

# Guidance on the WHO review of psychoactive substances for international control



World Health  
Organization

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## INTRODUCTION

In January 2010, the Executive Board of the World Health Organization's (WHO) adopted a revision of the Guidelines for The WHO Review of Psychoactive Substances for International Control. These Guidelines govern the evaluation of substances for WHO's recommendations to the Commission on Narcotic Drugs (CND) as required by the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

This publication provides a comprehensive overview for all those who are involved in the evaluation process. It can be consulted by the Experts who serve on the Expert Committee on Drug Dependence, in order to make the right recommendation while following correct procedures, or by Representatives to the CND, in order to better understand any recommendations made to the Commission by WHO. Furthermore, it can help any interested person to understand the scheduling process in international drug control.

This publication contains the text in its final form as it was adopted by the Executive Board, including three Appendices, of which Appendix 3 is a visual representation of the evaluation process in the format of a Flow Chart. Furthermore, this publication presents the Report by the Secretariat which contains the elucidation of the document by the WHO Secretariat to the Executive Board and the part of the Summary Records from the Executive Board session that reflects the discussion on the proposal, its amending and its adoption.



# GUIDELINES FOR THE WHO REVIEW OF PSYCHOACTIVE SUBSTANCES FOR INTERNATIONAL CONTROL

as adopted by EB 126

## I. MANDATE

1. The World Health Organization (WHO) is the specialized agency of the United Nations that conducts the medical, scientific and public health evaluation 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).<sup>1</sup> The guidance document for this evaluation has been developed pursuant to resolutions of the World Health Assembly<sup>2</sup> and of the United Nations Commission on Narcotic Drugs (CND). This document amends the previous version of these guidelines and sets out guidelines establishing the underlying principles of the review procedure, working arrangements within the 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>3</sup> WHO first developed the guidelines document for the evaluation and assessment of narcotic and psychotropic substances for decisions on international control in consultation with CND in 1986,<sup>4</sup> which document was revised in 1990.<sup>5</sup> Amendments and decisions subsequently adopted by the Executive Board in 1994<sup>6</sup> and 1999<sup>7</sup> resulted in a further revision in 2000. Subsequently, at the request of the Expert Committee on Drug Dependence (Expert Committee), supplementary guidelines were submitted to the Executive Board in order to clarify certain issues.<sup>8</sup> The Board considered the proposed supplementary guidelines in May 2004<sup>9</sup> and January 2005<sup>10</sup> when it requested the Secretariat and the Expert Committee to continue their work on the issue. This revision of the guidelines has been prepared in response to that request.

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<sup>1</sup> See Appendix 1 for the most relevant excerpts from these conventions.

<sup>2</sup> Resolution WHA33.27.

<sup>3</sup> Resolution EB73.R11.

<sup>4</sup> Decision EB77(3).

<sup>5</sup> Decision EB85(10).

<sup>6</sup> Decision EB93(16).

<sup>7</sup> Decision EB103(5).

<sup>8</sup> Documents EB114/7 and EB115/12.

<sup>9</sup> Document EB114/2004/REC/1, summary record of the third meeting.

<sup>10</sup> Document EB115/2005/REC/2, summary record of the sixth meeting.



## II. UNDERLYING PRINCIPLES

4. The Preamble of the Single Convention on Narcotic Drugs, 1961 provides:

*“The Parties,  
Concerned with the health and welfare of mankind,  
Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,  
Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,  
Conscious of their duty to prevent and combat this evil,  
Considering that effective measures against abuse of narcotic drugs require coordinated and universal action,  
Understanding that such universal action calls for international cooperation guided by the same principles and aimed at common objectives,  
Acknowledging the competence of the United Nations in the field of narcotics control and desirous that the international organs concerned should be within the framework of that Organization,  
Desiring to conclude a generally acceptable international convention replacing existing treaties on narcotic drugs, limiting such drugs to medical and scientific use, and providing for continuous international cooperation and control for the achievement of such aims and objectives ...”*

- The Preamble of the Convention on Psychotropic Substances, 1971 provides:

*“The Parties,  
Being concerned with the health and welfare of mankind,  
Noting with concern the public health and social problems resulting from the abuse of certain psychotropic substances,  
Determined to prevent and combat abuse of such substances and the illicit traffic to which it gives rise,  
Considering that rigorous measures are necessary to restrict the use of such substances to legitimate purposes,  
Recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted,  
Believing that effective measures against abuse of such substances require coordination and universal action,  
Acknowledging the competence of the United Nations in the field of control of psychotropic substances and desirous that the international organs concerned should be within the framework of that Organization,  
Recognizing that an international convention is necessary to achieve these purposes ...”*

The WHO review procedure, grounded in considerations of public health and with an evidence-based approach, will utilize the best available relevant information. Consistent with the requirements of the 1961 and 1971 Conventions, WHO will develop scheduling recommendations guided by the provisions in the Conventions regarding the changes in the scope of control of substances and also taking into account the preambles of the Conventions, the need to reduce the risk to public health, including the risk of abuse and ensuring medical availability, and the relevant resolutions of its governing bodies. The Conventions are legal instruments; the WHO review procedure shall be applied in a manner consistent with the letter and the spirit of the Conventions.

