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# **Guidelines for the WHO review of dependence- producing psychoactive substances for international control**

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# GUIDELINES FOR THE WHO REVIEW OF DEPENDENCE-PRODUCING PSYCHOACTIVE SUBSTANCES FOR INTERNATIONAL CONTROL

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## **I. MANDATE**

1. The World Health Organization (WHO) is the specialized agency designated for the evaluation of the medical, scientific and public health aspects of psychoactive substances under the Single Convention on Narcotic Drugs, 1961 (the 1961 Convention), as amended by the 1972 Protocol, and the Convention on Psychotropic Substances, 1971 (the 1971 Convention). A procedure for this assessment has been developed pursuant to resolutions of the Health Assembly and of the United Nations Commission on Narcotic Drugs (CND). This document sets out guidelines dealing with the underlying principles of the review procedure, working arrangements within the WHO Secretariat and with external bodies, and the nature of the documentation to be prepared. The guidelines cover WHO's responsibilities under Article 3 of the 1961 Convention and Article 2 of the 1971 Convention concerning whether or not to recommend international control of substances, as well as the assessment of exempted preparations under Article 3 of the 1971 Convention. Common terms and abbreviations are listed in Section VII.

2. The Thirty-third World Health Assembly, by resolution WHA33.27 (1980), requested the Director-General "to promote the initiation and strengthening of national and international programmes for the assessment, scheduling, control and appropriate use of narcotic and psychotropic substances including those of plant origin, and to support such programmes by the development of appropriate guidelines", and further "to strengthen the coordination between the WHO programmes relating to narcotic and psychotropic substances, those dealing with drug policy and management, and other related programmes, and to strengthen collaboration with interested nongovernmental organizations".

3. In the light of experience gained over later years, and following the guidance of the Executive Board,<sup>1</sup> WHO developed a procedure for the evaluation and assessment of narcotic and psychotropic substances for decisions on international control in consultation with CND in 1986,<sup>2</sup> which was revised in 1990.<sup>3</sup> Amendments and decisions subsequently adopted by the Executive Board in 1994<sup>4</sup> and 1999<sup>5</sup> have laid the foundation for another revision of the procedure as presented in this document.

## **II. UNDERLYING PRINCIPLES**

4. The review procedure uses relevant information, systematically collected and screened through continuing WHO collaboration with scientific institutions, health services and regulatory agencies, government health and law enforcement authorities, and relevant intergovernmental and nongovernmental organizations.

5. The relevant information is collected, analysed and compiled for each psychoactive substance as the basis of review by the Expert Committee on Drug Dependence and its advice to the Director-General.

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<sup>1</sup> Resolution EB73.R11.

<sup>2</sup> Decision EB77(3).

<sup>3</sup> Decision EB85(10).

<sup>4</sup> Decision EB93(16).

<sup>5</sup> Decision EB103(5).

### III. PROVISIONS OF THE CONVENTIONS

6. The 1961 and 1971 conventions entrust WHO with the responsibility of reviewing and assessing any substance which may need to be included in one of their schedules. Such a review can be initiated by a notification to the Secretary-General of the United Nations by a Party to the Conventions or by WHO.<sup>1</sup> The assessment by WHO is forwarded to CND which has the responsibility of taking the decision concerning the international control of a psychoactive substance under the provisions of the Conventions.<sup>2</sup>

7. The basis for the scheduling recommendation made by WHO is an evaluation of whether specific criteria set forth in the Conventions have been met. Under the provisions of the 1961 Convention, CND must accept or refuse the WHO recommendation as a whole, whereas in the case of the 1971 Convention it may accept a WHO proposal but may also decide to place a substance in a schedule other than that recommended by WHO. With respect to control under the 1971 Convention, WHO's assessment is determinative for scientific and medical matters, but CND may also take into account legal, administrative, economic, social and other factors in reaching its decision. Under the provisions of both Conventions, a Party which disagrees with CND's decision may request a review of such a decision by the Economic and Social Council; the Council may confirm, alter or reverse CND's decision.

