33925

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

EB85/23

24 November 1989

EXECUTIVE BOARD

Eighty-fifth Session

Provisional agenda item 19

ACTION IN RESPECT OF INTERNATIONAL CONVENTIONS ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

Report by the Director-General

This report describes the action taken by WHO during 1989 in compliance with the statutory obligations assigned to it by the international drug control treaties. It also gives a brief account of other WHO activities to promote the rational use of psychoactive drugs. A revised version of the WHO guidelines for review of psychoactive drugs for international control is annexed to the report.

At its thirty-third session, the United Nations Commission on Narcotic Drugs unanimously approved WHO's recommendations on buprenorphine, pemoline,, pyrovalerone, propylhexedrine and two sets of exemptions granted by the United States of America and Thailand.

The Director-General, taking into account the advice of the Expert Committee on Drug Dependence, as contained in its twenty-sixth report, made recommendations to the Secretary-General of the United Nations to place midazolam in Schedule IV of the 1971 Convention, six analogues of fentanyl in Schedules I and IV of the 1961 Convention and three analogues of MDA and aminorex in Schedule I of the 1971 Convention, and to transfer dronabinol, an isomer of delta-9-tetrahydrocannabinol, from Schedule I to Schedule II of the 1971 Convention. These recommendations by WHO will be debated at the forthcoming session of the Commission in Vienna in February 1990.

I. INTRODUCTION

1. This report describes the activities undertaken during 1989 in compliance with WHO's statutory obligations under the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (hereinafter referred to as the Single Convention) and the Convention on Psychotropic Substances, 1971. The previous report on this subject was submitted by the Director-General to the Executive Board at its eighty-third session.[1]

[1] Document EB83/8 (1988).

II. COLLABORATION WITH THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

2. Taking into account the advice of the WHO Expert Committee on Drug Dependence, as contained in its twenty-fifth report,[1] the Director-General in 1988 made the following recommendations to the Secretary-General of the United Nations:

Recommendations for scheduling

(1) Buprenorphine to be placed in Schedule III of the 1971 Convention.

(2) Pemoline to be placed in Schedule IV of the 1971 Convention.

Recommendations for descheduling

(3) Propylhexedrine and pyrovalerone:

The Expert Committee reviewed data following a notification to the Secretary-General by the United States of America to delete these two substances from Schedule IV of the 1971 Convention. The Committee recommended the postponement of consideration of the notification for descheduling propylhexedrine. It also recommended that pyrovalerone should not be descheduled and should therefore remain in Schedule IV.

Exemptions under provision of Article 3 of the 1971 Convention

(4) Exemptions granted by the United States of America:

(i) Vicks inhaler, a combination product containing levo-metamphetamine, in combination with other substances, had been exempted from certain control measures.

(ii) Benzedrex inhaler and Dristan inhaler, both of which have propylhexedrine as an active substance in combination with other substances, had been exempted from certain control measures.

(5) Exemptions granted by Thailand:

Notification was received concerning seven exempted preparations containing phenobarbital, a substance controlled under Schedule IV of the 1971 Convention.

In the absence of any objection to these exemptions, the Director-General of WHO recommended to the Secretary-General of the United Nations that no further action was required.

3. The thirty-third session of the United Nations Commission on Narcotic Drugs (Vienna, 6-17 February 1989) unanimously approved all the recommendations made by WHO.

4. The Commission also approved a resolution on "Intensification and coordination of measures for demand reduction". In another resolution on "Supply of and demand for opiates for medical and scientific purposes", the Commission requested the International Narcotics Control Board to assess legitimate needs for opiates in various regions of the world hitherto unmet because of insufficient health care, a difficult economic situation or other conditions. Following a request from the Board, WHO is collaborating with that body in preparing a report on the subject.

---

[1] WHO Technical Report Series, No. 775, 1989.