## III. PROVISIONS OF THE CONVENTIONS

5. The 1961 and 1971 Conventions entrust WHO with the responsibility of reviewing and assessing substances to determine whether they should be controlled under the Conventions. A request for

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 itself.<sup>1</sup> WHO will forward the results of this review to CND which has the responsibility to decide whether to schedule substances under the provisions of the Conventions.<sup>2</sup>

6. 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, the CND must accept or refuse the WHO recommendation as a whole, except that it may decide to place a substance only in Schedule I and not in Schedule IV if WHO has recommended simultaneous inclusion in both schedules. The CND should in principle accept the medical, scientific, chemical and pharmacological findings of WHO, and when the CND rejects a recommendation, it should be guided by other considerations such as those of an administrative or social nature.<sup>3</sup> In the case of the 1971 Convention, the CND may accept a WHO proposal, but it 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.<sup>4</sup> 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.
7. Under the provisions of Article 3 of the 1971 Convention, a Party may exempt from specific control measures a preparation containing one or more psychotropic substances if the preparation is compounded in such a way that it presents no, or a negligible, risk of abuse, and the substance cannot be recovered by a readily applicable means in a quantity liable to abuse, so that the preparation does not give rise to a public health and social problem. A party shall notify the Secretary-General of the United Nations who in turn shall transmit the notification to other Parties, to WHO and to the International Narcotics Control Board. 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 notification. WHO reviews the data submitted by the Parties that wish to avail themselves of this provision for exemption under the 1971 Convention by applying specific guidelines that have been approved by CND.<sup>5</sup>
8. 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.
9. 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

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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 defined in Article 3 of the 1961 Convention and Articles 2 and 17 (para. 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> Commentary on the 1961 Single Convention on Narcotic Drugs (1961 Convention), para. 16–18 (p. 90).

<sup>4</sup> 1971 Convention, Art. 2, para. 5; See also, Commentary on the Convention of Psychotropic Substances (1971 Convention), para. 20 (p. 71).

<sup>5</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).

manufacture of narcotic drugs or psychotropic substances. These substances are listed in Table I and Table II of the 1988 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 address such a situation is provided below under the subsection *Assessment for scheduling by the Expert Committee*.

#### **IV. WHO REVIEW PROCEDURE<sup>1</sup>**

10. The purpose of the WHO review procedure is to evaluate substances for international control. Using data provided by the Secretariat, the Expert Committee conducts pre-reviews and critical reviews in order to provide scheduling advice to the Director-General.
11. The review of exempted preparations notified by a Party involves a preliminary review by the Secretariat and an evaluation by the Expert Committee.
12. 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**

13. The Secretariat should routinely collect relevant data related to psychoactive substances that are being abused or might have abuse potential and substances convertible into such substances from the literature, WHO programmes, WHO collaborating centres, national health and drug control authorities, intergovernmental and nongovernmental organizations, research and academic institutions and other competent sources.

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

14. The purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review.
15. A pre-review is initiated when a proposal has been 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 in accordance with paragraph 35. The Secretariat will put the proposed pre-review of a substance on the agenda of the first possible Expert Committee meeting.
16. The categories of information for evaluating substances in pre-reviews are identical to those used in critical reviews. The Secretariat shall supply the supporting information required for pre-review in the form of a brief summary of relevant information. At this stage the Expert Committee must decide whether the information warrants a critical review. If the Expert Committee determines that a critical review is not warranted then the Expert Committee should recommend no further evaluation of the substance. The pre-review is a preliminary analysis and findings at this stage should not determine whether the control status of a substance should be changed. The confidentiality of information received by WHO for use in the review will be respected if so requested by the provider. Appropriate arrangements to sustain confidentiality will be made when the Expert Committee has access to the information used to prepare the pre-review.
17. The Expert Committee shall recommend a critical review if it finds that information may justify the scheduling or a change in the scheduling of the substance in the 1961 or 1971 Conventions, using the criteria in paragraphs 48 to 59.

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<sup>1</sup> See appendix 3 for a flow chart of the evaluation procedure.

## **Critical review**

18. The purpose of the critical review is to consider whether the Expert Committee should advise the Director-General to recommend the scheduling of, or amending of the scheduling status of, a substance.
19. A critical review is initiated when:
  - (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 an Expert Committee recommendation for critical review; or
  - (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 Party.

In respect of case (4), if therapeutic use of the substance is confirmed subsequently by any Party the substance shall be subjected to a pre-review.

## **Critical review documents**

20. The purpose of the critical review document is to provide comprehensive data for use by the Expert Committee in assessing individual substances.
21. The Secretariat is responsible to collect and assemble the data on substances selected for critical review. The Secretariat will use a questionnaire to request information from ministers of health in the Member States and international drug control bodies and will circulate the agenda of the next meeting.
22. The critical review document should be as thorough as possible, and balanced in its presentation. It should include the adequate and relevant data, including medical literature and abuse studies. In order to accomplish this, the Secretariat may seek assistance from advisers and ad hoc working groups.
23. When preparing the draft critical review document, including a separate report on the questionnaire, 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, including general information on synthesis, preparation and properties;
  - (3) ease of convertibility into controlled substances;
  - (4) general pharmacology, including pharmacokinetics and pharmacodynamics;
  - (5) toxicology,
  - (6) adverse reactions in humans;

- (7) dependence potential;
  - (8) abuse potential;
  - (9) therapeutic applications, extent of therapeutic use and epidemiology of medical use;
  - (10) listing on the WHO Model List of Essential Medicines;
  - (11) marketing authorizations (as a medicine);
  - (12) industrial use;
  - (13) non-medical use, abuse and dependence;
  - (14) nature and magnitude of public health problems related to abuse and dependence;
  - (15) licit production, consumption and international trade;
  - (16) illicit manufacture and traffic, and related information;
  - (17) current international controls and their impact;
  - (18) current and past national controls;
  - (19) other medical and scientific matters relevant for a recommendation on the scheduling of the substance.
24. The data in the critical review should be presented in a manner that will facilitate an evidence-based assessment by the Expert Committee. The critical review will comprise a summary and a section that compares the data directly against the scheduling criteria.
  25. The draft critical review document and the report on the questionnaire are transmitted to all governments, institutions, organizations, or other interested parties that have directly and substantially collaborated in its preparation and have requested it. The recipients may provide comments on the draft. To help to ensure that all material submitted to the Expert Committee is up to date, the Secretariat will circulate the agenda of the next meeting to those collaborating information sources.
  26. For each substance, the draft critical review document and the report on the questionnaire will be peer-reviewed by two experts from WHO's Expert Advisory Panels, including an evaluation of the strength of evidence they present. If there are data limitations or omissions, they should be identified, discussed and adapted as needed.
  27. The critical review document and the report on the questionnaire will be provided to all members of the Expert Committee at least thirty days before its meeting, and posted on the WHO web site, according to WHO rules for publication.
  28. The confidentiality of information received by WHO for use in the review will be respected if so requested by the provider. Appropriate arrangements to sustain confidentiality will be made when the Expert Committee has access to the information used to prepare the pre-review and the critical review.