8. Under the provisions of Article 3 of the 1971 Convention, a Party may exempt from specific control measures a preparation containing one or more scheduled substances if the preparation is compounded in such a way that it presents no, or a negligible, risk of abuse. In order to do so, it must address a notification to the Secretary-General of the United Nations who in turn sends a copy of the notification to other Parties and to WHO. If a Party or WHO has information which it believes requires that the exemption of a preparation should be terminated, it should notify the Secretary-General of the United Nations accordingly and submit information in support of that decision. WHO reviews the data submitted by Parties which wish to avail themselves of this provision for exemption under the 1971 Convention by applying specific guidelines that have been approved by CND.<sup>3</sup>

9. Under the provisions of the 1961 Convention, preparations of narcotic drugs exempted from specific control measures are listed in Schedule III. New exemptions can be made only by including a preparation in Schedule III, and relevant proposals are reviewed by WHO in the same way as those for single substances.

10. The United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 (the 1988 Convention), entered into force in November 1990. Article 12 of the 1988 Convention places under international control substances frequently used in the illicit manufacture of narcotic drugs or psychotropic substances. These substances are listed in Table I and Table II of the Convention. WHO has no formal role to play in the scheduling of such substances under the 1988 Convention. However, it is possible that the same substance may be considered for control simultaneously under the 1961 Convention, the 1971 Convention, or the 1988 Convention. Guidance on how to deal with such a situation is provided in paragraphs 34, 35, 42 and 43 under the subsection on assessment for scheduling by the Expert Committee.

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<sup>1</sup> The Director-General represents WHO for the purpose of receiving notifications under the international drug control conventions and of making recommendations concerning the international control of psychoactive substances under those conventions on the basis of recommendations and advice provided to him or her as described in these guidelines.

<sup>2</sup> The scheduling process is covered by the provisions of Article 3 of the 1961 Convention and Articles 2 and 17.2 of the 1971 Convention. The scheduling process is described in detail in the commentaries on these conventions, published by the United Nations.

<sup>3</sup> The specific WHO procedure for review of exempted preparations was developed in accordance with the Commission's guidelines for exemption. These guidelines, which were largely based on recommendations made by WHO, were approved by CND at its Eighth special session and are set forth in its resolution 1(S-VIII). See the report of the Commission in Economic and Social Council, Official Records, 1984, Supplement No. 3 (document E/CN.7/1984/13).

#### **IV. WHO REVIEW PROCEDURE**

11. The WHO review of dependence-producing psychoactive substances for international control includes the routine collection of information by the Secretariat, and the pre-review and critical review conducted by the Expert Committee. The review of exempted preparations notified by a Party involves a preliminary review by the Secretariat and an assessment by the Expert Committee. The time schedule for the review procedure should be set by the Secretariat bearing in mind the calendar of CND and its procedural requirements.

##### **Information collection**

12. The Secretariat should routinely collect from the literature, WHO programmes, WHO collaborating centres, national health and drug control authorities, intergovernmental and nongovernmental organizations, and research and academic institutions, information related to psychoactive substances considered to have abuse potential.

##### **Pre-review**

13. Pre-review is conducted by the Expert Committee in order to determine whether a psychoactive substance should be subjected to a critical review in the context of its international control under either the 1961 or the 1971 Convention. A proposal to pre-review a substance can be submitted to the Expert Committee with supporting information either by (1) the Secretariat, (2) any member of the Expert Committee, or (3) representatives of other organizations invited to participate in the Expert Committee meeting. The Expert Committee shall recommend critical review if it has found that WHO has information that may justify the scheduling of the substance. In view of Article 2, paragraph 4(b) of the 1971 Convention, this will require, in the case of a psychotropic substance, that the substance causes significant public health and social problems in more than one country.

##### **Pre-review data sheet**

14. The supporting information required for pre-review is a short (two- to three-page) summary of relevant information, presented in a form acceptable to the Expert Committee.

##### **Critical review**

15. Critical review is conducted by the Expert Committee in any of the following cases: (1) there has been notification from a Party to the 1961 or the 1971 Convention concerning the scheduling of a substance; (2) there has been an explicit request from CND to review a substance; (3) pre-review of a substance has resulted in a recommendation for critical review as indicated in paragraph 13 above; (4) information is brought to WHO's attention that a substance is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any Member State. If therapeutic use of the substance is confirmed subsequently by any Member State in respect of case (4), the substance shall be subjected to a pre-review.

