

Bill No. LIV of 2005

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2005

A

BILL

further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Fifty-sixth Year of the Republic of India as follows:—

1. (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2005.

Short title
and com-
mencement.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint:

5 Provided that different dates may be appointed for different provisions of this Act and any reference in any such provision to the commencement of this Act shall be construed as a reference to the commencement of that provision.

Amendment of section 27. **2.** In section 27 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), — 23 of 1940.

(i) in clause (a),—

(A) for the words “punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;”, the words “punishable with imprisonment for a term which shall not be 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 value of the drugs confiscated, whichever is more:” shall be substituted;

(B) the following provisos shall be inserted, namely:—

“Provided that the fine imposed on and realised from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation.—For the purposes of the second proviso, the expression “relative” means—

(i) spouse of the deceased person; or

(ii) a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

(iii) if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

(iv) any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death,—

(a) the parent; or

(b) a minor brother or an unmarried sister; or

(c) a widowed daughter-in-law; or

(d) a widowed sister; or

(e) a minor child of a pre-deceased son; or

(f) a minor child of a pre-deceased daughter where no parent of the child is alive; or

(g) the paternal grandparent if no parent of the member is alive;”;

(ii) in clause (b),—

(A) for the words “not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees”, the words “not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees” shall be substituted;

(B) in the proviso, for the words “less than one year and of fine of less than five thousand rupees”, the words “less than three years and of fine of less than one lakh rupees” shall be substituted;

(iii) in clause (c),—

(A) for the words “not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees”, the words “not less than seven years but which may extend to imprisonment for life and with fine which shall not be three lakhs rupees or three times the value of the drugs confiscated, whichever is more” shall be substituted;

(B) in the proviso, for the words “less than three years but not less than one year”, the words “less than seven years but not less than three years and of fine of less than one lakh rupees” shall be substituted;

(iv) in clause (d), for the words “and with fine”, the words “and with fine which shall not be less than twenty thousand rupees” shall be substituted.

3. In section 28 of the principal Act, for the words “with fine which may extend to one thousand rupees or with both”, the words “with fine which shall not be less than twenty thousand rupees or with both” shall be substituted. Amendment of section 28.

4. In section 28A of the principal Act, for the words “with fine which may extend to one thousand rupees or with both”, the words “with fine which shall not be less than twenty thousand rupees or with both” shall be substituted. Amendment of section 28A.

5. In section 30 of the principal Act,— Amendment of section 30.

(a) in sub-section (1),—

(i) in clause (a),—

(A) for the words “not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees”, the words “not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakhs rupees” shall be substituted;

(B) in the proviso, for the words “less than two years and of fine of less than ten thousand rupees”, the words “less than seven years and of fine of less than one lakh rupees” shall be substituted;

(ii) in clause (b), for the words “shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees”, the words “shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakhs rupees” shall be substituted;

(iii) clause (c) shall be omitted;

(b) sub-section (2) shall be omitted.

6. In section 32 of the principal Act, for sub-sections (1) and (2), the following sub-sections shall be substituted, namely:— Amendment of section 32.

“(1) No prosecution under this Chapter shall be instituted except by—

(a) an Inspector; or

(b) any police officer (not below the rank of Sub-Inspector of Police) as referred to in the Police Act, 1861 or any member of the police establishment not below the rank of Sub-Inspector of the Special Police Force constituted under the Delhi Special Police Establishment Act, 1946; or

(c) any officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government by a general or special order made in this behalf by that Government; or

5 of 1861.

25 of 1946.

(d) the person aggrieved; or

(e) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.”.

Insertion of new section 32B.

Compounding of certain offences.

7. After section 32A of the principal Act, the following section shall be inserted, namely:—

“32B. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (b) of sub-section (1) of section 13, clause (b) of sub-section (2) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify: 2 of 1974.

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded.

(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.”.

Amendment of section 33.

8. In section 33 of the principal Act, in sub-section (2), after clause (q), the following clause shall be inserted, namely:—

“(r) sum which may be specified by the Central Government under section 32B.”.

Amendment of section 36A.

9. In section 36A of the principal Act, for the words “all offences under this Act”, the words, brackets, figures and letters “all offences (except the offences triable by the Special Court under section 36AB or Court of Session) under this Act” shall be substituted.

Insertion of new sections 36AB, 36AC, 36AD and 36AE.

Special Courts.