III. EXPERT COMMITTEE ON DRUG DEPENDENCE, TWENTY-SIXTH REPORT[1]

5. The Committee, which met from 17 to 22 April 1989, reviewed 14 single substances, including four benzodiazepines (brotizolam, etizolam, midazolam and quazepam), nine analogues of controlled substances (designer drugs), and delta-9-tetrahydrocannabinol.

6. The Committee recommended that midazolam be placed in Schedule IV of the 1971 Convention, that six analogues of fentanyl be placed in Schedules I and IV of the Single Convention, and that the other three analogues (two MDA analogues and an analogue of aminorex) be placed in Schedule I of the 1971 Convention. The Committee considered a request from the Government of the United States of America that delta-9-tetrahydrocannabinol, which is presently in Schedule I of the 1971 Convention, should be transferred to Schedule II of the same Convention. It recommended to the Director-General that only dronabinol, an isomer of delta-9-tetrahydrocannabinol, should be transferred.

7. The Director-General of WHO, in accordance with the Committee's recommendation in relation to the 11 substances, as contained in its twenty-sixth report, addressed a note verbale to the Secretary-General of the United Nations to this effect. It will be debated by the eleventh special session of the United Nations Commission on Narcotic Drugs (Vienna, 29 January to 2 February 1990).

IV. OTHER ACTIVITIES UNDERTAKEN DURING THE YEAR UNDER REVIEW

Promoting the rational use of psychoactive drugs

8. WHO's activities in this area have been developed in response to resolution EB69.R9 (1982) which requested the Director-General "to intensify efforts aimed at improving prescription, delivery and utilization practices regarding psychoactive drugs, through educational programmes for physicians and other health workers ...".

9. The WHO publication Psychoactive drugs: improving prescribing practices[2] has been translated into Arabic, Croatian and Italian.

10. In Yugoslavia, a second biennial national meeting was held on the topic "Advances in pharmacotherapy" (Portorož, 18-20 September 1989), with a special session devoted to the rational use of psychoactive drugs. About 560 pharmacists and physicians participated.

11. WHO collaborated with the Ministry of Public Health of China, the School of Pharmacy of West China University in Chengdu and the National Institute on Drug Dependence, Beijing Medical University in organizing a national seminar on "The role of pharmacy in the rational use of psychoactive drugs" (Chengdu, 12-16 December 1988). It was attended by 30 participants from 18 schools of pharmacy in China as well as four experts from abroad. The report of the meeting is being published.

12. An international meeting was convened in Pakistan on "The role of nursing/midwifery education in the rational use of psychoactive drugs" (Islamabad, 7-11 August 1989). It was attended by 41 participants from 10 countries, the International Council of Nurses, the International Council on Alcohol and Addictions and the International Narcotics Control Board. The report of the meeting[3] is available.

---

[1] WHO Technical Report Series, No. 787, 1989.

[2] Ghodse, H. & Khan, I., ed. Psychoactive drugs: improving prescribing practices. Geneva, World Health Organization, 1988.

[3] Document DMP/PND/89.5 (1989).

13. WHO collaborated in the development of a comprehensive drug control programme in West Africa with UNFDAC, which is implementing a master plan drawn up by representatives of 12 countries at a meeting convened for this purpose (Padova, Italy, 31 October to 5 November 1988).

14. WHO also collaborated with the USSR Ministry of Health and UNFDAC in the organization of a seminar on "The control of narcotic drugs and psychotropic substances at different levels as a preventive measure in illicit traffic" (Moscow, 2-11 October 1989). It was attended by 42 participants from 16 developing countries in all WHO regions. The main emphasis was on the reduction in demand, but papers on illicit traffic were also presented. Three earlier travelling seminars, organized by the USSR Ministry of Health and WHO in 1978, 1979 and 1981, had dealt with the question of the safe use of psychotropic and narcotic drugs, on which a report was issued in 1984.[1]

Revised guidelines for WHO review of psychoactive substances for international control

