Bill No. 59 of 2019

THE DRUGS AND COSMETICS (AMENDMENT) BILL, 2019

By

SHRI N.K. PREMACHANDRAN, M.P.

A

BILL

further to amend the Drugs and Cosmetics Act, 1940.

BE it enacted by Parliament in the Seventieth year of the Republic of India as follows:—

Short title and commencement.

1. (*1*) This Act may be called the Drugs and Cosmetics (Amendment) Act, 2019.

(*2*) It extends to the whole of India.

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

Amendment of section 3.

23 of 1940.

2. In section 3 of the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the principal Act),—

(*a*) the existing clause (*a*) shall be renumbered as (*aii*) and before the clause (*aii*) so as renumbered, the following clause shall be inserted, namely:—

"(*a*) "active pharmaceutical ingredients or bulk drug" means any pharmaceutical chemical biological plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in this Act, which is used as such or as an ingredient in any formulation;

(*ai*) "Authority" means the Drugs and Cosmetics Price (Control, Regulate and Monitoring) Authority constituted under section 7B.";

(*b*) after clause (*aa*), the following clauses shall be inserted, namely:—

"(*aai*) "brand" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers;

(*aaii*) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;

(*aaiii*) "Chairperson" means the Chairperson of the Drugs and Cosmetics Price (Control, Regulate, Monitoring) Authority.";

(*c*) after clause (*aaa*), the following clauses shall be inserted, namely:—

"(*aaai*) "dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent;

(*aaaii*) "distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer.";

(*d*) in clause (*b*), after sub-clause (*iv*), the following sub-section shall be inserted, namely:—

"(*v*) in relation to [Ayurvedic, Siddha or Unani] drugs means the drugs specified from time to time by the Central Government by notification in the Official Gazette after consultation with the Board constituted under section 33C;

(*vi*) all the items covered under (*i*) to (*v*) above which the Authority constituted under section 4 of this Act deems fit to treat as drug or cosmetics for the implementation of provisions of this Act with or without notification by the Central Government.";

(*e*) after clause (*b*), the following clauses shall be inserted, namely:—

"(*ba*) "expert member" means expert member of the Drugs and Cosmetics Price (Control, Regulate, Monitoring) Authority established under section 7B;

(*bb*) "formulation" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include,

(*i*) any medicine included in any bonafide Ayurvedic (including Siddha) or Unani (Tibb) systems of medicines;

(*ii*) any medicine included in the Homoeopathic system of medicine; and

(*iii*) any substance to which the provisions of this Act not apply;

(*bc*) "generic version of a medicine" means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name.";

(*f*) after clause (*f*), the following clause shall be inserted, namely:—

"(*fa*) "maximum retail price" means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;

(*fb*) “moving annual turnover” in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are substracted;

(*fc*) “National List of Essential Medicines” means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time in the Official Gazette;

(*fd*) “new drug” means a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines;

(*fe*) “non-scheduled formulation” means a formulation, the dosage and strengths of which are not specified in the First Schedule.”;

(*g*) after clause (*g*), the following clause shall be inserted, namely:—

“(*ga*) “local taxes” means any tax or levy (except excise or import duty included in retail price) paid or payable to the Central Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer;

(*gb*) “market share” means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of all the brands and generic versions of that medicine sold in the domestic market having same strength and dosage form;

(*gc*) “margin to retailer” for the purposes of this Order shall mean a percentage of price to retailer;

(*gd*) “market based data” means the data of sales related to drug collected or obtained by the Government as deemed fit, from time to time;”;

(*h*) after clause (*h*), the following clause shall be inserted, namely:—

"(*ha*) “pharmaco economics” means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another;”;

(*i*) after clause (*i*), the following clauses shall be inserted, namely:—

"(*j*) “price list” means the price fixed by the Authority for the sale of drugs;

(*k*) “price to retailer” means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes;

(*l*) “retail price” means the price fixed by the Authority;

(*m*) “retailer” means a dealer carrying on the retail business of sale of drugs to customers;

(*n*) “scheduled formulation” means any formulation, included in the Schedule of the Authority whether referred to by generic versions or brand name;

(*o*) “schedule” means a Schedule published by the Authority from time to time;

(*p*) “wholesaler” means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency; and

(*q*) “wholesale price index” means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.”.