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

29. 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 shall be evaluated by the Expert Committee.

## **Expert Committee on Drug Dependence**

30. In accordance with WHO's regulations, the Expert Committee meets when necessary to discuss the appropriate issues within its responsibility. As a guide, the Expert Committee should meet at least every second year.
31. **Membership.** The Expert Committee members are chosen by the Director-General in accordance with WHO's Regulations on Expert Advisory Panels and Committees. The Director-General shall establish the number of experts to be invited to a meeting of an Expert Committee on Drug Dependence, determine its date and duration, and convene the Expert Committee meeting.
32. **Functions.** The functions of the Expert Committee are to review information available to it on substances being considered for international control and for exemptions, and to advise the Director-General on such control. The advice of the Expert Committee concerns scientific, medical and public health findings and must comply with the criteria established in the Conventions. Specific responsibilities of the Expert Committee are:
- (1) pre-review: to determine whether a substance should be subject to 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 substance under review; and to advise on the appropriate schedule under one of the Conventions;
  - (3) exempted preparations: to evaluate the need to terminate notified exemptions of preparations under the 1971 Convention.
33. **Procedure.** WHO's Regulations on Expert Advisory Panels and Committees are applicable.
34. **Secretariat.** The Expert Committee is assisted by a secretariat, in particular by the Expert Committee's Secretary and furthermore by staff members from appropriate WHO programmes, consultants and temporary advisers, as required. The functions of the Secretary are executed by a technical officer competent in the subject concerned.
35. **Other organizations.** Representatives of United Nations organizations such as the United Nations Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB), and appropriate nongovernmental organizations (NGOs) in official relations with WHO may be invited to attend the meetings of the Expert Committee as observers. In consultation with the members and the Secretariat, the Chair may decide to have a session of the Expert Committee with the members only.
36. The Expert Committee's recommendations and advice remain confidential until the clearing of their publication according to WHO's internal rules. All participants are required to respect the

confidentiality of all information received as part of the Expert Committee process as well as the confidentiality of the Expert Committee's deliberations.

### **Information meeting**

37. Interested parties that intend to make submissions of data may request the convening of an information meeting with the Expert Committee for this purpose. Requests for such a meeting should be submitted to the Secretariat at least twenty days before the start of the Expert Committee meeting. The request should state the nature and content of the presentation to be made at the meeting. All participants to the Expert Committee meeting are invited to this information meeting.
38. The purpose of the information meeting is to afford the Expert Committee the opportunity, before the Committee's meeting, to receive presentations and to question representatives of interested parties concerning data that have been provided about substances under review.
39. The information meeting will be held before the Expert Committee convenes its meeting. The Secretariat at its discretion shall decide the agenda of the information meeting, taking into account the nature of the proposed presentations and the time constraints for the meeting of the Expert Committee. The decisions of the Secretariat concerning the information meeting will be communicated to requesting interested parties at least 10 days before the Expert Committee meeting.

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

40. 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 industry research may be asked to collaborate as advisers in WHO ad hoc working groups, as appropriate, but they are not invited to participate in the Expert Committee meeting.
41. Experts participating in the WHO review should be selected with careful attention given to the avoidance of conflicts of interest. 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**

42. The Expert Committee bases its deliberations mainly on the documents provided by the Secretariat: these consist of the critical review document, the report on the questionnaire and comments received by the Secretariat concerning the critical review. The Expert Committee may also consider additional information presented in the information meeting. The information on which the critical review is based will be made available to the Expert Committee. The dissemination of this information may otherwise be restricted if needed to protect confidentiality requirements pursuant to paragraph 28.
43. Proposals for the change in control of a substance should be subjected to the same assessment that is given to substances proposed for initial scheduling; the same criteria as mentioned below in paragraphs 46 to 59 should be used in making the assessment.
44. To facilitate efficient administration of the international control system, it is not advisable to place a substance under more than one Convention. This is also true of substances that have been placed in a Table of the 1988 Convention, or have been recommended by INCB for inclusion in a Table.

45. A recommendation to delete a substance from one Convention with a simultaneous recommendation to add the same substance to another Convention may affect administration of the international scheme of regulation. Like all recommendations, consideration of such changes in control may be undertaken in light of new information to justify such a change. Any proposal to move a substance from one convention to another 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 availability for legitimate medical and scientific purposes.

