



महाराष्ट्र शासन राजपत्र

असाधारण भाग आठ

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असाधारण क्रमांक १५४

प्राधिकृत प्रकाशन

महाराष्ट्र विधानमंडळाचे अधिनियम व राज्यपालांनी प्रख्यापित केलेले अध्यादेश व केलेले विनियम आणि विधि व न्याय विभागाकडून आलेली विधेयके (इंग्रजी अनुवाद).

In pursuance of clause (3) of article 348 of the Constitution of India, the following translation in English of the Drugs and Cosmetics (Maharashtra Amendment) Bill, 2018 (L. A. Bill No. LXXIII of 2018), introduced in the Maharashtra Legislative Assembly on the 26th November 2018, is hereby published under the authority of the Governor.

By order and in the name of the Governor of Maharashtra,

RAJENDRA G. BHAGWAT,
Secretary (Legislation)
to Government,
Law and Judiciary Department.

L. A. BILL No. LXXIII OF 2018.

A BILL

further to amend the Drugs and Cosmetics Act, 1940, in its application to the State of Maharashtra.

23 of
1940.

WHEREAS it is expedient further to amend the Drugs and Cosmetics Act, 1940, in its application to the State of Maharashtra, for the purposes hereinafter appearing; it is hereby enacted in the Sixty-ninth Year of the Republic of India as follows :—

1. This Act may be called the Drugs and Cosmetics (Maharashtra Short title. Amendment) Act, 2018.

Insertion of a new section 33-1B in Act 23 of 1940.

2. After section 33-1A of the Drugs and Cosmetics Act, 1940, in its application to the State of Maharashtra (hereinafter referred to as "the principal Act"), the following section shall be inserted, namely :—

Power of State Government to make rules for cancellation or suspension of licenses or imposing penalty.

"**33-1B.** Notwithstanding anything contained in this Act or rules framed thereunder, the State Government may, by notification in the *Official Gazette* and subject to the condition of previous publication, make rules to provide for the cancellation or suspension of licenses issued for the following matters or for imposing penalty in case of contraventions of any of the conditions subject to which they are issued, namely :—

(i) Sell, stock, exhibit, offer for sale or distribute Drugs other than Homoeopathic Medicines;

(ii) Sell, stock, exhibit, offer for sale or distribute Homoeopathic Medicines;

(iii) Manufacture for Sale or for Distribution of Drugs other than Homoeopathic Medicines;

(iv) Manufacture for Sale or for Distribution of Homoeopathic Medicines;

(v) Manufacture for Examination, Test or Analysis of any drug in small quantity;

(vi) Requirements for the Collection, Storage, Processing and Distribution of Whole Human Blood, Human Blood Components by Blood Banks, Manufacture of Blood Products and Collection, Processing, Testing, Storage, Banking and Release of Umbilical Cord Blood Stem Cells;

(vii) Manufacture of Cosmetics for Sale or for Distribution;

(viii) Approval of Institutions for carrying out Tests on Drugs, Cosmetics and Raw Materials used in their manufacture on behalf of licensees for manufacture for sale of Drugs or Cosmetics."

Insertion of a new section 33N- 2 in Act 23 of 1940.

3. After section 33N-1 of the principal Act, the following section shall be inserted, namely :—

Power of State Government to make rules for cancellation or suspension of licenses or imposing penalty.

"**33N-2.** Notwithstanding anything contained in this Act or the rules framed thereunder, the State Government may, by notification in the *Official Gazette* and subject to the condition of previous publication, make rules to provide for the cancellation or suspension of licenses issued for the following matters or for imposing penalty in case of contraventions of any of the conditions subject to which they are issued, namely :—

(i) Manufacture for Sale of Ayurvedic (including *Siddha*) or Unani Drugs;

(ii) Approval of Institutions for Carrying out Tests on Ayurvedic, *Siddha* and Unani Drugs and Raw Materials used in their manufacture on behalf of licensees for Manufacture for Sale of Ayurvedic, *Siddha* and Unani Drugs."

STATEMENT OF OBJECTS AND REASONS.

The Drugs and Cosmetics Act, 1940 (23 of 1940) is enacted to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The said Act provides for standards for drugs and cosmetics, prohibits manufacture, sale or distribution of misbranded, adulterated and spurious drugs and cosmetics, regulates manufacture, sale or distribution of drugs and cosmetics of standard quality only under licence issued thereunder and provides for punishment for violation of the provisions of the Act and Rules framed thereunder.

2. The Central Government has, in exercise of the powers conferred upon it by sections 6, 12, 33 and 33-N, framed the Drugs and Cosmetics Rules, 1945. The said Rules *inter alia* provide for licensing authorities, forms, terms and conditions, etc., in respect of licences for manufacture, sale or distribution of drugs, manufacture of cosmetics, manufacture and sale of Homeopathic, Ayurvedic, *Siddha* or Unani Drugs, operation of Blood Banks, etc.

Rules 66, 66H, 85, 122-O, 143 and 159 of the said Rules provides for cancellation or suspension of aboveresferred licences by the licensing authorities if in their opinion the licensee has failed to comply with any of the conditions of licence or with any provisions of the Act or Rules thereunder. However, the said Act and Rules do not empower licensing authorities to impose penalty for contraventions of any of the conditions of licence which are of minor nature instead of suspension or cancellation of licences.

At present there are about 76,800 selling establishments and 4400 manufacturing establishments in the State of Maharashtra and the numbers are increasing in thousands year by year. In view of the existing provisions of the said Rules, the licensing authorities have to suspend or cancel licence even for minor procedural violations of conditions of licence. Therefore, there is an urgent need to empower licensing authorities to impose penalty for minor contraventions of any of the conditions of licence instead of suspending or cancelling the licence.

3. Hence, it is proposed to insert new sections 33-1B and 33N-2 in the Drugs and Cosmetics Act, 1940, in its application to the State of Maharashtra, with a view to empower the State Government to frame rules to provide for the cancellation or suspension of such licenses or for imposing penalty in case of contraventions of any of the conditions subject to which they are issued.

4. The Bill seeks to achieve the above objectives.

Mumbai,

Dated the 22nd November, 2018.

GIRISH BAPAT,

Minister for Drugs.

MEMORANDUM REGARDING DELEGATED LEGISLATION.

The Bill involves the following proposals for delegation of legislative power, namely:—

Clause 2.—Under this clause, which seeks to insert a new section 33-1B in the Drugs and Cosmetics Act, 1940, in its application to the State of Maharashtra, power is taken to the State Government to make rules to provide for the cancellation or suspension of licenses issued for matters specified therein or for imposing penalty in case of contraventions of any of the conditions subject to which they are issued.

Clause 3.—Under this clause, which seeks to insert a new section 33N-2 in the said Act, power is taken to the State Government to make rules to provide for the cancellation or suspension of licenses issued for matters specified therein or for imposing penalty in case of contraventions of any of the conditions subject to which they are issued.

2. The above-mentioned proposals for delegation of legislative power are of normal character.