##### **Critical review document**

16. The Secretariat prepares the critical review document which is a summary of available data compiled for use by the Expert Committee in assessing individual substances. In the preparation of the critical review document, the Secretariat collects and assembles data on the substances selected for critical review, and requests information on these substances through a questionnaire to ministers of health of Member States and to other relevant collaborating information sources. The Secretariat may also be assisted by advisers and ad hoc working groups in order to produce a balanced document.

17. The critical review document is sent for information and comments to governments, institutions and organizations which have directly and substantially collaborated in its preparation or which have requested it. Examples include international narcotics control organs and relevant governmental, intergovernmental, and nongovernmental organizations in official relations with WHO. To help ensure that all material submitted to the Expert Committee is up to date, the Secretary of the Committee will circulate the agenda of the next meeting to those collaborating information sources.

18. When preparing the critical review document, the Secretariat should include, where feasible, information under the following headings:

- (1) substance identification by International Nonproprietary Name (INN), chemical or other common name and trade names, other identifying characteristics, Chemical Abstracts Service (CAS) registry number
- (2) chemistry
- (3) general pharmacology
- (4) toxicology, including adverse reactions in humans
- (5) pharmacokinetics
- (6) dependence potential
- (7) epidemiology of use and abuse, with an estimate of the abuse potential of the substance
- (8) nature and magnitude of public health problems
- (9) national control
- (10) therapeutic and industrial use
- (11) production, consumption and international trade
- (12) illicit manufacture and illicit traffic, and related information
- (13) current international controls in place and their impact.

19. If abundant, the information presented under each heading will be limited to that which is essential and consistent with the need to facilitate assessment by the Expert Committee.

20. Not all the headings listed above may be covered in all instances or to the same extent. For example, it may not be possible to cover (4), (5), (7), (8), (10) and (11) for new hallucinogenic substances. The production of data in such circumstances may not be justifiable on ethical grounds. If, for any reason, the Expert Committee bases its assessment on limited data, it would need to provide full justification for reaching conclusions on incomplete data.

21. The confidentiality of information received by WHO for use in the review will be respected to the maximum if so requested by the provider. In this case, appropriate arrangements will be made for the Expert Committee to have access to the information used to prepare the critical review.

### **Preliminary review of exempted preparations containing psychotropic substances**

22. The Secretariat should review the notification of exemption received from a Party to the 1971 Convention in order to ascertain whether the preparation containing a psychotropic substance is for

domestic use only, or is being exported outside the exempting country. Where the preparation is for domestic use only, and if the exempting Party gives assurance in its notification that, to the best of its knowledge, there is no significant abuse, the Secretariat will assume that the exemption does not require an evaluation by the Expert Committee. However, if WHO receives evidence of national abuse, or information that the preparation may constitute a public health and social problem to another Party (e.g. illicit trade and/or abuse), the exemption is evaluated by the Expert Committee.

### **Expert Committee on Drug Dependence**

23. **Membership.** The Expert Committee usually has a membership of 10, chosen by the Director-General in accordance with the regulations for expert committees.

24. **Secretariat.** The Expert Committee is assisted by a secretariat, composed of a secretary and staff members from appropriate WHO programmes, consultants and temporary advisers, as required. The functions of Secretary are executed by a technical officer competent in the subject concerned. Consultants and temporary advisers may, as appropriate, be chosen from WHO collaborating centres.

25. **Other organizations.** Representatives of the United Nations International Drug Control Programme (UNDCP), the International Narcotics Control Board (INCB) and Interpol are invited to attend meetings of the Expert Committee. Representatives of appropriate nongovernmental organizations in official relations with WHO are also invited.

26. **Information meeting.** Before the start of the Expert Committee's meeting, the secretariat may decide, when requested by interested nongovernmental organizations, to convene an information meeting. The purpose of the meeting is to permit these organizations to present additional information concerning the reviewed substances to the members of the Committee and to clarify written submissions. Requests for such a meeting should be submitted at least 10 working days before the start of the Expert Committee's meeting and should be accompanied by reasons for the request and relevant new information. The decision of the secretariat shall be communicated within five working days to the requesting nongovernmental organization. Representatives of UNDCP, INCB and Interpol are also invited to this information meeting.