## **The assessment process**

### **Orientation**

46. Both the 1961 and 1971 Conventions provide for control of substances that are liable to “similar abuse and similar ill-effects” as substances already controlled under those Conventions. Many substances exhibit similarity in their “abuse” and “ill-effects” to substances in both the 1961 Convention and the 1971 Convention. Amphetamines, barbiturates and tranquillizers are only subject to the 1971 Convention, by virtue of an understanding of the Parties to the Conventions that the 1961 Convention did not apply to these substances even though the effects of amphetamines, barbiturates and tranquillizers were recognized to be similar to cocaine and morphine in some respects.<sup>1</sup> When considering other substances that exhibit abuse characteristics similar to substances regulated under both Conventions, the Expert Committee should follow the sequence for analysis established by the guidelines for all substances; that is, first consider applicability of the 1961 Convention and, if it is found not to apply, then the 1971 Convention. As such, the Committee would first assess whether the substance under review shows similar abuse liability profile (based on animal and human studies) and dependence-producing properties to drugs already controlled under the 1961 Convention. This assessment should not be limited to a narrow consideration of a single pharmacologic property. If the substance under review shows sufficiently similar abuse liability profile and dependence-producing properties to drugs already controlled under the 1961 Convention, then it should be recommended for scheduling under the 1961 Convention; if not, then the analysis should be made using the criteria in the 1971 Convention.
47. The 1961 Convention provides for the control of substances convertible to narcotic drugs. The 1971 Convention provides for no such control of precursors. The 1988 Convention fills the void that existed for controlling precursors of psychotropic substances and the control of other chemicals frequently used in the illicit production of all controlled substances. INCB has responsibility for reviewing precursors of both narcotic and psychotropic substances for potential control. The Expert Committee might be asked to assess a substance to determine if it is convertible to a substance controlled under the 1961 Convention. If so, the Committee should determine if the substance is “convertible” as defined in paragraph 49 of these Guidelines, and then determine whether it is convertible to a substance controlled by the 1961 Convention.

### **Step 1: 1961 Convention**

48. The Expert Committee, when deciding whether to recommend international control, or a change in international control, after completion of its discussions, first decides, with regard to the 1961 Convention, whether the substance in accordance with Article 3, paragraph 3 (iii) of that Convention: (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.

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<sup>1</sup> Commentary on the 1961 Convention, Art.3, para. 3, subpara (iii), Comment 6 (p. 87).



49. In addition to the principle of “Similarity”, laid down in Article 3, paragraph 3 (iii) of that Convention and mentioned in paragraph 48, the Convention also contains the principle of “Convertibility”. A substance is convertible if it is of such a kind as to make it, by the ease of the process and by the yield, practicable and profitable for a clandestine manufacturer to transform the substance in question into controlled drugs.<sup>1</sup>
50. The Secretariat will promptly advise the INCB Secretariat of all Expert Committee assessments relating to substances that might be convertible into a narcotic drug. If the advice of the Expert Committee is to schedule a substance, whether psychoactive or convertible into a psychoactive substance, that is already in Table I or Table II of the 1988 Convention, the 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.
51. If a substance meets the criteria for inclusion in Schedule I of the 1961 Convention, 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, with regard to substances being particularly liable to abuse and to produce ill-effects and if such liability is not offset by substantial therapeutic advantages not possessed by substances other than drugs in Schedule IV.
52. If the Expert Committee finds that a substance does not meet the criteria for control under the 1961 Convention, then it makes an assessment in accordance with the 1971 Convention.

### **Step 2: 1971 Convention**

53. In considering the scheduling under the 1971 Convention, the Expert Committee determines whether, in accordance with Article 2, paragraph 4:
- (a) The substance has the capacity to produce:
    - (i) (1) A state of dependence,<sup>2</sup> 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) 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.
54. In applying paragraph 53 of the Guidelines, the principle of similarity described in Article 2, paragraph 4(a)(ii) of the 1971 Convention applies only in situations when the substance does not

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<sup>1</sup> Commentary on the 1961 Convention, para. 13 (p. 89).

<sup>2</sup> Dependence was defined by the 28th Expert Committee on Drug Dependence as: “A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behaviour. Determinants and the problematic consequences of drug dependence may be biological, psychological or social, and usually interact.” The Committee also mentioned that in its opinion this definition is compatible with the ICD-10 diagnostic guidelines. (WHO Expert Committee on Drug Dependence. Twenty-eighth report. Geneva, World Health Organization, 1993 (WHO Technical Report Series, No. 836)).

produce a state of dependence. In the absence of a finding that a substance produces dependence, similarity takes on importance; otherwise it is secondary.

55. The Commentary on the 1971 Convention provides the following considerations to be taken into account in such an evaluation:

(i) “The 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 (...)*” Commentary on the 1971 Convention, para. 41 (p. 58);

(ii) “WHO must also establish *the extent of abuse or the degree of likelihood of abuse (...)* 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.” Id., para. 42 (p. 58);

(iii) WHO must “*assess the degree of seriousness of the public health and social problem (...)*. Since in arriving at its decision the [Commission on Narcotics Drugs will] weigh the dangerous properties of the substance against the non-medical considerations ... it would find it useful to have the views of WHO on the *degree* of seriousness of the health and social problem which it has to take into account.” Article 2, paragraph 5 ... Id., para. 43 (p. 59);

(iv) WHO is required to include an assessment of “*the degree of usefulness of the substance in medical therapy* based on two considerations: (a) the degree of risk to public health and (b) the usefulness of the drug in medical therapy... [which 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.” Id., para. 44 (pp. 59–60);

(v) It is safe to state that WHO in recommending a particular Schedule for a substance, “*will be guided by its views of the degree of risk to public health which the substance presents and its usefulness in medical therapy.*” Id., para. 49 (p. 61).

56. On the basis of the above considerations, more specific criteria for proposing to include a substance for control in a particular schedule were developed by the Expert Committee at its seventeenth meeting.<sup>1</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.

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:

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<sup>1</sup> WHO Expert Committee on Drug Dependence. Seventeenth report. Geneva, World Health Organization, 1970 (WHO Technical Report Series, No. 437).

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.

In cases where the above criteria apply only in part, the scheduling recommendation should be made with a higher regard to the risk to that dimension of public health specific to abuse liability.

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.