Insertion of new Chapter IIA.

3. After Chapter II of the principal Act, the following chapter and sections thereunder shall be inserted, namely:—

"CHAPTER IIA

THE DRUGS AND COSMETICS PRICE (CONTROL, REGULATE, MONITORING) AUTHORITY

Establishment of the Drugs and Cosmetics Price (Control, Regulate, Monitoring) Authority.

7B. The Central Government shall, by notification in the Official Gazette, establish, with effect from such date as may be specified therein, within six months from the date of commencement of this Act an Authority to be known as the Drugs and Cosmetics Price (Control, Regulate, Monitoring) Authority to exercise the jurisdiction, powers and authority conferred on such Authority by or under this Act.

Composition of Authority.

7C. (*1*) The Authority shall consist of—

(*a*) a full time Chairperson; and

(*b*) not less than five but subject to maximum of ten full time expert members from different fields and not more than one from the same field to be appointed by the Central Government in such manner as may be prescribed.

(*2*) The Chairperson of the Authority may, if he considers necessary, invite any one or more persons having specialized knowledge and experience in a particular drug or cosmetic before the Authority to assist the Authority in that case.

(*3*) The Headquarters of the Authority shall be at New Delhi and the Authority may establish its offices at other places in the States and Union territories as it may deem necessary for carrying out the purposes of this Act.

Functions of the Authority.

7D. The Authority shall—

(*a*) control, regulate and monitor the price of drugs and cosmetics;

(*b*) ensure the availability of drugs and cosmetics at reasonable and affordable price;

(*c*) analyze the quality, composition of drugs and cosmetics.

(*d*) calculate the price of drugs and cosmetics at various levels such as manufacturer, wholesale dealer, retail dealer and retail shops, pharmacies, margin to retailer and maximum retail price including all taxes and levies;

(*e*) for ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.

(*f*) regulate, control and monitor, import, export, patent or proprietary of medicine, manufacturer, margin to retailer, market based data, maximum retail price, moving annual turnover, national list of essential medicines, new drug, pharmaco economics, price list, price to retailer, retail price, retailer, wholesaler and whole sale price index;

(*g*) calculate ceiling price of rise of drugs, calculation of retail price of new drugs for existing manufacturers, ceiling price of drugs in case of no reduction in price due to absence of competition, fix margin to retailer, maximum retail price, market base data, ceiling price or retail price of a pack and all other matters require for fix, regulate and monitor the price of drugs.

(*h*) maintain records and production thereof for inspection, power of entry, search and seizure;

(*i*) prepare schedule of medicines;

(*j*) suspend, cancel and terminate the license for manufacture and sale;

(*k*) suspend, cancel and terminate the regulation or manufacturer and seller of drugs and cosmetics;

(*l*) levy fine on the defaulters; or

(*m*) undertake such other functions as may be assigned to it, from time to time:

Provided that a person shall not be qualified for appointment as the Chairman of the Authority, unless he is, or has been, a Judge of the Supreme Court of India or Chief Justice of a High Court:

Provided further that a person shall not be qualified for appointment as full time expert member unless he is, or has been, a Director General of Health Services, Drugs Controller of India, Director of the Central Drugs Laboratory, Director of All India Institute of Medical Sciences, Director of Medical Education, Director of Central Research Institute (Drugs and Pharmaceuticals), Director of Indian Veterinary Research Institute, President, Medical Council of India, President, Pharmacy Council of India, Director of Medical, Research and Technology Institute constituted as per the law enacted by the Parliament, Director, Chemical and Pharmaceuticals of India, Government Analyst and Pharmacologist from Indian Council of Medical Research.

