

August 2023

Decriminalisation of minor offences in legislations in the pharmaceutical sector

The Jan Vishwas (Amendment of Provisions) Bill, 2023 (the "Jan Vishwas Bill") was passed by the Lok Sabha on July 27, 2023 and by the Rajya Sabha on August 2, 2023. The Jan Vishwas Bill was introduced with the aim of decriminalising and rationalising minor offences to further enhance trust-based governance for ease of living and doing business.

The Jan Vishwas Bill seeks to reduce compliance burden by proposing decriminalization of 183 (one hundred eighty three) provisions in 42 (forty two) central acts administered by 19 (nineteen) ministries/departments. The Jan Vishwas Bill has been designed to foster a balance between the severity of the offence and the gravity of the prescribed punishment. With this aim, the Jan Vishwas Bill proposes a pragmatic revision of fines and penalties commensurate to the offence. Further, the Jan Vishwas Bill also proposes establishment of adjudicating officers and appellate authorities, and a periodic increase in quantum of fines and penalties.

In the pharmaceutical sector, the Jan Vishwas Bill proposes revisions to the Drugs and Cosmetics Act, 1940 and the Pharmacy Act, 1948 which have been detailed below

Drugs and Cosmetics Act, 1940

Jan Vishwas Bill proposes to revise fines, decriminalise penalties and include compounding process under the Drugs and Cosmetics Act, 1940 ("**D&C Act**"). Some of the key provisions that would be amended under the Jan Vishwas Bill are detailed below:

Section	Existing Provision	Amendment
Section 27(d)	Under Section 27(d), any person convicted with the manufacture, sale, distribution, storage of drugs other than adulterated or spurious drugs, must be punishable with imprisonment of up to 2 (two) years and a fine of a minimum of INR 20,000 (Indian Rupees twenty thousand) or with both.	Penalty for manufacture, sale, etc., of drugs and cosmetics in contravention of the provisions of the D&C Act can be compounded by way of an amendment to Section 32(B) of the D&C Act.
Section 27A(ii)	Under Section 27A(ii), any person convicted with the manufacture, sale,	Penalty for manufacture, sale, etc., of drugs and cosmetics in contravention of the provisions of

Section	Existing Provision	Amendment
	distribution, storage of cosmetics other than adulterated or spurious cosmetics, must be punishable with imprisonment of up to 2 (two) year and a fine of a minimum of INR 20,000 (Indian Rupees twenty thousand) or with both.	the D&C Act can be compounded by way of an amendment to Section 32(B) of the D&C Act.
Section 29	Under Section 29, whoever uses Government Analyst's report for the purpose of advertising any drug or cosmetic, must be punishable with fine, which may extend to INR 5,000 (Indian Rupees five thousand).	Penalty for use of Government Analyst's report for advertising is enhanced to INR 1,00,000 (Indian Rupees one lakh)
Section 30(2)	Penalty for subsequent offence under Section 29 In case of continuing contravention under Section 29, the penalty as set out in Section 30(2) was imprisonment of up to 2 (two) years, or with fine of up to INR 10,000 (Indian Rupees ten thousand), or both.	The punishment of imprisonment is proposed to be removed for subsequent offence for using Government Analyst's report for advertisement. A monetary penalty of INR 5,00,000 (Indian Rupees five lakh) can be imposed.

Pharmacy Act, 1948

Jan Vishwas Bill proposes to revise fines and decriminalise penalties under the Pharmacy Act, 1948 ("**Pharmacy Act**"). Some of the key provisions that would be amended under the Jan Vishwas Bill are detailed below:

Section	Existing Provision	Amendment
Section 18(2)	As per Section 18(2), the Central Council may, with the approval of the Central Government by notification in the Official Gazette make regulations consistent with purpose of the Pharmacy Act and such regulations must provide for specific procedures, powers and duties.	Insertion of new sub-sections (i) and (j) for framing of regulations for holding inquiry and penalty under Section 43Aand form and manner of preferring an appeal under Section 43A respectively. Section 43A is a new provision which has been inserted for adjudication of penalties.
Section 26A(3)	Under Section 26A (3), any person that obstructs an Inspector in the exercise of his powers, must be punishable with imprisonment of up to 6 (six) months or with fine up to INR 1,000 (Indian Rupees one thousand), or with both.	The punishment of imprisonment is proposed to be removed. The penalty for obstructing an inspector while exercising powers in line with the Pharmacy Act, enhanced to INR 100,000 (Indian Rupees one lakh).

Section	Existing Provision	Amendment
Section 41(1)	Any person whose name is not entered in the register of pharmacists, falsely pretends that it has been entered, must be punishable with fine of up to INR 500 (Indian Rupees five Hundred) on first conviction, and on continuing contravention with imprisonment of up to 6 (six) months or with a fine of maximum INR 1,000 (Indian Rupees one thousand) or both.	The first conviction is punishable with maximum fine INR 1,00,000 (Indian Rupees one lakh) and subsequent contravention is punishable with imprisonment up to 3 (three) months or with maximum fine up to INR 2,00,000 (Indian Rupees two lakh) or with both imprisonment and fine.
Section 42(2)	Dispensing by unregistered person is punishable with maximum 6 (six) months imprisonment, or with fine up to INR 1,000 (Indian Rupees one thousand), or with both.	Dispensing by unregistered person is punishable with maximum 3 (three) months imprisonment, or with fine up to INR 200,000 (Indian Rupees two lakh), or with both fine and imprisonment
Section 43A		A new provision (Section 43A) has been inserted for adjudication of penalties under Section 26A. The President of the State Council is authorised as an adjudicating officer for holding inquiry and imposing penalties.

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