10. After section 36A of the principal Act, the following sections shall be inserted, namely:—

‘36AB. (1) The Central Government, or the State Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to adulterated drugs or spurious drugs and punishable under clauses (a) and (b) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and clause (b) of sub-section (1) of section 30 and other offences relating to adulterated drugs or spurious drugs, by notification, designate one or more Courts of Session as a Special Court or Special Courts for such area or areas or for such case or class or group of cases as may be specified in the notification.

Explanation.—In this sub-section, “High Court” means the High Court of the State in which a Court of Session designated as Special Court was functioning immediately before such designation.

(2) While trying an offence under this Act, a Special Court shall also try an offence, other than an offence referred to in sub-section (1), with which the accused may, under the Code of Criminal Procedure, 1973, be charged at the same trial. 2 of 1974.

- 2 of 1974. 36AC. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, —
- Offences to be cognizable and non-bailable in certain cases.
- (a) every offence, relating to adulterated or spurious drug and punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable;
- (b) no person accused, of an offence punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless—
- (i) the Public Prosecutor has been given an opportunity to oppose the application for such release; and
- (ii) where the Public Prosecutor opposes the application, the court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail:
- Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be released on bail, if the Special Court so directs.
- 2 of 1974. (2) The limitation on granting of bail specified in clause (b) of sub-section (1) is in addition to the limitations under the Code of Criminal Procedure, 1973 or any other law for the time being in force on granting of bail.
- 2 of 1974. (3) Nothing contained in this section shall be deemed to affect the special powers of the High Court regarding bail under section 439 of the Code of Criminal Procedure, 1973 and the High Court may exercise such powers including the power under clause (b) of sub-section (1) of that section as if the reference to "Magistrate" in that section includes also a reference to a "Special Court" designated under section 36AB.
- 2 of 1974. 36AD. (1) Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973 (including the provisions as to bails or bonds), shall apply to the proceedings before a Special Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of Session and the person conducting the prosecution before the Special Court, shall be deemed to be a Public Prosecutor:
- Application of Code of Criminal Procedure, 1973 to proceedings before Special Court.
- Provided that the Central Government or the State Government may also appoint, for any case or class or group of cases, a Special Public Prosecutor.
- (2) A person shall not be qualified to be appointed as a Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an advocate for not less than seven years, under the Union or a State, requiring special knowledge of law.
- (3) Every person appointed as a Public Prosecutor or a Special Public Prosecutor under this section shall be deemed to be a Public Prosecutor within the meaning of clause (u) of section 2 of the Code of Criminal Procedure, 1973 and the provisions of that Code shall have effect accordingly.
- 2 of 1974.
- 2 of 1974. 36AE. The High Court may exercise, so far as may be applicable, all the powers conferred by Chapter XXIX or Chapter XXX of the Code of Criminal Procedure, 1973, on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.
- Appeal and revision.

ANNEXURE

EXTRACTS FROM THE DRUGS AND COSMETICS ACT, 1940

(23 OF 1940)

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27. Whoever, himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes,—

Penalty for manufacture, sale, etc., of drugs in contravention of this Chapter.

45 of 1860.

(a) any drug deemed to be adulterated under section 17A or spurious under section 17B or which when used by any person for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grievous hurt within the meaning of section 320 of the Indian Penal Code, solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than five years but which may extend to a term of life and with fine which shall not be less than ten thousand rupees;

(b) any drug—

(i) deemed to be adulterated under section 17A, but not being a drug referred to in clause (a), or

(ii) without a valid licence as required under clause (c) of section 18,

shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less than five thousand rupees;

(c) any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons, to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years but not less than one year;

(d) any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine:

Provided that the Court may for any adequate and special reasons to be recorded in the judgment impose a sentence of imprisonment for a term of less than one year.

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28. Whoever contravenes the provisions of section 18A or section 24 shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

Penalty for non disclosure of the name of the manufacturer etc.

Penalty for not keeping documents, etc., and for non-disclosure of information.

28A. Whoever, without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to one thousand rupees or with both.

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Penalty for subsequent offences.

30. (1) Whoever having been convicted of an offence,—

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than ten thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than ten thousand rupees;

(b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than six years but which may extend to ten years and with fine which shall not be less than ten thousand rupees;

(c) under clause (d) of section 27, is again convicted of an offence under that clause 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.

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(2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to ten years or with fine, or with both.

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Cognizance of offences.

32. (1) No prosecution under this Chapter shall be instituted except by an Inspector or by the person aggrieved or by a recognised consumer association whether such person is a member of that association or not.

(2) No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under this Chapter.

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Power of Central Government to make rules.

33. (1) * * * * *

(2) Without prejudice to the generality of the foregoing power, such rules may—

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Certain offences to be tried summarily.