57. The criteria given in the foregoing paragraph do not specifically address the dimension of social problems, although the Commentary on the 1971 Convention does. It is also noted that the above criteria do not cover all cases. The “risk to public health” in the above criteria should be interpreted to mean both social and public health problems. Note that under Article 2, paragraph 4(b) there must be a finding of an “international” need for control, meaning that controls of the Convention are suitable to solve or alleviate the problem and that lack of those controls in one country, no matter whether it has itself the public health and social problem caused by the substance under examination, weakens the control in other countries which have such a problem. International control is also warranted if the public health and social problem exists only in a single country if the efforts of control by that country are weakened by the lack of control in other countries.
58. If the advice of the Expert Committee is to include a substance 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.
59. The Expert Committee shall provide its recommendation on the scheduling status on all drugs or substances under review as described in paragraph 60. Should the Expert Committee be unable to make a recommendation concerning substances under review, then it should request another critical review in order to refer the matter to a subsequent Expert Committee.<sup>1</sup>

### **Step 3: The report**

60. The Expert Committee prepares a summary assessment of each substance reviewed. This assessment should include the Expert Committee’s findings regarding pharmacological similarity, similar abuse, and similar ill-effects of the substance to substances in Schedules I and II of the 1961 Convention and, in the case of a “convertible” substance, an assessment of the convertibility of the substance into a substance already controlled as a narcotic drug. If the substance is recommended for control under the 1971 Convention, the assessment should also indicate whether the substance is being recommended for such control as a dependence-producing substance or on the basis of similarity. For all substances reviewed, the summary assessment should give a description of the Expert Committee’s 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. The Expert Committee’s report will be published and made available on the WHO web site in conformity with WHO rules for publication of Expert Committee reports.

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<sup>1</sup> WHO Expert Committee on Drug Dependence. Thirty-fourth report. Geneva, World Health Organization, 2007 (WHO Technical Report Series, No. 942), pp. 17–18.

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

61. 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 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.<sup>1</sup>

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

62. After receiving the advice of the Expert Committee to schedule or to amend the scheduling status of a substance, the Director-General will, as appropriate, communicate the recommendation on behalf of WHO to the United Nations. Copies of the recommendation are made available on the WHO web site concurrently.
63. Any recommendation to terminate an exemption in whole or in part will be 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**

64. The Director-General will submit to the Executive Board a report of the meetings of the ECDD in accordance with paragraph 4.23 of the Regulations on Expert Advisory Panels and Committees, and the report of the Expert Committee is published according to the WHO rules, both in the WHO Technical Report Series and on the WHO web site. 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, 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.

## **VII. ABBREVIATIONS AND DEFINITIONS**

CND	The Commission on Narcotic Drugs of the Economic and Social Council of the United Nations.
Expert Committee	In this document, “the Expert Committee” refers to the WHO Expert Committee on Drug Dependence. The First World Health Assembly decided in 1948, by resolution WHA1.25, to establish the Expert Committee on Habit-Forming Drugs which, since its sixteenth meeting (1968), is named Expert Committee on Drug Dependence.
INCB	The International Narcotics Control Board established by the Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961.
Member State	A State which is a Member of WHO.

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<sup>1</sup> See also Appendix 2.

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, whether natural or synthetic.
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.
Psychotropic substance	Any substance, natural or synthetic, or any natural material in Schedule I, II, III or IV of the Convention on Psychotropic Substances, 1971.
Secretariat	The Secretariat of WHO.
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.
UNODC	United Nations Office on Drugs and Crime.

## APPENDIX 1

### EXCERPTS FROM THE UNITED NATIONS DRUG CONTROL CONVENTIONS

#### 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, 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 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 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.

# 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 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.
5. The Commission, taking into account the communication from the World Health Organization, whose assessments 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 add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.

...

## 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 a 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.

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



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:

- a) article 8 (licences), 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 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.

