Guidelines for the exemption of preparations from certain control measures under the provisions of article 3 of the 1971 Convention on Psychotropic Substances

The Commission on Narcotic Drugs,

Having taken note of documents MNH/78.1 and MNH/82.51 containing proposals by World Health Organization consultative groups concerning guidelines for granting exemptions under the provisions of article 3 of the 1971 Convention on Psychotropic Substances,

Having considered the report by the Secretary-General of 16 December 1983 entitled "Review of establishment of guidelines for the exemption of preparations under the provisions of article 3 of the 1971 Convention on Psychotropic Substances" (E/CN.7/1984/4),

Recalling its resolutions 2(S-VI) of 19 February 1980 and 5(XXX) of 16 February 1983,

Bearing in mind that decisions taken by it in respect of the termination of an exemption must consider the social and economic conditions pertaining in the country granting the exemption, including the level of development of its national medical services and national drug distribution system,

Convinced of the need for Governments to contribute to the development of further guidelines, in light of the experience gained during the application of the guidelines currently in force,

Approves the following guidelines for use by national authorities, the World Health Organization and the Commission on Narcotic Drugs:

Guidelines proposed for use by national authorities

(a) A preparation containing a psychotropic substance in association with (i) another psychotropic substance, (ii) a narcotic drug or (iii) a psychoactive substance not under international control with known abuse potential, should not be exempted; nevertheless, exemption of a preparation in any of the three above categories which is compounded in such a manner that it presents a negligible risk of abuse may be envisaged;

(b) A preparation containing a psychotropic substance in association with a narcotic drug listed in Schedule I or II of the Single Convention on Narcotic Drugs, 1961, should not be exempted; exemption can only be authorized if the preparation has been listed in Schedule III of that Convention by the Commission, in accordance with the amendment procedure established by the provisions of article 3, paragraph 4, of the Convention;
(c) A preparation containing a psychotropic substance in injectable dosage form should not be exempted;

(d) A preparation containing a psychotropic substance should not be exempted from the provisions of article 10, paragraph 1, of the 1971 Convention on Psychotropic Substances;

(e) A preparation containing a psychotropic substance should not be exempted from the provisions of article 10, paragraph 2, of the 1971 Convention on Psychotropic Substances, unless such exemption would be in keeping with national statutory requirements;

(f) A preparation containing a psychotropic substance should not be exempted from the requirements of article 12 of the 1971 Convention on Psychotropic Substances;

(g) Guidelines (d), (e) and (f) notwithstanding, in vitro diagnostic reagents, buffers and analytical standards containing psychotropic substances may be exempted from the provisions of articles 10 and 12 of the 1971 Convention;

Guidelines proposed for use by the World Health Organization

(h) The World Health Organization should not routinely review Parties' notifications of exemptions intended only for domestic use; however, where there is evidence that a specific exemption granted by a competent national authority does not comply with guidelines (a) - (e) above, and might constitute a danger to the public health of the country concerned, the World Health Organization should immediately draw the attention of the competent national authority to the possible public health hazard and advise the Commission on Narcotic Drugs of its action in this regard. If, however, there is evidence that such exemption constitutes a danger to another country, the World Health Organization should proceed to examine the exemption as a matter of urgency.

946th meeting
9 February 1984