15. The Convention on Psychotropic Substances, 1971, came into force in August 1976, having been ratified by 40 countries. WHO was entrusted with the responsibility to review psychotropic substances and to make recommendations concerning international control. In the early 1980s, WHO developed an administratively formalized review procedure,[2] characterized by openness and transparency. The review procedure calls for the preparation by WHO of a Critical Review Document, containing available data on individual substances, for use by the Expert Committee on Drug Dependence. A Programme Planning Working Group was set up to assist in organizing the work involved in the review process. During this period a number of whole classes of substances as well as individually identified substances (primarily psychotropic substances, but also narcotic drugs) were reviewed and assessed by the Expert Committee. A paper has been prepared on WHO's activities in this field since the 1971 Convention came into force.[3] Approximately 200 substances were reviewed during this period.

16. Experience gained over the years has shown that this complex review procedure can be simplified. A revised procedure has therefore been drafted and is annexed to this report.

---

[1] Ministry of Health of the USSR/World Health Organization. The safe use of psychotropic and narcotic drugs. Moscow, 1984.

[2] See document EB77/1986/REC/1, Annex 9 (1986) for original guidelines.

[3] Document DMP/PND/88.3 (1988).

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

CONTENTS

I. MANDATE

1. 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, as amended by the 1972 Protocol (referred to below as "the Single Convention"), and the Convention on Psychotropic Substances, 1971 (referred to below as "the Psychotropic Convention"). A procedure for this assessment has been developed pursuant to resolutions of the World Health Assembly and the United Nations Commission on Narcotic Drugs (CND).[1] This paper sets out guidelines dealing with the underlying principles of the review procedure, the working arrangements within the Secretariat as well as with external agencies, the nature of the documentation to be prepared and the time schedules for the different activities. 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.

2. The Thirty-third World Health Assembly,[2] by resolution WHA33.27, 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 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. WHO, in the light of experience gained over later years and following an Executive Board decision in January 1990, has adopted a revised procedure for the evaluation and assessment of narcotic and psychotropic substances for decisions on international control. According to this procedure, the WHO Secretariat is assisted by the Expert Committee on Drug Dependence (ECDD).[3]

II. UNDERLYING PRINCIPLES

4. The WHO review procedure is made known through administrative decisions and formalized in its main parts. The review is carried out under the guidance of the Secretariat, and results in recommendations by WHO for international control formulated on the basis of advice from the Expert Committee.

5. The procedure utilizes relevant scientific knowledge, systematically collected and screened through continuing WHO collaboration with scientific institutions, industrial laboratories, health services and regulatory agencies, government health and law enforcement authorities, and relevant international agencies. Research and development information and expertise from the industry are fully reflected.

6. In the course of the procedure, the relevant scientific information is collected, analysed and compiled for each psychoactive substance recommended for control. This material is the basis for the advice by the Expert Committee to the Director-General and summaries of it will be transmitted in English, French and Spanish with his recommendation to the Secretary-General, for distribution to the governments in good time prior to the decision on international control by the CND.

---

[1] The Commission on Narcotic Drugs is a functional Commission of the United Nations Economic and Social Council. It is the central policy-making body of the United Nations system in respect of narcotic drugs and psychotropic substances. Decisions concerning the international control of substances are taken by the Commission.

[2] Document WHA33/1980/REC/1, p. 27.

[3] The First World Health Assembly decided, by resolution WHA1.25 (WHO Official Records, No. 13, 1948, p. 309), to establish the Expert Committee on Habit-Forming Drugs, which later came to be called the Expert Committee on Drug Dependence.

7. The procedure has been designed to give ample time for governments to study the WHO recommendations and their justification prior to the session of the Commission and for the collection and evaluation of information on legal, administrative, social and economic factors whenever required.

8. Consistent with the principles of openness and transparency and of providing information and opportunity for comment to all parties concerned, the information collected is generally made available for publication, particularly information contained in the report of the Expert Committee. However, questions of confidentiality must be considered.

