



WORLD HEALTH ORGANIZATION

EXECUTIVE BOARD
105th Session
Provisional agenda item 5

EB105/16
5 November 1999

Collaboration within the United Nations system and with other intergovernmental organizations

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

Report by the Secretariat

1. Both the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971, assign to WHO the obligation to review dependence-producing psychoactive substances, and to make recommendations to the United Nations concerning the need for, and appropriate levels of, international control for these substances. In the light of experience gained over the years, and following the guidance of the Executive Board, WHO developed a procedure for this review in 1986, which was revised and adopted by the Board at its eighty-fifth session in 1990.
2. At its 103rd session in 1999, the Board, recognizing the need to update the guidelines and, in particular, to clarify the roles of the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, and the Convention on Psychotropic Substances, 1971, requested the Director-General to review and revise the guidelines as necessary, for adoption by the Board at a future session.¹
3. In response to this request, a working group was convened in September 1999, to review and revise the guidelines. The draft revised guidelines, based on the outcome of the working group, are contained in the Annex to the present report.²
4. The new guidelines will set the principles and procedures that WHO should apply in reviewing dependence-producing psychoactive substances for international control in the future, beginning with the 32nd meeting of the WHO Expert Committee on Drug Dependence (June 2000). Implementation of the new guidelines will call for further strengthening of coordination with the Secretariat of the International Narcotics Control Board, as described below.
5. The following paragraphs indicate major changes from the previous guidelines.
6. **Clarification of the roles of different conventions.** The roles of the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988, and the

¹ Decision EB103(5).

² Texts of existing conventions and resolution 1(S-VIII) of the United Nations Commission on Narcotic Drugs are available on request.

Convention on Psychotropic Substances, 1971, have been clarified, recognizing that the control measures required under the two Conventions may partially overlap in certain situations. Although WHO is not given any formal role to play in implementation of the 1988 Convention, practical guidance is provided with a view to avoiding unnecessary duplication of controls. Similar guidance is given with regard to the relationship between the 1988 Convention and the Single Convention on Narcotic Drugs, 1961. The successful application of this new procedure will require further strengthening of coordination between WHO and the International Narcotics Control Board, which is given the mandate to formulate scheduling recommendations with regard, under the 1988 Convention, to chemicals frequently used in the illicit manufacture of narcotic drugs and psychotropic substances.

7. **Rationalization of the structure.** The structure of the previous guidelines has been maintained except where specific problems were identified. For example, the order of Section IV and several others was unsystematic and information on single topics was presented in a confusing manner in different sections. These sections have therefore been rearranged as subsections under “WHO review procedure” in the order of the actual sequence of events.

8. **Clarification of the function of the Expert Committee on Drug Dependence and that of the WHO Secretariat.** There was no clear distinction between the function of the Expert Committee on Drug Dependence and that of the WHO Secretariat. This has been clarified wherever there was ambiguity.

9. **Unification of the scheduling criteria.** Scheduling criteria were given in different sections in the previous guidelines. The new guidelines set out comprehensive and consolidated information on scheduling under the subsection “Assessment for scheduling by the Expert Committee”. They also clarify that there is only one set of scheduling criteria, but different judgement criteria should apply to pre-review (whether or not WHO has information that may justify the scheduling of the substance) and to critical review (whether or not the scheduling criteria are indeed met).

10. **Updating to incorporate recent decisions and recommendations.** Decisions of the Board on partial modification of the previous guidelines¹ and a recommendation of the Expert Committee on how to interpret the scheduling criteria² have been incorporated into the relevant sections.

11. **Clarification concerning the publication of documents.** Ambiguous statements in the previous guidelines with regard to transparency and disclosure of information have been changed to clarify the scope of information to be disclosed to the general public and the discussion documents to be shared only with the parties directly concerned.

ACTION BY THE EXECUTIVE BOARD

12. The Board may wish to adopt the following draft decision:

The Executive Board, having considered the report on collaboration within the United Nations system and with other intergovernmental organizations,³ approved the guidelines for the WHO review of dependence-producing psychoactive substances for international control.

¹ Decisions EB93(16) and EB103(5).

² WHO Technical Report Series, No. 856, 1995.

³ Document EB105/16.

ANNEX

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

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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,¹ WHO developed a procedure for the evaluation and assessment of narcotic and psychotropic substances for decisions on international control in consultation with CND in 1986,² which was revised in 1990.³ Amendments and decisions subsequently adopted by the Executive Board in 1994⁴ and 1999⁵ 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 for the Expert Committee on Drug Dependence and its advice to the Director-General.

¹ Resolution EB73.R11.

² Decision EB77(3).

³ Decision EB85(10).

⁴ Decision EB93(16).

⁵ 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.¹ 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.²

7. The basis for the scheduling recommendation made by WHO is an evaluation as to 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.³

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 only be made 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

¹ 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.

² 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.

³ 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).

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.

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 transmitted in reasonable time for information and comments to those invited to participate in the Expert Committee, including relevant nongovernmental organizations in official relations with WHO, before its assessment by the Expert Committee.

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.

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 may also be 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.¹

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

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

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 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 of 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 following principles: (1) 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; (2) a proposal for a change in the existing status of the substance should be made only if new control measures are likely to decrease the extent or likelihood of abuse or the use of the substance in illicit drug manufacturing, but 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:¹

- (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);

¹ *Commentary on the Convention on Psychotropic Substances*. New York, United Nations, 1976.

(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.¹ 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:

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:²

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.

¹ WHO Technical Report Series, No. 437, 1970.

² WHO Technical Report Series, No. 856, 1995.

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 following principles: (1) 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; (2) a proposal for a change in the existing status of the substance should be made only if new control measures are likely to decrease the extent or likelihood of abuse, but 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 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.

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.¹

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 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.
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.

¹ Resolution WHA35.10.

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.

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