A BILL

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

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 Amendment) Act, 2018.
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 :

**“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;


(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.”.

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

**“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 abovereferred 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.