

रजिस्ट्री सं० डी० एल—(एन)04/0007/2003—08

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# भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II — खण्ड 1

PART II — Section 1

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं० 35] नई दिल्ली, शुक्रवार, दिसम्बर 5, 2008/अग्रहायण 14, 1930  
No. 35] NEW DELHI, FRIDAY, DECEMBER 5, 2008 / AGRAHAYANA 14, 1930

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।  
Separate paging is given to this Part in order that it may be filed as a separate compilation.

## MINISTRY OF LAW AND JUSTICE

(Legislative Department)

*New Delhi, the 5th December, 2008/Agrahayana 14, 1930 (Saka)*

The following Act of Parliament received the assent of the President on the 5th December, 2008, and is hereby published for general information:—

### THE DRUGS AND COSMETICS (AMENDMENT) ACT, 2008

No. 26 OF 2008

[5th December, 2008.]

An Act further to amend the Drugs and Cosmetics Act, 1940.

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

1. (1) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2008.

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:

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.

Insertion of  
new section  
17E.

Adulterated  
cosmetics.

2. After section 17D of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act), the following section shall be inserted, namely,—

"17E. For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated,—

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength."

Amendment  
of section 18.

3. In section 18 of the principal Act, in clause (a), for sub-clause (ii), the following sub-clause shall be substituted, namely,—

"(ii) any cosmetic which is not of a standard quality, or is misbranded, adulterated or spurious;"

Amendment  
of section  
26A.

4. In section 26A of the principal Act, for the word "prohibit", the words "regulate, restrict or prohibit" shall be substituted.

Insertion of  
new section  
26B.

5. After section 26A of the principal Act, the following section shall be inserted, namely,—

Power of  
Central  
Government to  
regulate or  
restrict,  
manufacture,  
etc., of drug in  
public interest.  
Amendment  
of section 27.

"26B. Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug."

6. In section 27 of the principal Act,—

(i) in clause (a),—

(A) for the figures, letter and words "17B or which", the figures, letter and words "17B and which" shall be substituted.

(B) 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.

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

"Provided that the fine imposed on and released 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) parent of the minor victim; or
  - (iv) 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
  - (v) 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 or three times the value of the drugs confiscated, whichever is more" 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 lakh 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.

Amendment  
of section  
27A.

7. In section 27A of the principal Act, for clauses (i) and (ii), the following clauses shall be substituted, namely,—

(i) any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the cosmetics confiscated, whichever is more;

(ii) any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both."

Amendment  
of section 28.

8. 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  
28A.

9. 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 29.

10. In section 29 of the principal Act, for the words "five hundred rupees", the words "five thousand rupees" shall be substituted.

Amendment  
of section 30.

11. In section 30 of the principal Act,—

(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 lakh 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 lakh rupees" shall be substituted;

(iii) in clause (c), for the words "five thousand rupees", the words "fifty thousand rupees" shall be substituted;

(b) in sub-section (2), for the words "ten years, or with fine, or with both", the words "two years, or with fine which shall not be less than ten thousand rupees or with both" shall be substituted.

Amendment  
of section 32.

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

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

(a) an Inspector; or

(b) any gazetted 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

(c) the person aggrieved; or

(d) 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."

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

Insertion of new section 32B.

2 of 1974.

"32B. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any offence punishable under clause (b) of sub-section (1) 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:

Compounding of certain offences.

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:

Provided further that in cases of subsequent offences, the same shall not be compoundable.

(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."

14. In section 33 of the principal Act, in sub-section (2),—

Amendment of section 33.

(i) after clause (dd), the following clause shall be inserted, namely,—

"(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;"

(ii) in clause (p), the word "and" occurring at the end shall be omitted;

(iii) in clause (q), the word "and" shall be inserted at the end;

(iv) after clause (q), the following clause shall be inserted, namely,—

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

15. In section 33-I of the principal Act,—

Amendment of section 33-I.

(a) in sub-section (1),—

(i) for clause (a), the following clause shall be substituted, namely:—

"(a) any Ayurvedic, Siddha or Unani drug—

(i) deemed to be misbranded under section 33E,

(ii) deemed to be adulterated under section 33EE, or

(iii) without a valid licence or in violation of any of the conditions thereof, as required under section 33 EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;";

(ii) in clause (b), for the words "five thousand rupees", occurring at both the places, the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(iii) after clause (b), the following clause shall be inserted, namely:—

"(c) any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.";

(b) in sub-section (2), for the words "three months and with fine which shall not be less than five hundred rupees", the words "six months and with fine which shall not be less than ten thousand rupees" shall be substituted.

Amenment of  
section 33J.

16. In section 33J of the principal Act,—

(a) in clause (a), for the words "two thousand rupees", the words "fifty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(b) in clause (b), for the words "five thousand rupees" occurring at both the places, the words "one lakh rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted;

(c) in clause (c), for the words "six months and with fine which shall not be less than one thousand rupees", the words "one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more" shall be substituted.

Insertion of  
new sections  
33KA and  
33KB.

17. After section 33K of the principal Act, the following sections shall be inserted, namely,—

Disclosure of  
name of  
manufacturer,  
etc.

"33KA. Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug.

Maintenance  
of records and  
furnishing of  
information.

33KB. Every person holding a licence under clause (c) of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act."

Amendment  
of section  
33N.

18. In section 33N of the principal Act, in sub-section (2),—

(i) in clause (gga), the word "and" occurring at the end shall be omitted;

(ii) after clause (gga), the following clause shall be inserted, namely,—

"(ggb) prescribe the records, registers or other documents to be kept and maintained under section 33KB; and"

Amendment  
of section  
36A.

19. 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.

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

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

‘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.

Special Courts.

*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.

36AC. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973,—

2 of 1974.

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.

Application of  
Code of  
Criminal  
Procedure,  
1973 to  
proceedings  
before Special  
Court.

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: 2 of 1974.

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.

Appeal and  
revision.

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. 2 of 1974.

T. K. VISWANATHAN,  
*Secy. to the Govt. of India*



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असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 10 अगस्त, 2009

का.आ. 2076(अ).—केन्द्रीय सरकार, औषध और प्रसाधन सामग्री (संशोधन) अधिनियम, 2008 (2008 का 26) की धारा 1 की उप-धारा (2) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, एतद्वारा 10 अगस्त, 2009 को उस तारीख के रूप में नियत करती है, जिसको उक्त अधिनियम की धाराओं में अन्तर्विष्ट उपबंध प्रवृत्त होंगे।

[फा. सं. एक्स. 11014/04/2009-डीएफक्यूसी]

देबाशीष पण्डा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th August, 2009

S.O. 2076(E).—In exercise of the powers conferred by sub-section (2) of Section 1 of the Drugs and Cosmetics (Amendment) Act, 2008 (26 of 2008), the Central Government hereby appoints the 10th August, 2009 as the date on which the provisions contained in the Sections of the said Act shall come into force.

[F. No. X. 11014/04/2009-DFQC]

DEBASISH PANDA, Jt. Secy.