

**Bill No. 70 of 2020**

THE REGULATION OF SALE OF SCHEDULE-H DRUGS BILL, 2020

By

SHRI RAHUL KASWAN, M.P.

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**BILL**

*to prohibit the sale of Schedule-H Drugs without prescription of a registered medical practitioner to ensure medical safety and for matters connected therewith.*

BE it enacted by Parliament in the Seventy-first year of the Republic of India as follows:—

1. (1) This Act may be called the Regulation of Sale of Schedule-H Drugs Act, 2020. Short title,  
extent and  
commencement.
- (2) It extends to the whole of India.
- 5 (3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.
2. In this Act, unless the context otherwise requires,— Definitions.
  - (a) "e-pharmacy" refers to an online site or an interface selling medicinal drugs;
  - (b) "prescribed" means prescribed by rules under this Act; and
  - 10 (c) "Schedule-H drug" means drugs mentioned in Schedule-H to the Drugs and  
23 of 1940 Cosmetics Rules, 1945 as framed under the Drugs and Cosmetics Act, 1940.

Revision of  
Schedule-H  
drugs.

**3.** Notwithstanding anything contained in any other law for the time being in force, the Central Government shall, by notification in the Official Gazette, revise the Schedule-H Drugs into two categories, namely:—

(a) "general drugs" which may be sold without any restriction; and

(b) "drugs causing serious harm" which shall be sold with restrictions as imposed on Schedule 'X' drugs under the Drugs and Cosmetics Rules, 1945 as framed under the Drugs and Cosmetics Act, 1940.

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23 of 1940.

Regulation of  
sale of  
Schedule-H  
drugs.

**4.** The Central Government shall make it mandatory for pharmacies, medical shops and e-pharmacies,—

(a) not to sell drugs causing serious harm under Schedule-H to any person without prescription of a registered medical practitioner in this behalf; and

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(b) to furnish appropriate bills to the customer purchasing Schedule-H drugs;

(c) to preserve the prescription of registered medical practitioner, in case of,—

(i) "general drugs" as mentioned under clause (a) of section 3 for one year; and

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(ii) "drugs causing serious harm" as mentioned under clause (b) of section 3 for two years.

Constitution  
of a body to  
regulate sale  
of Schedule-H  
Drugs.

**5. The Central Government shall, by notification in the Official Gazette, constitute a body to impose punishment including fines and cancellation of licences of the pharmacies, medical shops or e-pharmacies selling Schedule-H drugs without prescription of a registered medical practitioner in such manner as may be prescribed.**

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Act not in  
derogation of  
any other law.  
Power to  
make rules.

**6.** The provisions of this Act shall be in addition to and not in derogation of any other law for the time being in force.

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

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(2) Every rule made this Act 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 the session immediately following the session or the successive sessions 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, that any such modifications, or annulment shall be without prejudice to the validity of anything previously done under that rule.

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## STATEMENT OF OBJECTS AND REASONS

Schedule-H drugs are those medicines which contain a very high alcoholic influence. These are used to treat some serious diseases like heart diseases, anxiety disorders and other diseases. Restricted sale of antibiotics to check drug resistance is emerging as a serious health issue in the country. Resistance to antibiotics and an increase in drug resistant TB cases are cited as a result of improper prescription and consumption of antibiotics which are easily available.

Strict measures would ensure that pharmacists do not take advantage of unawareness of consumers to drain profits from the sale of these drugs. It would also ensure that people do not take these drugs lightly and know the importance of medical advice.

Having separate sets of antibiotics depending on the disease—mild ones for out-patient and emergency patients and strong and high-end antibiotics for those under intensive care will hopefully make sure that antibiotics are used judiciously so that resistance to commonly used antibiotics does not develop rapidly, and that the medicines are available for critically ill patients.

It is definitely in the best interest of people to avoid consumption of harmful drugs until it's very necessary.

The Bill, therefore, seeks to ban the sale of Schedule-H drugs without doctor's prescription to provide medical safety.

Hence this Bill.

NEW DELHI;  
*January 20, 2020.*

RAHUL KASWAN

#### FINANCIAL MEMORANDUM

Clause 5 of the Bill provides for the constitution a body to impose punishment including fines and cancellation of licences of the pharmacies, medical shops or e-pharmacies selling drugs without prescription of a registered medical practitioners. The Bill, therefore, if enacted, would involve expenditure from the Consolidated Fund of India. It is estimated that a recurring expenditure of about rupees Fifty Crores per annum would be involved from the Consolidated Fund of India.

No non-recurring expenditure is likely to be involved.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 7 of the Bill empowers the Central Government to make rules for carrying out the purposes of the Bill. As the rules will relate to matter of detail only, the delegation of legislative power is of a normal character.

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*(Shri Rahul Kaswan, M.P.)*