III. PROVISIONS OF THE CONVENTIONS

9. The international drug control conventions entrust WHO with the responsibility to review and make an assessment of 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 by a State Party to the Conventions or by WHO.[1] The assessment by WHO is forwarded to the CND which has the responsibility of taking the final decision concerning the international control of a psychoactive substance under the provisions of the treaties.[2]

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

11. Under the provisions of Article 3 of the Psychotropic Convention, a Party may, if certain conditions are met, exempt preparations containing psychotropic substances from specific control measures. 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

---

[1] The Director-General represents WHO, in accordance with decisions of the World Health Assembly, for the purpose of receiving notifications under the international drug control treaties and of making recommendations concerning the international control of psychoactive substances under those treaties on the basis of recommendations and advice provided to him as described in these Guidelines.

[2] The scheduling process is covered by the provisions of Article 3 of the Single Convention and Articles 2 and 17.2 of the Convention on Psychotropic Substances. The scheduling process is described in detail in the Commentaries on the Single Convention and the Convention on Psychotropic Substances, published by the Secretary-General of the United Nations. The process is also described in more general terms in Rexed, B. et al. Guidelines for the control of narcotic and psychotropic substances in the context of the international treaties. Geneva, World Health Organization, 1984.

of this provision of exemption of the 1971 Convention by applying specific guidelines that have been approved by the CND.[1]

12. Under the provisions of the Single 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 by an amendment of the Convention, and relevant proposals are reviewed by WHO in the same way as single substances.

IV. WHO REVIEW PROCEDURE

13. The WHO review of dependence-producing psychoactive substances for international control includes a number of stages: (1) initiation of the review; (2) selection for a complete, documented Critical Review; (3) notification on a problem of extreme urgency; (4) preparation of the Critical Review Document (see Chapter V).

14. (1) A review will be initiated in any of the following cases:

(i) There is a notification from a Party.

(ii) There is a request from the CND.

(iii) Information is brought to WHO's attention that the substance may fulfil the criteria for inclusion in either of the two international drug treaties.

(iv) An abuse problem of extreme urgency has arisen.

(2) The following criteria apply with respect to the selection of a substance for a complete, documented Critical Review:

(i) Substances are immediately evaluated for a Critical Review if they have been notified by a Party or their review has been requested by the Commission;

(ii) When WHO has information that may justify the scheduling of a substance, the selection can be done according to <u>two alternative principles</u>, both of which are reflected in the Conventions:

(a) The first principle is that of <u>similarity</u>; selection based only on "similarity" is used for substances similar to those listed in Schedule IV of the Single Convention or Schedule I of the Psychotropic Convention (this would be the alternative for analogues of controlled substances, the so-called "designer drugs").

(b) The second principle is to examine a substance according to <u>its pharmacological characteristics and the occurrence of public health and social problems</u>. This is the main method used for WHO's own initiation of a Critical Review, and it should not be used in the case of laboratory substances.[2] For a substance to be selected, there should be some evidence that it will fulfil both of the following criteria:

---

[1] The specific WHO procedures for review of exempted preparations in accordance with the Commission guidelines are set forth in United Nations document E/1984/13 (E/CN.7/1984/13). The guidelines on exemption adopted by the Commission are largely based on recommendations which were made by WHO and are set forth in the Commission's resolution 1(S-VIII). See United Nations document E/CN.7/1984/13 (1984), pp. 43-44.

[2] A laboratory substance here means a substance under study for therapeutic use in the laboratory of an industry or in another established scientific institution.

(a) it is a psychoactive substance that presents a risk of dependence production; and

(b) it causes significant public health and social problems in more than one country.

(3) If a government notifies an abuse problem of extreme urgency requiring immediate international action, the Secretariat will summarily evaluate the existing evidence for the next Expert Committee meeting, when appropriate action could be taken.

V. PREPARATION OF THE CRITICAL REVIEW DOCUMENT

15. The Critical Review Document is a summary compiled by the WHO Secretariat, for use by the Expert Committee in assessing available data on individual substances. The basis for "a critical review" of each substance are data on its pharmacological properties, and clinical, public health and epidemiological data concerning its use and abuse.