Term of office and other conditions of service of Chairperson and Expert Member.

7E. The Chairperson and expert member of the Authority shall hold office as such for a term of five years from the date on which he enters upon his office, but shall not be eligible for re-appointment:

Provided that in case a person, who is or has been a Judge of the Supreme Court, has been appointed as Chairperson of the Authority, he shall not hold office after he has attained the age of seventy years:

Provided further that in case a person, who is or has been the Chief Justice of a High Court, has been appointed as Chairperson of the Authority, he shall not hold office after he has attained the age of sixty-seven years:

Provided also that no expert member shall hold office after he has attained the age of sixty-five years.

Resignation.

7F. The Chairperson and expert member of the Authority may, by notice in writing under his hand addressed to the Central Government, resign from his office.

Salaries, allowances and other terms and conditions of service.

7G. The salaries and allowances payable to, and the other terms and conditions of service (including pension, gratuity and other retirement benefits) of, the Chairperson and expert member of the Authority shall be such as may be prescribed:

Provided that neither the salary and allowances nor the other terms and conditions of service of the Chairperson and expert Member shall be varied to their disadvantage after their appointment.

Removal of Chairperson and expert member.

7H. The Central Government may, in consultation with the Chief Justice of India, remove from office of the Chairperson of the Authority, who,—

(*a*) has been adjudged an insolvent; or

(*b*) has been convicted for an offence which, in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable; or

(*d*) has acquired such financial or other interest as is likely to affect prejudicially his functions; or

(*e*) has so abused his position as to render his continuance in office prejudicial to the public interest.

(*2*) The Chairperson shall not be removed from his office except by an order made by the Central Government after an inquiry made by a Judge of the Supreme Court in which such

Chairperson has been informed of the charges against him and given a reasonable opportunity of being heard in respect of those charges.

(*3*) The Central Government may suspend from office the Chairperson in respect of whom a reference of conducting an inquiry has been made to the Judge of the Supreme Court until the Central Government passes an order on receipt of the report of inquiry made by the Judge of the Supreme Court on such reference.

(*4*) The Central Government may, by rules, regulate the procedure for inquiry referred to in sub-section (*2*).

(*5*) The expert member may be removed from his office by an order of the Central Government on the grounds specified in sub-section (*1*) and in accordance with the procedure as may be notified by the Central Government:

Provided that the expert member shall not be removed unless he has been given an opportunity of being heard in the matter.

To act as Chairperson of Authority or to discharge his functions in certain circumstances.

7I. In the event of the occurrence of any vacancy in the office of the Chairperson of the Authority, by reason of his death, resignation or otherwise, the Central Government may, by notification, authorise in this behalf, shall as the Chairperson until the date on which a new Chairperson is appointed in accordance with the provisions of this Act.

Officers and Staff of Authority.

7J. (*1*) The Central Government shall appoint such number of officers and other employees to the Authority to assist the discharge of its functions.

(*2*) The recruitment of the officers and other employees of the Authority shall be made by the Chairperson in such manner as may be prescribed.

(*3*) The officers and other employees of the Authority shall discharge their functions under the general superintendence of the Chairperson.

(*4*) The salaries and allowances and conditions of service of the officers and other employees of the Authority shall be such as may be prescribed.

Financial and administrative powers of Chairperson.

7K. The Chairperson of the Authority shall exercise such financial and administrative powers as may be vested in him under the rules made by the Central Government:

Provided that the Chairperson may delegate such of financial and administrative powers, as he may think fit, to any expert member or an officer of the Authority subject to the condition that the member or such officer, while exercising such delegated power, continues to act under the direction, control and supervision of the Chairperson.

Authority to settle disputes.

7L. The Authority shall have the jurisdiction to settle dispute regarding fixation, control, regulation, monitoring of drugs and cosmetics.

