

Regulation of preparations exempted from certain control measures pursuant to Article 3 of the 1971 Convention

1. A preparation of a psychotropic substance is any solution or mixture, in whatever physical state, containing one or more psychotropic substances or one or more psychotropic substances in a dosage¹ form. According to article 3, paragraph 1, of the Convention on Psychotropic Substances of 1971, a preparation is subject to the same measures of control as the psychotropic substance which it contains, and, if it contains more than one such substance, to the measures applicable to the most strictly controlled of those substances.²

2. However, the 1971 Convention also allows for some exemptions regarding the control of pharmaceutical preparations containing substances controlled under that Convention.³ Pursuant to article 3, paragraph 2 of the 1971 Convention, a State Party may decide to exempt a preparation containing psychotropic substances from certain control measures provided in the Convention. If a preparation containing a psychotropic substance⁴ listed in Schedules II, III and IV is compounded in a way that doesn't present any (or insignificant) risk of abuse and the substance cannot be recovered by readily applicable means in a quantity liable to abuse, the preparation can be exempted from some control measures. The same applies to combinations in dosage form of two or more psychotropic substances which do not contain any counteracting non-psychotropic material, as well as to a single psychotropic substance in dosage form which is not compounded with such a material.⁵

3. Preparations may be exempted, inter alia, from the requirement of prior approval that applies to international trade in substances listed in Schedule II and from the requirement of a post-export declaration applicable with respect to substances in Schedule III. It should be stressed, however, that when a Government is considering making such exemptions, it should weight the impact that the exemption will have on the functioning of the international drug control system.

4. An exemption is valid only in the country that has decided to apply it and has notified the Secretary-General accordingly. A Party shall notify the Secretary-General about the name and composition of the exempt preparation, and of the measures of control from which it is exempted. The Secretary-General shall transmit the notification to the other Parties, to the World Health Organization, and to the International Narcotics Control Board. Governments that have not exempted the same preparation from the same control measures are required to apply to the preparation in question the full scope of controls applicable to the preparation's base substance.

5. It should be noted that according to paragraph 3, article 3 of the Convention, an exempted preparation is not exempted from all controls in the Convention. The following still apply:⁶

- a) Article 8 (licences), as it applies to manufacture;
- b) Article 11 (records), as it applies to exempted preparations;
- c) Article 13 (prohibition of and restrictions on export and import);
- d) Article 15 (inspection), as it applies to manufacture;
- e) Article 16 (reports to be furnished by the Parties), as it applies to exempted preparations; and
- f) Article 22 (penal provisions), to the extent necessary for the repression of act contrary to laws or regulations adopted pursuant to the foregoing obligations.

¹ Dosage form, according to the Commentary on the 1971 Convention, refers to a measured small quantity of a psychotropic drug or a combination of psychotropic drugs in whatever form (tablet, ampoule or powder) ready to consumption.

² United Nations, Treaty Series, vol. 1019, No. 14956.

³ United Nations, Treaty Series, vol. 1019, No. 14956.

⁴ Preparations containing substances controlled under Schedule I cannot be exempted

⁵ Commentary on the Convention on Psychotropic Substances of 1971, Article 3, Paragraph: 2 and 3,

http://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_Convention_1971.pdf

⁶ United Nations, Treaty Series, vol. 1019, No. 14956.

6. Over the past several years some countries have reported the use of psychotropic substances for the manufacture of preparations that are exempt from certain measures of control under article 3 of the 1971 Convention.

INCB is the independent, quasi-judicial body charged with promoting and monitoring Government compliance with the three international drug control conventions: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

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