16. The WHO Secretariat collects and assembles data on the substances selected for review, sending a questionnaire to ministers of health of Member countries and to other relevant collaborating information sources, and prepares the Critical Review Document. In carrying out the Critical Review, the Secretariat, with the assistance of consultants, identifies, collates and analyses data from the various sources described in paras 31-43 under the heading "Information collection" as a basis for the evaluation of the substances under review. Studies will as far as possible include the activities of the manufacturing industry. Clinical studies on the testing and on the use and abuse of psychoactive substances are also taken into consideration. The resulting information material, reports and reviews are studied and analysed by consultants or by ad hoc working groups to help provide a critical and balanced evaluation.

17. The Critical Review Document is sent for information to institutions and organizations which have directly collaborated in its preparation, such as international narcotics control organs and relevant intergovernmental organizations and nongovernmental organizations in official relations with WHO. To help ensure that all material presented to the Expert Committee is up to date, the Secretary to the Committee will circulate the agenda of the next meeting to those collaborating information sources.

18. As to the formulation of the Critical Review Document, the data for each substance will, where feasible, be organized 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 man

(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. The information under each heading, with salient references, 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. Indeed, the production of data in such circumstances may not be justifiable on ethical grounds. Likewise, extensive epidemiological data may not be available. In such instances, the Expert Committee would need to provide full justification for reaching conclusions on incomplete (e.g., preclinical) data.

21. The confidentiality of any inforamtion received by WHO for use in the review will be respected to the maximum extent possible. In preparing the Critical Review Document, the Secretariat will ensure that confidential information is either screened so as to avoid disclosure or, if appropriate, rearranged so as to protect the source. Subject to the need for certain information to remain confidential as provided above, appropriate arrangements will be made to provide access to the information used to prepare the Critical Review by relevant collaborating information sources as defined in paragraph 17.

VI. WHO REVIEW OF EXEMPTED PREPARATIONS

22. The Psychotropic Convention, as stated in Article 3, permits a Party to exempt 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 being abused.

23. If a Party, or WHO, has information that, in its opinion, may require the termination of such an exemption, it notifies the Secretary-General of the United Nations, and WHO communicates to the CND an assessment of the preparation and any relevant recommendations.[1]

24. The extent to which an assessment is carried out is guided by the following principles:

A. Where the preparation is for domestic use only

A.1. 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 immediate WHO evaluation and will keep it for study at a later date.

A.2. If WHO has received evidence of national abuse, the exemption is evaluated by WHO, and any resulting recommendation(s) as to change or termination of the exemption is brought to the attention of the Party.

A.3. If WHO has received 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 WHO, and any resulting recommendation(s) as to change or termination of the exemption are communicated by the Director-General to the country of origin of the preparation, or if the abuse problems are widespread, to the Secretary-General of the United Nations.

---

[1] In its assessment, WHO takes into account the guidelines of the Commission on Narcotic Drugs as set forth in its resolutions 2(S-VI), 1(S-VIII) and 3(S-IX).

B. Where the preparation is being exported outside the exempting country

An assessment is carried out in all cases, and appropriate recommendations are communicated to the Secretary-General at the United Nations unless both of the following conditions are met:

(i) The exemption appears to be in conformity with the requirements of Article 3, paragraph 2, of the Convention (concerning abuse liability and recoverability of the psychotropic substance(s) as well as with resolution 1(S-VIII) of the CND (see Appendix 5); and

(ii) WHO has not received evidence that the preparation may constitute a public health and social problem to an importing country or to a country where it is illictly traded.

VII. ASSESSMENT FOR SCHEDULING BY THE EXPERT COMMITTEE ON DRUG DEPENDENCE AND RECOMMENDATIONS FOR INTERNATIONAL CONTROL

25. The evaluation and assessment of a substance for a recommendation on its scheduling (its level of control) is described in detail only in the Psychotropic Convention, since the Single Convention evaluates the need for control of a substance only by reference to its similarity to other drugs, already controlled under that Convention.

