1983-84); and the Pharmaceutical Research and Development Committee (1999). In addition, the Supreme Court, National Human Rights Commission and Standing Committee of Parliament made recommendations.
4. Report of Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs (Chairperson: Dr R.A. Mashelkar), Ministry of Health and Family Welfare, November 2003.
5. 12th Report on Drugs and Cosmetics (Amendment) Bill, 2005, Standing Committee on Health and Family Welfare, Dec 21, 2005.