“36A. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, all offences under this Act, punishable with imprisonment for a term not exceeding three years, other than an offence under clause (b) of sub-section (1) of section 33-I, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.

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STATEMENT OF OBJECTS AND REASONS

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.

2. 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.

3. 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 organised 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.

4. 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 sub-standard drugs and 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 and 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. The Central Government, *inter alia*, proposes to make the following amendments in the Drugs and Cosmetics Act, 1940, broadly on the lines of the earlier Bill introduced with certain modifications which relate to enhancement of punishment and doing away with the death penalty as proposed in the said Bill, namely:—

(i) The existing provisions contained in section 27 of the aforesaid Act, *inter alia*, provide for scale of punishment for the first offence in respect of adulterated or spurious drugs. Clause (a) of section 27 of the aforesaid Act, provides for imprisonment for not less than five years which may extend to life and with fine of not less than rupees ten thousand for the manufacture and sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death of the patients or harm on the patient's body as would amount to grievous hurt. It is proposed to enhance the period of imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine of ten lakh rupees or three times the value of the drugs confiscated, whichever is more;

(ii) It is also proposed to insert two provisos in the said clause (a) so as to provide that the fine imposed on the convicted person and realised from him under the said clause shall be paid to the person who used such adulterated or spurious drugs and in case of his death, to his relative;

(iii) Clause (b) of said section 27 provides for punishment of imprisonment for not less than one year which may extend to three years and fine of not less than rupees five thousand for manufacture and sale of any adulterated drug (not being a drug referred to in section 17A) or manufacture and sale of drugs without a valid licence. It is proposed to enhance the said punishment of imprisonment being not less than three years but may extend to five years and with fine which shall not be less than one lakh rupees;

(iv) Clause (c) of aforesaid section 27 provides for punishment of imprisonment for not less than one year which may extend to three years but which may extend to five years and with fine which shall not be less than rupees five thousand for manufacture and sale of any spurious drug (not being a drug referred to in section 17B). It is proposed to enhance the said punishment of imprisonment being not less than seven years but which may extend to imprisonment for life and with fine which shall be three lakh rupees or three times the value of the drugs seized, whichever is more;

(v) Clause (d) of aforesaid section 27 provides for punishment of imprisonment for a term which shall not be less than one year but which may extend to two years and with fine. It is proposed to provide that the fine shall not be less than twenty thousand rupees;

(vi) It is also proposed to provide for a fine of not less than twenty thousand rupees under section 28 for non-disclosure of the name of the manufacturer and under section 28A for not keeping documents, etc., and for not disclosure of information;

(vii) It is also proposed to enhance punishment specified under section 30 for subsequent offences. Clause (a) of said section 30 provides for punishment for imprisonment not less than two years which may extend to six years and with fine of not less than rupees ten thousand for manufacture and sale of any adulterated drug or manufacture and sale of drugs without a valid licence. It is proposed to enhance the said punishment which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees. Clause (b) of aforesaid section 30 provides for punishment for imprisonment for not less than six years which may extend to ten years and with fine of not less than rupees ten thousand for manufacture and sale of a spurious drug. It is proposed to enhance the punishment of imprisonment which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees;

(viii) It is also proposed to designate one or more Court of Session as Special Court for trial of offences related to adulterated or spurious drugs;

(ix) It is also proposed to make offences relating to adulterated or spurious drugs as cognizable and non-bailable in certain cases;

(x) It is also proposed to confer powers upon the police officers not below the rank of sub-inspector of police and other officers of the Central Government or State Government authorised by it to institute the prosecution under the aforesaid Act;

(xi) It is also proposed to provide compounding of certain offences not being an offence punishable with imprisonment only or with imprisonment and also with fine.

5. The Bill seeks to achieve the above objects.

NEW DELHI;

ANBUMANI RAMDOSS.

The 2nd May, 2005.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 7 of the Bill proposes to insert a new section 32B in the Drugs and Cosmetics Act, 1940 to provide for compounding of certain offences by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government on payment for credit to that government of such sum as that Government may, by rules specify. Clause 8 of the Bill proposes to insert a clause (*r*) in sub-section (2) of section 33 of the said Act to confer power upon the Central Government to make such rules.

2. The matter in respect of which rules may be made are matter of procedure and detail and it is not practicable to provide for it in the Bill itself. The delegation of legislative power is, therefore, of a normal character.

RAJYA SABHA

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further to amend the Drugs and Cosmetics Act, 1940.

(Dr. Anbumani Ramadoss, Minister of Health and Family Welfare)