(*2*) No application for adjudication of dispute under this section shall be entertained by the Authority unelss it is made within a period of six months from the date on which the cause of action for such dispute first arose:

Provided that the Authority may, if it is satisfied that the applicant was prevented by sufficient cause from filing the application within the said period, allow it to be filed within a further period not exceeding sixty days.

Decision to be taken by majority.

7M. The decision of the Authority by majority of Members present and voting shall be binding:

Provided that if there is a difference of opinion among the Members hearing an application, the opinion is equally divided, the Chairperson shall hear (if he has not heard earlier such application) such application and decide:

Provided further that where the Chairperson himself has heard such application along with other members of the Authority, and if there is a difference of opinion among the Members in such cases and the opinion is equally divided, he shall refer the matter to other Members of the Authority who shall hear such application and decide.

Appeal to Supreme Court.

7N. Any person aggrieved by any decision or order of the Authority, may, file an appeal to the Supreme Court, within ninety days from the date of communication of the decision or order of the Authority, to him, on any one or more of the grounds specified in section 100 of the Code of Civil Procedure, 1908 (5 of 1908):

Provided that the Supreme Court may entertain any appeal after the expiry of ninety days, if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal.

Cost.

7O. (*1*) While disposing of an application under this Act, the Authority shall have power to make such order as to costs, as it may consider necessary.

(*2*) Where the Authority holds that a claim is not maintainable, or is false or vexatious, and such claim is disallowed, in whole or in part, the Authority may, if it so thinks fit, after recording its reasons for holding such claim to be false or vexatious, make an order to awards costs, including lost benefits due to any interim injunction.

Deposit of amount payable for damage to environment.

7P. Where any amount by way of fine, compensation or relief is ordered to be paid under any order made by the Authority on the ground of any damage, that amount shall be remitted to the authority.

(*2*) The amount of fine or compensation or relief credited in the Authority under sub-section (*1*), may, notwithstanding anything contained in the Public Liability Insurance Act, 1991 (6 of 1991) be utilized for the treatment and welfare of such persons as prescribed.

Execution of order or decision of Authority.

7Q. (*1*)An award or oder or decision of the Authority under this Chapter shall be excutable by the Authority as a decree of a civil court, and for this purpose, the Authority shall have all the powers of a civil court.

(*2*) Notwithstanding any thing contained in sub-section (*1*), the Authority may transmit any order or award made by it to a civil court having local jurisdiction and such civil courts shall execute the order or award as if it were a decree made by that court.

(*3*) Where the person responsible, for death of, or injury to any person or damage against whom the order is made by the Authority, fails to make the payment or deposit the amount as directed by the Authority within the period so specified in the order, such amount, without prejudice to the filing of complaint for prosecution for an offence under this Act, or any other law for the time being in force, shall be recoverable from the aforesaid person as arrears of land revenue of public demand.

Penalty for failure to comply with orders of Authority.

7R. (*1*)Whoever, fails to comply with any order or decision of the Authority under this Act, he shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to twenty crore rupees, or with both and in case the failure or contravention continues, with additional fine which may extend to fifty thousand rupees for every day during which such failure or contravention continues after conviction for the first such failure or contravention:

Provided that in case a company fails to comply with any order or award or a decision of the Authority under this Act, such company shall be punishable with fine which may extend to thirty crore rupees, and in case the failure or contravention continues, with additional fine which may extend to two lakh rupees for every day during which such failure or contravention continues after conviction for the first such failure or contravention.

(*2*) Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974) every offence under this Act shall be deemed to be non-cognizable within the meaning of the said Code.

Offences by companies.

7S. (*1*) Where any offence under this Chapter has been committed by a company, every person who, at the time the offence was committed, was directly in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

an offence under this Act has been committed by the company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, ay director, manager, secretary or other officer of the company such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.—For the purposes of this section,—

(*a*) "company" means anybody corporate and includes a firm or other association of individuals; and

(*b*) "director" in relation to a firm means a partner in the firm.