27. **Procedure.** The regulations and rules of procedure for expert committees, adopted by the Health Assembly, are applicable.<sup>1</sup>

28. **Functions.** The function of the Expert Committee is to review information available to it on psychoactive substances being considered for international control and on exempted preparations, and to advise the Director-General of WHO on such control. The advice of the Expert Committee concerns scientific, medical and public health findings and must comply with the criteria set down in the Conventions. Specific responsibilities of the Expert Committee within these functions are: (1) pre-review: to select a substance for a critical review; (2) critical review: to assess the dependence-producing capability, the likelihood of abuse and of causing public health and social problems, and usefulness in medical therapy of each selected substance; (3) assessment of exempted preparations: to assess the need to terminate notified exemptions of preparations under the 1971 Convention.

### **Experts collaborating in the WHO review**

29. Experts collaborating in the review should have a well-documented scientific career at a high level and professional background, and should represent relevant behavioural, pharmacological, pharmaceutical, medical, biological or epidemiological disciplines, as well as public health administration. Scientists representing industrial research may be asked to collaborate as advisers in

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<sup>1</sup> Regulations for Expert Advisory Panels and Committees, adopted by resolution WHA35.10, as amended by decision WHA45(10) and resolution WHA49.29.

WHO ad hoc working groups, as appropriate, but they are not invited to participate in the Expert Committee meeting.

30. The selection of experts to collaborate in the WHO review is given careful consideration so as to avoid conflict of interests. Similar considerations shall apply to all concerned with the process. In this connection, experts invited to participate in the WHO review and, in particular, in the work of the Expert Committee, sign a statement concerning potential conflicts of interest.

### **Assessment for scheduling by the Expert Committee**

31. This subsection applies to the critical review by the Expert Committee. However, the scheduling criteria described herein are equally valid for the Expert Committee to draw a conclusion from the pre-review, which should be based on its judgement as to whether WHO has information that may justify the scheduling of that substance.

32. The Expert Committee bases its deliberations mainly on the documents provided by the secretariat: these consist of the critical review document, and any comments received by the secretariat concerning the critical review. They are forwarded to the members of the Expert Committee, in so far as it is possible to do so, at least three weeks before their meeting. The Expert Committee may have for consideration additional information presented in accordance with the procedure set forth in paragraph 26 above. Where feasible, and subject to the provision of paragraph 21 above, the information on which the critical review is based is made available to the Expert Committee as required.

33. The Expert Committee, when deciding whether to recommend international control after completion of its discussions, first decides, with regard to the 1961 Convention, whether the substance has morphine-like, cocaine-like, or cannabis-like effects or is convertible into a scheduled substance having such effects. If so, it then determines, in accordance with Article 3, paragraph 3(iii) of that Convention, if the substance: (1) is liable to similar abuse and productive of similar ill-effects as the substances in Schedule I or Schedule II; or (2) is convertible into a substance already in Schedule I or Schedule II.

34. After reviewing a substance which is convertible into a narcotic drug and which therefore can be placed in Schedule I or II of the 1961 Convention, if the Expert Committee is not proposing it for inclusion in a schedule of the 1961 Convention, the WHO Secretariat should convey the relevant information to the INCB secretariat.

35. If a substance invoked in the preceding paragraph has been placed in a table of the 1988 Convention, the Expert Committee should be guided by the principle that, for the practical application of controls, it is not advisable to place the same substance under more than one convention, and different stereoisomers of the same substance should not be controlled under different conventions. Any proposal for a change in the existing status of the substance should be made only if specific new control measures are necessary in order to decrease the extent or likelihood of abuse or the use of the substance in illicit drug manufacturing, and will not unduly limit its availability for legitimate medical and scientific purposes.

36. If the substance meets the criteria for inclusion in Schedule I of the 1961 Convention described above, the Expert Committee should further consider whether the drug meets the requirements for inclusion in Schedule IV in accordance with Article 3, paragraph 5 of that Convention.

37. If the Expert Committee finds that the psychoactive substance does not meet the criteria described in paragraph 33 and cannot therefore be appropriately controlled under the 1961 Convention, it makes its recommendations in terms of the 1971 Convention.