# 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.

## 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;

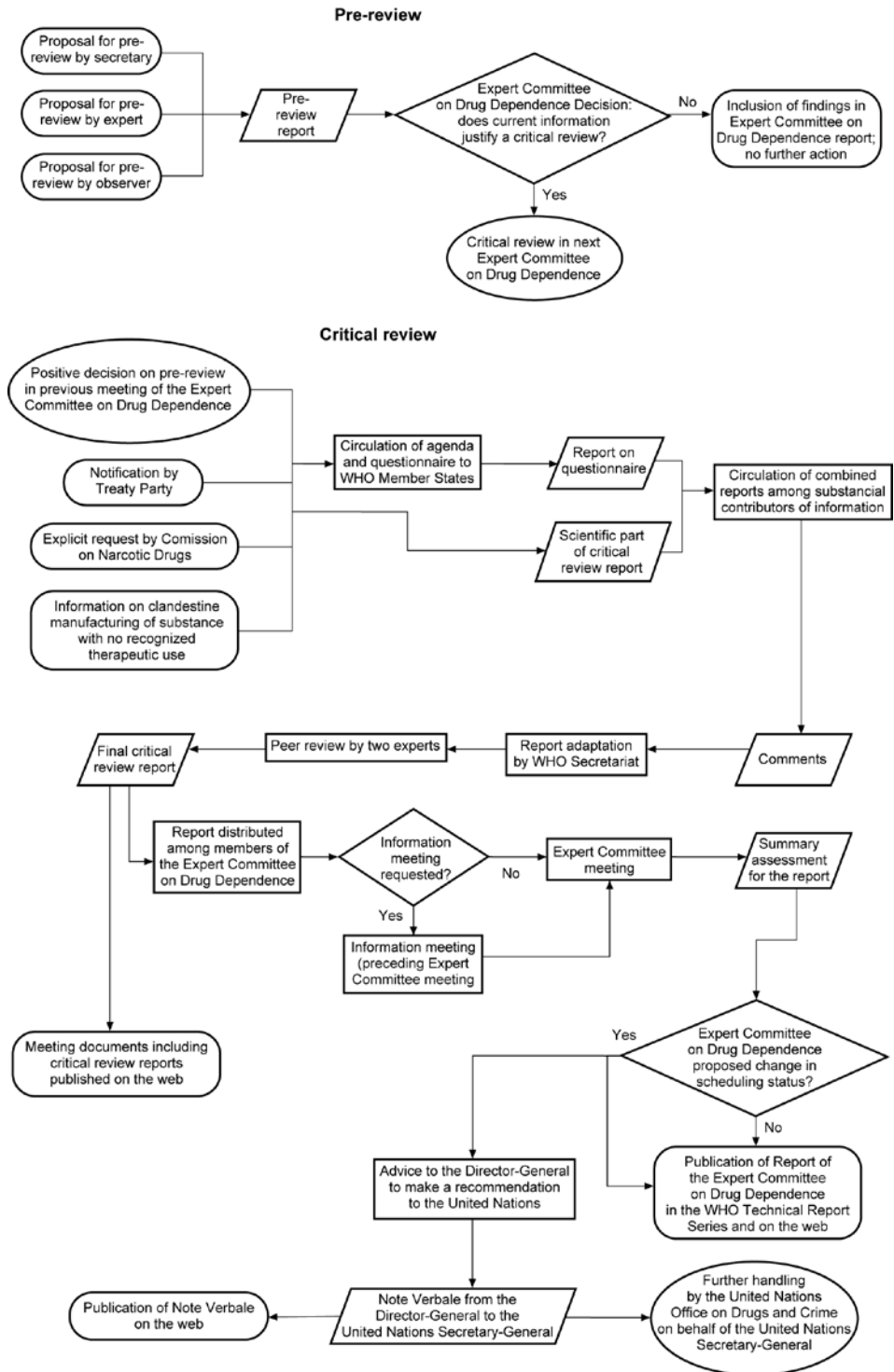
f) A preparation containing a psychotropic substance should not be exempted from the requirements of article 12 of the 1971 Convention on Psychotropic Substances;

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.

APPENDIX 3  
**FLOW CHART OF THE EVALUATION PROCEDURE**  
**WHO review of psychoactive substances**  
**for international control**



WHO 09.28

## REPORT BY THE SECRETARIAT<sup>1</sup>

1. In May 2009 the Executive Board at its 125th session considered an agenda item on guidance on the WHO review of psychoactive substances for international control: proposed revision. The Board decided to postpone further discussion to the present session in order to allow comments to be collected from Member States, from the Expert Advisory Panel on Drug Dependence,<sup>2</sup> and also from further online consultation with Member States.<sup>3</sup> Comments received were taken into consideration by the Secretariat and incorporated into the present proposed revision (at Annex).
2. The United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, and the United Nations Convention on Psychotropic Substances, 1971, entrust WHO with the responsibility of assessing substances for abuse liability in order to make recommendations on their control under the two aforementioned Conventions.
3. *Abuse liability assessment* is defined as a scientifically guided strategy for developing an objective basis for the regulation of drugs. Appropriate drug regulation is intended to ensure that the medical needs of patients can be addressed without undue or inappropriate limitations to access while also preventing abuse through legal provisions. Abuse liability assessment determines the extent to which a drug has the pharmacological properties predictive of its likelihood to produce abuse and dependence.
4. Abuse liability assessment provides the science base for establishing control that achieves a balance between access and prevention of dependence. The broader goal of all drug abuse control measures is to ensure minimal interference with legitimate medical use while maximizing the control of non-medical use.
5. A request for a review of a substance can be initiated by a notification to the Secretary-General of the United Nations, by a Party to the Conventions or by WHO itself. After completing a review process, WHO forwards recommendations to the Commission on Narcotic Drugs, a functional commission of the United Nations Economic and Social Council. The Commission has the responsibility to decide whether to schedule recommended substances under the provisions of the Conventions.
6. The process and procedures to be followed for the WHO review process are detailed in the *Guidelines for the WHO review of dependence-producing psychoactive substances for international control*, which were first drawn up in 1986.
7. Using the experience of the Expert Committee on Drug Dependence, and following the developments in science, the guidelines were updated in 1990, 1994, 1999 and 2000. Subsequently, a proposal for supplementary guidelines was made at the request of the Expert Committee in order to clarify certain issues, but was rejected by the Executive Board in 2004 and 2005. However, the Board invited the Secretariat and the Expert Committee to develop revised guidelines, resulting in the current proposed revision.
8. This revision should not be considered as final or definitive, but as a reflection of the current state of the art in the science of abuse-liability assessment. Future scientific or other events can or will

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<sup>1</sup> Executive Board, 126th Session, Provisional agenda item 4.18, Document EB126/21

<sup>2</sup> See document EB125/REC/1, summary record of the first meeting, section 5.

<sup>3</sup> Report on the Internet Consultation on Guidance on the WHO review of psychoactive substances for international control: Proposed revision (EB126/6) at [http://www.who.int/medicines/areas/quality\\_safety/ReportInternetConsultation\\_vs091009.pdf](http://www.who.int/medicines/areas/quality_safety/ReportInternetConsultation_vs091009.pdf)

lead to future revision. One such expected development is that of pharmacovigilance techniques as an additional means of assessment.