Offences by Government Department.

7T. (*1*) Where any Department of the Government fails to comply with any order or award or decision of the Authority under this Chapter, the Head of the Department shall be deemed to be guilty of such failure and shall be laible to be proceeded against for having committed an offence under this Chapter and punished accordingly:

Provided that nothing contained in this section shall render such Head of the Department liabel to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(*2*) Notwithstanding anything contained in sub-section (*1*) where an offence under this Chapter has been committed by a Department of the Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Bar of jurisdiction.

7U. (*1*) With effect from the date of establishment of the Authority under this Chapter, no civil court shall have jurisdiction to entertain any dispute in respect of any matter, which the Authority is empowered to determine under its jurisdiction.

(*2*) No civil court shall have jurisdiction to settle dispute or entertain any question relating to any claim for granting any relief or compensation which may be adjudicated upon by the Authority, and no injunction in respect of any action taken or to be taken by or before the Authority in respect of the settlement of such dispute or granted by the civil court.

Cognizance of offences.

7V. (*1*) No court shall take cognizance of any offence under this Chapter except on a complaint made by—

(*a*) the Central Government or any authority or officer authorised in this behalf by that Government; or

(*b*) any person who has given notice of not less than sixty days in such manner as may be prescribed, of the alleged offence and of his intention to make a complaint, to the Central Government or the authority or officer authorised as aforesaid.

(*2*) No court inferior to that of a Metropolitan Magistrate or, a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Members and staff of Authority to be public servants.

7W. The Chairperson, and Expert Members, officers and other employees of the Authority shall be deemed to be public servants within the meaning of section 21 of the Indian Penal Code (45 of 1860).

Protection of action taken in good faith.

7X. (*1*) No suit or other legal proceeding shall lie against the employees of the Central Government or a State Government or any statutory authority, for anything which is in good faith done or intended to be done in pursuance of this Chapter or any rule or order made there under.

(*2*) No suit, prosecution or other legal proceeding shall lie against the Chairperson or Expert Member of the Authority or any other person authorised by the Chairperson or the Expert Member for anything which is in good faith done or intended to be done in pursuance of this Act or any rule or order made there under.

Act to have overriding effect.

7Y. The provisions of this Act, shall have effect notwithstanding anything inconsistent contained in any other law for the time being in force or in any instrument having effect by virtue of any law other than this Act.

Power to make rules.

7Z. (*1*) The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

(*2*) Every rule made under this section shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of thirty days as aforesaid, both Houses agree in making any modification in the rule or both the Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, prejudice to the validity of anything previously done under the rule.

Power to amend Schedule.

7ZA. (*1*) The Central Government may, by notification, amend the Schedule by including therein any other Act, enacted by Parliament having regard to the objective of fix, control, regulate and monitor the price of drugs and cosmetics there from on the date of publication of such notification, such Act shall be deemed to be included in or, as the case may be, omitted from the Schedule.

(*2*) A copy of every notification proposed to be issued under sub-section (*1*), shall be laid in draft before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in disapproving the issue of the notification or both Houses agree in making any modification in the notification, the notification shall not be issued or, as the case may be, shall be issued only in such modified form as may be agreed upon by both the Houses.

Power to remove difficulties.

7ZB. (*1*) If any difficulty arises in giving effect to the provisions of this Chapter, the Central Government, may, with the consent of the Chairman of the Authority by order published in the Official Gazette, make such provisions, not inconsistent with the provisions of this Act as may appear to it to be necessary for removing the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.".