38. In considering the scheduling under the 1971 Convention, the Expert Committee determines, in accordance with Article 2, paragraph 4, whether:

- (1) the substance has the capacity to produce (a) a state of dependence, and (b) central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function, thinking, behaviour, perception or mood; or
- (2) the substance has the capacity to produce similar abuse and similar ill-effects as a substance in Schedules I, II, III or IV; and
- (3) there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control.

39. The Commentary on that Convention spells out the following considerations to be taken into account in such an evaluation:<sup>1</sup>

- (i) “... **an assessment of the substance** ... should not only comprise the factual results of [WHO’s] examination ... but also an evaluation of the data which it may have found in the light of such considerations of public health as it may consider appropriate ...” (page 58, paragraph 41);
- (ii) “... **extent or likelihood of abuse must be established**... in order to be able to determine whether ... [this] ... constitutes a public health and social problem warranting the placing of the substance under international control ...” (page 58, paragraph 42);
- (iii) “... **the degree of seriousness of the public health and social problem** ... must be assessed ... [so that the Commission on Narcotic Drugs could] ... weigh the dangerous properties of the substance against the non-medical considerations (economic, social, legal, administrative and other factors) mentioned in Article 2, paragraph 5 ...” (page 59, paragraph 43);
- (iv) “... **the degree of usefulness of the substance in medical therapy** ... [means] not only its potential beneficial effects, its value in the case of grave medical indications and the extent and frequency of its employment, but also the intensity of its dangerous properties ... and other harmful side-effects may have to be taken into account ...” (page 60, paragraph 44);
- (v) “... **together with recommendations on control measures, if any, that would be appropriate in the light of the assessment** ... WHO will be guided by its views of the degree of risk to public health which the substance presents and its usefulness in medical therapy ...” (page 61, paragraph 49).

40. The more specific criteria for proposing to include a substance for control in a particular Schedule go back to considerations by the Expert Committee in its seventeenth report.<sup>2</sup> They are as follows:

For inclusion in Schedule I:

Substances whose liability to abuse constitutes an especially serious risk to public health and which have very limited, if any, therapeutic usefulness.

For inclusion in Schedule II:

Substances whose liability to abuse constitutes a substantial risk to public health and which have little to moderate therapeutic usefulness.

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<sup>1</sup> *Commentary on the Convention on Psychotropic Substances*. New York, United Nations, 1976.

<sup>2</sup> WHO Technical Report Series, No. 437, 1970.

For inclusion in Schedule III:

Substances whose liability to abuse constitutes a substantial risk to public health and which have moderate to great therapeutic usefulness.

For inclusion in Schedule IV:

Substances whose liability to abuse constitutes a smaller but still significant risk to public health and which have a therapeutic usefulness from little to great.

41. Different from the text of the 1971 Convention, the criteria given in paragraph 40, do not specifically address the dimension of social problems, although the 1971 Convention does. It is also noted that the above criteria do not cover all cases. In order to fill these gaps, the Expert Committee agreed that the “risk to public health” in the above criteria should be interpreted to mean both social and public health problems, and drafted the following supplementary guidelines at its 29th meeting:<sup>1</sup>

In cases where the above criteria apply only in part, the scheduling recommendation should be made with a higher regard to the risk to public health than to therapeutic usefulness.

Notwithstanding the above, recommendations for inclusion in Schedule I should be made only when the above criteria are fully met, with respect to both therapeutic usefulness and the risk to public health.

42. In the case of a review of a psychoactive substance which is already included in Table I or Table II of the 1988 Convention, or has already been recommended by INCB for inclusion therein, the Expert Committee should be guided by the principle that, for the practical application of controls, it is not advisable to place the same substance under more than one convention, and different stereoisomers of the same substance should not be controlled under different conventions. Any proposal for a change in the existing status of the substance should be made only if specific new control measures are necessary in order to decrease the extent or likelihood of abuse, and will not unduly limit its availability for legitimate medical and scientific purposes.

43. If the advice of the Expert Committee is to include a substance mentioned in paragraph 35 or paragraph 42, i.e. that is already in Table I or Table II of the 1988 Convention, the WHO Secretariat will take steps to coordinate its proceedings with the INCB secretariat. Such steps will enable INCB to review the possibility of recommending deletion of the substance from the Table of the 1988 Convention before WHO communicates its recommendation to the United Nations. If both WHO and INCB make such recommendations, CND could consider the two proposals simultaneously.