9. The proposed revision was drafted and discussed in a working group in May 2007. The draft was posted on the Internet for public comment before the meeting. Individuals, nongovernmental organizations and other bodies submitted comments, which were taken into consideration by the working group when discussing the draft.
10. One or more Member States from each WHO region were invited to send a representative to the working group. Several experts from the Expert Advisory Panel on Drug Dependence (Dependence Liability Evaluation) were also invited and the working group finally consisted of six representatives of Member States from four regions<sup>1</sup> and three experts. Six invited observers<sup>2</sup> attended, as well as specialists from the Secretariat.
11. The working group agreed on a draft that was posted on the Internet and opened to public comment. Several comments were submitted and considered by the Secretariat, which then drafted a report and designed a flow chart (see Annex, Appendix 3).
12. It is not expected that this revision will result in the substances currently controlled under the two Conventions being removed from their schedules (“Un-scheduling”). However, the revision will allow for a more precise and scientific assessment in the review of substances in the future.
13. If this proposal is accepted by the Executive Board, the revised Guidelines (see Annex) will become fully effective for application by the Expert Committee in its thirty-fifth and subsequent meetings and during the preparation of these meetings by the Secretariat.

## REVISION OF THE GUIDELINES

14. The *Guidelines for the WHO review of dependence-producing psychoactive substances for international control* and their proposed revision, entitled *Guidelines for the WHO review of psychoactive substances for international control*, provide guidance to the Expert Committee and to the Secretariat.
15. The Expert Committee is composed of members of the Expert Advisory Panel on Drug Dependence (Dependence Liability Evaluation) and of other Expert Advisory Panels in the area of pharmaceutical and medical science. Therefore, there is strong medical, pharmacological and pharmaceutical expertise represented within the group. Legal support is provided by the Secretariat.
16. The role of the Guidelines is to give procedural guidance to the Expert Committee and to operationalize the rules provided by both Conventions and their Commentaries, especially on issues beyond the Experts’ specialization in abuse liability assessment.
17. The Guidelines ensure that the WHO review process is based on scientific and public health-related principles. The current revision provides additional clarity to the process and procedures as a whole. In particular, it includes current best practices for assessing substances for their abuse liability; transparency of the process making use of the Internet; and reporting and publishing

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<sup>1</sup> Australia, Canada, France, India, Switzerland and the United States of America sent representatives. South Africa and the European Community (through the European Monitoring Centre for Drugs and Drug Abuse) were invited but did not attend.

<sup>2</sup> Observers represented the following organizations: the International Narcotics Control Board; the United Nations Office on Drugs and Crime; the White House Office of National Drug Control Policy in the United States of America; the College for Problems of Drug Dependence (the WHO Collaborating Centre for Research and Training in Drug Dependence); and the International Federation of Pharmaceutical Manufacturers & Associations (two observers).

procedures for Expert Committee decisions. It also clearly details the methodology by which the Expert Committee shall arrive at its decision. The process for review and the roles of each player are clearly defined so that the recommendation process proceeds with greater efficiency.

18. The title is changed, with the deletion of “*dependence-producing*”, as that term suggests that it had already been established that the substances under review were dependence-producing.
19. A reference to the preambles of the Conventions has been added to the Guidelines in order to clarify the purpose of the Conventions and of the assessment of substances. Furthermore it is made clear that the provisions in the Conventions regarding changes in the scope of control of substances (i.e. Article 3 of the Single Convention on Narcotic Drugs and Article 2 of the Convention on Psychotropic Substances) govern the drafting of a recommendation for a change of the scheduling of a substance. Furthermore, the new text ensures that the process is grounded in the spirit of the Conventions by referring to their preambles and it makes clear that any evaluation on medical and scientific aspects as mentioned in Articles 2 and 3 includes the need for universal access to essential medicines for medical purposes and considerations of public health. As the evaluation will be performed scientifically, its approach will be evidence-based.
20. Paragraphs 21 to 26 describe how the Secretariat will generate the documents to be considered by the Expert Committee. In the first place, for each substance under critical review it will draft a *critical review report* by collecting and assembling data from relevant sources, including medical literature and abuse studies. Furthermore, a separate *report of additional country-specific data* will be drafted from responses to a questionnaire by the ministers of health and international drug control bodies. Paragraph 24 introduces the principle that the data will be presented in a way that will facilitate the evidence-based assessment by the Expert Committee.
21. The chapters in the critical review report are newly defined in paragraph 23. The order of the topics is adapted to a more logical approach. There are other aspects, not limited to a medical or scientific nature only, but for consideration by the Expert Committee, as pointed out in the Commentary on the Convention on Psychotropic Substances (e.g. paragraph 49 to Article 2, Paragraph 4 of the Convention, or paragraph 19 to Article 2, Paragraphs 5 and 6 of the Convention). The current wording also offers sufficient flexibility to allow for the application of the most advanced science at all times.
22. The report, including an evaluation of the strength of the evidence, will be peer-reviewed by two experts before it is distributed to the entire Expert Committee (paragraph 26). Such peer review is already practised in the Expert Committee on the Selection and Use of Essential Medicines. However, although vital, it has never been a component of the WHO substance review process. The introduction of peer review will add credibility to each report and contribute to guarantee that all medical and scientific content is accurate.
23. Paragraph 36 introduces a confidentiality clause, comparable to the confidentiality clause related to the information provided in the critical review document, with regard to the Expert Committee on Drug Dependence’s deliberations and decisions. This will allow the members of that Expert Committee to provide freely their opinions and for open discussion throughout the meetings. It will also prevent pre-emptive or inaccurate disclosure of the Expert Committee’s recommendations.
24. Paragraph 43 introduces a solution to a previously unsolved problem. In the current version of the Guidelines no guidance was given on how to decide whether a substance should be transferred from one Convention to the other. The proposed text of the revision makes it clear that the same criteria apply as for the assessment of substances that were not previously scheduled, or that were considered for a rescheduling in a different schedule within one Convention. (Previously the more complex Additional Guidelines were proposed to the Executive Board and subsequently rejected twice; see paragraph 7 above.)