STATEMENT OF OBJECTS AND REASONS

The price of drugs and cosmetics is increasing. Manufacturing companies, dealers and retailers are not providing drugs and cosmetics in reasonable price. Even the life saving medicines are not available in the market in a reasonable price. This sector becomes a profit making sector without considering the life and health of people. There are no criteria fixed for fixing the price of drugs and cosmetics. The existing system is regulation, control and monitoring of the price of drugs and cosmetics. It is also important to make available the medicines at affordable prices. The mechanism introduced by the existing system was flouted. The branded drugs and cosmetics are marketing without scientific and systematic system for regulate, control and monitoring. Even though the Drugs and Cosmetics Act, 1940 is there to regulate the import, manufacture, distribution and sale of drugs and cosmetics, but, it had not yield the desired results.

The Bill, therefore, seeks to amend the Drugs and Cosmetics Act, 1940 with a view to establish the Drugs and Cosmetics Price (Control, Regulate and Monitoring) Authority to—

(*a*) control, regulate and monitor the price of drugs and cosmetics;

(*b*) ensure the availability of drugs and cosmetics at reasonable and affordable price;

(*c*) analyze the quality, composition of drugs and cosmetics;

(*d*) calculate the price of drugs and cosmetics at various levels such as manufacturer, wholesale dealer, retail dealer and retail shops, pharmacies, margin to retailer and maximum retail price including all taxes and levies;

(*e*) for ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition;

(*f*) regulate, control and monitor, import, export, patent or proprietary of medicine, manufacturer, margin to retailer, market based data, maximum retail price, moving annual turnover, national list of essential medicines, new drug, pharmaco economics, price list, price to retailer, retail price, retailer, wholesaler and wholesale price index;

(*g*) calculate ceiling price of rise of drugs, calculation of retail price of new drugs for existing manufacturers, ceiling price of drugs in case of no reduction in price due to absence of competition, fix margin to retailer, maximum retail price, market base data, ceiling price or retail price of a pack and all other matters require for fix, regulate and monitor the price of drugs.

(*h*) maintain records and production thereof for inspection, power of entry search and seizure;

(*i*) prepare schedule of medicines;

(*j*) suspend, cancel and terminate the licence for manufacture and sale;

(*k*) suspend, cancel and terminate the regulation of manufactures and seller of drugs and cosmetics;

(*l*) levy fine on the defaulters; or

(*m*) undertake such other functions as may be assigned to it, from time to time.

Hence this Bill.

NEW DELHI;
June 3, 2019.

N.K. PREMACHANDRAN

FINANCIAL MEMORANDUM

Clause 3 of the Bill provides for the establishment of the Drugs and Cosmetics Price (Control, Regulate, Monitoring) Authority. The Bill, if enacted, will involve expenditure from the Consolidated Fund of India. It is estimated that a sum of rupees fifty crore may involve as recurring expenditure per annum. A non-recurring expenditure to the tune of rupees ten crore is also likely to be involved from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 3 of the Bill *vide* proposed section 7Z empowers the Central Government to make rules for carrying out the purpose of this Bill. As the rules will relate to matters of detail only, the delegation of legislative powers is of a normal character.

ANNEXURE

[EXTRACTS FROM THE DRUGS AND COSMETICS ACT, 1940]

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3(*a*) "Ayurvedic, Siddha or Unani] drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule; Definitions.

(*aa*) "the board" means—

(*i*) in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C; and

(*ii*) in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;

(*aaa*) "cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic 3;

* * * * *

(*b*) "drug" includes—

(*i*) * * * *

(*ii*) * * * *

(*iii*) * * * *

(*iv*) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

* * * *

(*f*) "manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug [or cosmetic] with a view to its sale or distribution] but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

* * * * *

(*g*) "to import" with its grammatical variations and cognate expressions means to bring into India;

* * * * *

2. (h) "patent or proprietary medicine" means,—

(*i*) * * * *

(*ii*) in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human

beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;

* * * * *

(*i*) "prescribed" means prescribed by rules made under this Act.

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further to amend the Drugs and Cosmetics Act, 1940.

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(*Shri N.K. Premachandran, M.P.*)

MGIPMRND—354LS(S3)—12-06-2019.