44. The Expert Committee prepares a summary assessment of each substance reviewed, giving a description of its findings on the extent or likelihood of abuse, the degree of seriousness of the public health and social problem, and the degree of usefulness of the substance in medical therapy, together with the advice on the control measures, if any, that would be appropriate in the light of its assessment. The Expert Committee will advise the Director-General on its assessment and recommendation.

### **Assessment of exempted preparations by the Expert Committee**

45. The assessment of exempted preparations by the Expert Committee should evaluate the following elements: (1) conformity with the requirements of Article 3, paragraph 2, of the 1971 Convention concerning abuse liability and recoverability of the psychotropic substances as well as with CND resolution 1(S-VIII); and (2) the evidence available to WHO that the preparation may

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<sup>1</sup> WHO Technical Report Series, No. 856, 1995.

constitute a public health and social problem to an importing country or to a country where it is illicitly traded. On conclusion of the assessment, the Expert Committee advises the Director-General accordingly.

## **V. COMMUNICATION OF WHO RECOMMENDATIONS**

46. After receiving the advice of the Expert Committee (see subsection “Assessment for scheduling by the Expert Committee”), the Director-General will, as appropriate, communicate his or her recommendation to the United Nations. Copies of the recommendation are made available to Member States upon request and concurrently on the WHO Internet site.

47. Any recommendation(s) to change or terminate an exemption (see subsection “Assessment of exempted preparations by the Expert Committee”) is communicated by the Director-General to the exempting Party if the abuse problem is limited to the country of origin of the preparation or to the United Nations if the problems are widespread.

## **VI. PUBLICATION OF DOCUMENTS RELATED TO THE WHO REVIEW**

48. The recommendations of the Expert Committee are reported to the WHO Executive Board for information, and the report of the Expert Committee is published in the WHO Technical Report Series. The publication of any other document prepared for the Expert Committee is subject to Rule 4.15 of the Regulations for Expert Advisory Panels and Committees adopted by the Health Assembly, which states that the Director-General may publish or authorize the publication of any document prepared for an expert committee, with due recognition of authorship if applicable.<sup>1</sup>

## **VII. ABBREVIATIONS AND DEFINITIONS**

CND	The Commission on Narcotic Drugs, a functional commission of the United Nations Economic and Social Council.
Expert Committee	In this document, “the Expert Committee” refers to the WHO Expert Committee on Drug Dependence. The First World Health Assembly decided, by resolution WHA1.25 (1948), to establish the Expert Committee on Habit-Forming Drugs which, since its sixteenth meeting (1968), is named the Expert Committee on Drug Dependence.
INCB	International Narcotics Control Board; designated as “Board” in the text of the 1988 Convention.
Interpol	International Criminal Police Organization.
Member State	A State which is a member of WHO.
Narcotic drug	Any of the substances in Schedules I and II of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.

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<sup>1</sup> Resolution WHA35.10.

Notification	A formal communication addressed to the Secretary-General of the United Nations by a Party to an international drug control convention or by WHO, or by the Secretary-General of the United Nations to a Party to an international drug control convention or to WHO. In the context of the present guidelines, reference to a notification means a notification relating to the scheduling of a substance under the provisions of either Article 3 of the Single Convention or Articles 2 and 3 of the Convention on Psychotropic Substances.
Party	A State which has become a Party to an international drug control convention, through signature, ratification, accession, or succession.
Psychoactive substance	Any substance, natural or synthetic, or any natural substance material, which has psychoactive properties. In the present guidelines the term psychoactive substance is used also for those substances which are at present not under international control.
Psychotropic substance	Any substance, natural or synthetic, in Schedule I, II, III or IV of the Convention on Psychotropic Substances, 1971.
The 1961 Convention	Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.
The 1971 Convention	Convention on Psychotropic Substances, 1971.
The 1988 Convention	United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.
UNDCP	United Nations International Drug Control Programme