25. The principle of scheduling substances that are convertible into scheduled drugs, as provided in paragraph 49 of the Guidelines, under the 1961 Convention stems from the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, which stated that “the term ‘conversion’ shall denote the transformation of a drug by a chemical process, with the exception of alkaloids into their salts” (Article 1, paragraph 4). The Health Assembly decided in resolution WHA7.7 of 14 May 1954 that “a substance will be considered (...) as ‘convertible’ where the ease of conversion and the yield obtained constitute a risk to public health, and that in cases where there is uncertainty as to whether a substance will fall under this definition, the substance will be considered as ‘convertible’ rather than as ‘not convertible’.” When the 1931 Convention was incorporated in the 1961 Convention, resolution WHA7.7 (1954) was declared applicable to the latter Convention as well.<sup>1</sup>
26. Paragraphs 60, and 62 to 64, divided over various chapters, deal with the publication of documents and the communication of recommendations. The different roles of the Expert Committee and the Director-General are clarified. Furthermore, the Guidelines encourage use of the Internet. The authors of reports used in the evaluation process will be acknowledged. The new procedures will contribute to a more transparent assessment process.
27. The flow chart in Appendix 3 gives a comprehensive diagrammatic overview of the pre-review and critical review procedures.

#### **ACTION BY THE EXECUTIVE BOARD**

28. The Board is invited to adopt the proposed revision entitled “Guidelines for the WHO review of psychoactive substances for international control”.

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<sup>1</sup> Commentary on the Single Convention on Narcotic Drugs, paragraph 12 referring to Article 3, paragraph 3, subparagraph (iii).

# SUMMARY RECORD FROM THE EXECUTIVE BOARD

## TWELFTH MEETING

Friday, 22 January 2010, at 18:15

Chairman: Dr S. ZARAMBA (Uganda)

### 1. TECHNICAL AND HEALTH MATTERS: Item 4 of the Agenda (continued)

#### **Guidance on the WHO review of psychoactive substances for international control: proposed revision:** Item 4.18 of the Agenda (Document EB126/21)

The CHAIRMAN said that, in May 2009, the Board had postponed discussion on the matter in order to implement a consultation process with Member States on the proposed revisions to the Guidelines.<sup>1</sup> The proposed amendments to the Guidelines were included as an annex to the report and he invited further comments.

Mr OULD ABDI SALEM (adviser to Dr Ould Horma, Mauritania), speaking on behalf of the Member States of the African Region, thanked the Secretariat for the report. The purpose of the review was to consolidate international recommendations on pharmacodependence and clarify the WHO review process, ensuring that it was based on scientific and public health-related principles. The proposed amendments to the Guidelines, prepared by a group comprising six Member States from four regions and three experts, suggested the use of current good practices for assessing the abuse liability of substances, the use of the Internet to improve the transparency of the process, and the reporting and publishing of the Expert Committee's procedures. He supported the proposed amendments.

Dr KÖKÉNY (Hungary), speaking on behalf of the European Union, expressed appreciation for the work carried out by Member States, the Expert Committee on Drug Dependence, the Expert Advisory Panel on Drug Dependence, and other experts and proposed the following amendments to the wording of paragraph 23: subparagraph 23(5) should be separated into two points so that subparagraph 23(5) read "toxicology", and a new subparagraph 23(6) would read "adverse reactions in humans"; in subparagraph 23(8) "and epidemiology of medical use" should be added to the end of the sentence; and in subparagraph 23(12) the words "of medical and" should be deleted so that the phrase read "epidemiology of non-medical use, abuse and dependence".

Ms ROCHE (New Zealand) proposed the following amendment: in paragraph 45 the phrase "Any proposal for a change in the existing status of the substance should be made only if specific new control measures are necessary ..." should be changed to "Any proposal to move a substance from one convention to another should be made only if specific new control measures are necessary ..." with the paragraph then continuing unchanged.

Ms BLACKWOOD (United States of America)<sup>2</sup> reported that her country had submitted comments to the online discussion and emphasized that the modifications had improved the review guidelines, allowing for a more precise and scientific assessment in the review of substances.

The steps in the control process for substances with narcotic abuse potential was the responsibility of multiple organizations and bodies, including the International Narcotics Control

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<sup>1</sup> See document EB125/2009/REC/1, summary record of the first meeting, section 5.

<sup>2</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Board, the Commission on Narcotic Drugs and WHO. Decisions relating to drug scheduling should be made based on several factors, including the abuse potential and the drug's availability for medical and scientific use.

She proposed the following amendments: the sixth line of paragraph 4 should be changed to read "including the risk of abuse and the need to ensure medical availability, as well as the relevant resolutions ..."; and in paragraph 45, "universal access to essential medicines for" should be deleted, so the last line would read "and will not unduly limit availability for medical and scientific purposes."

In addition, she commented that the phrase "essential medicines" should not be used in guidelines for narcotic drugs scheduling as the term had a specific meaning to WHO and the list of essential medicines was not reviewed by the Expert Committee. The term "universal access" could also cause confusion, as it did not appear in either the Single Convention on Narcotic Drugs, 1961 or the 1971 Convention on Psychotropic Substances.

Dr DAHL-REGIS (Bahamas), in response to the CHAIRMAN's request for support for the amendments proposed by the representative of the United States of America, offered her support, and emphasized the importance of the removal of the term "essential medicines".

Dr ETIENNE (Assistant Director-General) expressed her appreciation for the contributions of the Member States on the issue. It was essential that the medical needs of patients who use psychoactive drugs were addressed without limiting access, while addressing the dependency and abuse potentials of those drugs. She had noted the proposed amendments; the changes would be implemented accordingly.

**The Board approved the revised guidelines on the WHO review of psychoactive substances for international control, as amended.<sup>1</sup>**

(...)

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<sup>1</sup> See EB126/2010/REC/1, Annex 6

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