## Appendix 1: EXCERPTS FROM THE UN DRUG CONTROL CONVENTIONS

### 1. SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AS AMENDED BY THE 1972 PROTOCOL (EXTRACT)<sup>1</sup>

#### *Article 3*

#### CHANGES IN THE SCOPE OF CONTROL

1. Where a Party or the World Health Organization has information which in its opinion may require an amendment to any of the Schedules, it shall notify the Secretary-General and furnish him with the information in support of the notification.
2. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission [on Narcotic Drugs], and, where the notification is made by a Party, to the World Health Organization.
3. Where a notification relates to a substance not already in Schedule I or in Schedule II,
  - (i) the Parties shall examine in the light of the available information the possibility of the provisional application to the substance of all measures of control applicable to drugs in Schedule I;
  - (ii) pending its decision as provided in subparagraph (iii) of this paragraph, the Commission may decide that the Parties apply provisionally to that substance all measures of control applicable to drugs in Schedule I. The Parties shall apply such measures provisionally to the substance in question;
  - (iii) if the World Health Organization finds that the substance is liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II or is convertible into a drug, it shall communicate that finding to the Commission which may, in accordance with the recommendation of the World Health Organization, decide that the substance shall be added to Schedule I or Schedule II.
4. If the World Health Organization finds that a preparation, because of the substances which it contains, is not liable to abuse and cannot produce ill effects (paragraph 3) and that the drug therein is not readily recoverable, the Commission may, in accordance with the recommendation of the World Health Organization, add that preparation to Schedule III.
5. If the World Health Organization finds that a drug in Schedule I is particularly liable to abuse and to produce ill effects (paragraph 3) and that such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV, the Commission may, in accordance with the recommendation of the World Health Organization, place that drug in Schedule IV.
6. Where a notification relates to a drug already in Schedule I or Schedule II or to a preparation in Schedule III, the Commission, apart from the measure provided for in paragraph 5, may, in accordance with the recommendation of the World Health Organization, amend any of the Schedules by:

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<sup>1</sup> Single Convention on Narcotic Drugs, 1961. New York, United Nations, 1977, pp. 17- 18.

- (a) transferring a drug from Schedule I to Schedule II or from Schedule II to Schedule I; or
- (b) deleting a drug or a preparation as the case may be, from a Schedule.

7. Any decision of the Commission taken pursuant to this article shall be communicated by the Secretary-General to all States Members of the United Nations, to non-Member States Parties to this Convention, to the World Health Organization and to the [International Narcotics Control] Board. Such decision shall become effective with respect to each Party on the date of its receipt of such communication, and the Parties shall thereupon take such action as may be required under this Convention.

8. (a) The decisions of the Commission amending any of the Schedules shall be subject to review by the [Economic and Social] Council upon the request of any Party filed within ninety days from receipt of notification of the decision. The request for review shall be sent to the Secretary-General together with all relevant information upon which the request for review is based;

(b) The Secretary-General shall transmit copies of the request for review and relevant information to the Commission, the World Health Organization and to all the Parties inviting them to submit comments within ninety days. All comments received shall be submitted to the Council for consideration;

(c) The Council may confirm, alter or reverse the decision of the Commission, and the decision of the Council shall be final. Notification of the Council's decision shall be transmitted to all States Members of the United Nations, to non-Member States Parties to this Convention, to the Commission, to the World Health Organization, and to the Board;

(d) During pendency of the review the original decision of the Commission shall remain in effect.

9. Decisions of the Commission taken in accordance with this article shall not be subject to the review procedure provided for in article 7.

## 2. CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971 (EXTRACTS)<sup>1</sup>

### *Article 2*

#### SCOPE OF CONTROL OF SUBSTANCES

....

4. If the World Health Organization finds:

(a) that the substance has the capacity to produce

(i) (1) a state of dependence, and

(2) central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood, or

(ii) similar abuse and similar ill effects as a substance in Schedule I, II, III or IV, and

(b) that there is sufficient evidence that the substance is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control,

the World Health Organization shall communicate to the Commission [on Narcotic Drugs] an assessment of the substance, including the extent or likelihood of abuse, the degree of seriousness of the public health and social problem and the degree of usefulness of the substance in medical therapy, together with recommendations on control measures, if any, that would be appropriate in the light of its assessment.

....

### *Article 3*

#### SPECIAL PROVISIONS REGARDING THE CONTROL OF PREPARATIONS

1. Except as provided in the following paragraphs of this article, 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. If a preparation containing a psychotropic substance other than a substance in Schedule I is compounded in such a way that it presents no, or a negligible, risk of abuse and the substance cannot be recovered by readily applicable means in quantity liable to abuse, so that the preparation does not give rise to a public health and social problem, the preparation may be exempted from certain of the measures of control provided in this Convention in accordance with paragraph 3.

3. If a party makes a finding under the preceding paragraph regarding a preparation, it may decide to exempt the preparation, in its country or in one of its regions, from any or all of the measures of control provided in this Convention except the requirements of:

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<sup>1</sup> Convention on Psychotropic Substances, 1971. New York, United Nations, 1977, pp. 9 and 12-13.

- (a) article 8 (licenses), as it applies to manufacture;
- (b) article 11 (records), as it applies to exempt 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 exempt preparations; and
- (f) article 22 (penal provisions), to the extent necessary for the repression of acts contrary to laws or regulations adopted pursuant to the foregoing obligations.

A Party shall notify the Secretary-General of any such decision, of 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.

4. If a Party or the World Health Organization has information regarding a preparation exempted pursuant to paragraph 3 which in its opinion may require the termination, in whole or in part, of the exemption, it shall notify the Secretary-General and furnish him with the information in support of the notification. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission and, when the notification is made by a Party, to the World Health Organization. The World Health Organization shall communicate to the Commission an assessment of the preparation in relation to the matters specified in paragraph 2, together with a recommendation of the control measures, if any, from which the preparation should cease to be exempted. The Commission, taking into account the communication from the World Health Organization, whose assessment shall be determinative as to medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may decide to terminate the exemption of the preparation from any or all control measures. Any decision of the Commission taken pursuant to this paragraph shall be communicated by the Secretary-General to all States Members of the United Nations, to non-Member States Parties to this Convention, to the World Health Organization and to the Board. All Parties shall take measures to terminate the exemption from the control measure or measures in question within 180 days of the date of the Secretary-General's communication.

3. UNITED NATIONS CONVENTION AGAINST ILLICIT TRAFFIC IN NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES, 1988 (EXTRACTS)<sup>1</sup>

*Article 12*

SUBSTANCES FREQUENTLY USED IN THE ILLICIT MANUFACTURE OF NARCOTIC DRUGS OR PSYCHOTROPIC SUBSTANCES

1. The Parties shall take the measures they deem appropriate to prevent diversion of substances in Table I and Table II used for the purpose of illicit manufacture of narcotic drugs or psychotropic substances, and shall co-operate with one another to this end.
2. If a Party or the Board has information which in its opinion may require the inclusion of a substance in Table I or Table II, it shall notify the Secretary-General and furnish him with the information in support of that notification. The procedure described in paragraphs 2 to 7 of this article shall also apply when a Party or the Board has information justifying the deletion of a substance from Table I or Table II, or the transfer of a substance from one Table to the other.
3. The Secretary-General shall transmit such notification, and any information which he considers relevant, to the Parties, to the Commission, and, where notification is made by a Party, to the Board. The Parties shall communicate their comments concerning the notification to the Secretary-General, together with all supplementary information which may assist the Board in establishing an assessment and the Commission in reaching a decision.
4. If the Board, taking into account the extent, importance and diversity of the licit use of the substance, and the possibility and ease of using alternate substances both for licit purposes and for the illicit manufacture of narcotic drugs or psychotropic substances, finds:
  - (a) That the substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance;
  - (b) That the volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public health or social problems, so as to warrant international action, it shall communicate to the Commission an assessment of the substance, including the likely effect of adding the substance to either Table I or Table II on both licit use and illicit manufacture, together with recommendations of monitoring measures, if any, that would be appropriate in the light of its assessment.
5. The Commission, taking into account the comments submitted by the Parties and the comments and recommendations of the Board, whose assessment shall be determinative as to scientific matters, and also taking into due consideration any other relevant factors, may decide by a two-thirds majority of its members to place a substance in Table I or Table II.

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<sup>1</sup> United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. Vienna, United Nations, 1994, pp.24-26

## **Appendix 2: RESOLUTION 1(S-VIII) OF THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS<sup>1</sup>**

### 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;

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<sup>1</sup> Extract from United Nations document E/CN.7/1984/13 (1984).

(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.

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