26. The relevant provision of the Psychotropic Convention, Article 2, para. 4(b), spells out the following considerations to be taken into account in such an evaluation (page and paragraph references refer to the Commentary on the Psychotropic Convention):[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, para. 41).

(ii) "... extent and 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 53, para. 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, para. 5 ..." (page 59, para. 43).

(iv) "... the degree of usefulness of the substance in medical therapy ... [means] not only its potential beneficial effects, its value in the case of grave medical indications and the extent and frequency of its employment, but also the intensity of its dangerous properties ... and other harmful side-effects may have to be taken into account. ..." (page 60, para. 44).

(v) "... together with recommendations of 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, para. 49).

---

[1] Commentary on the Convention on Psychotropic Substances. New York, United Nations, 1976 (E/CN.7/589).

27. 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."

28. If the Expert Committee finds that a substance fulfils the conditions for control, or that the exemption of a preparation should be terminated, the Committee will advise the Director-General to communicate a recommendation for appropriate international control to the Secretary-General.

VIII. COMMUNICATION OF WHO RECOMMENDATIONS FOR INTERNATIONAL CONTROL BY THE DIRECTOR-GENERAL TO THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

29. Both the international drug control conventions state that WHO, after finalizing its evaluation of a dependence-producing substance, should communicate its assessment (finding) to the CND.

30. No specific organ of WHO is mentioned in the Conventions. In May 1954 the Seventh World Health Assembly, by resolution WHA7.6, decided that decisions as to classification of substances under specified international agreements should be taken by the Director-General "upon receipt of the appropriate expert advice".[2]

The Commentaries deal with this situation in the following manner:

(i) The Commentary on the Single Convention:[3]

"It is left to the WHO to determine which of its organs should exercise the functions with which it is entrusted under the Single Convention. At the time of this writing it is the Director-General. He may act on the advice of such bodies or experts as he chooses to consult. As a rule he acts at present on the recommendation of the WHO Expert Committee on Drug Dependence". (Page 85, para. 2).

(ii) The Commentary on the Psychotropic Convention:[4]

"Which organ of the WHO is entitled to act for that Organization under Article 2 or other provisions of the Vienna Convention is to be determined by that Organization in accordance with its own constitutional provisions". (Page 33, para. 12).

---

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

[2] WHO Official Documents, No. 55, 1954, p. 19.

[3] Commentary on the Single Convention on Narcotic Drugs, 1961. United Nations Publication, New York, 1973.

[4] Commentary on the Convention on Psychotropic Substances. New York, United Nations, 1976.

IX. INFORMATION COLLECTION

WHO programmes

31. The review of dependence-producing substances aims at assessing the degree of usefulness of a substance in medical therapy and the degree of seriousness of any public health and social problem as a prerequisite to making recommendations concerning international control. WHO's responsibilities under the international drug control treaties are currently a part of its Programme on Drug Management and Policies.

32. Other parts of this programme are concerned with the collection and analysis of data related to the general acceptability of psychoactive substances at the time of registration at national level, to adverse drug reactions in general and potential dependence of psychoactive substances in particular, and to dependence-producing properties of herbal remedies; with educational efforts to enable members of health teams to use psychoactive drugs more rationally; and with measures to ensure wide use of knowledge acquired in the WHO review process.

33. WHO's Programme on Mental Health obtains data through projects dealing with the management of drug dependence, and through work in the epidemiology of drug use and abuse, in the treatment of neurological and psychiatric disorders, and in mental health aspects of health care.

34. Other programmes of the Organization in which the use of narcotic and psychotropic substances is an important concern are also involved in the review procedure. Collaboration with other programmes should, for example, help to identify consultants and members of ad hoc working groups for participation in the WHO review.

Nongovernmental organizations

35. Nongovernmental organizations in official relations with WHO, representing, for instance, associations of drug manufacturers, consumers, health workers, etc., provide relevant information which is very useful in view of the wide spectrum of issues which have a bearing on the need to make psychoactive substances available for therapeutic purposes whilst at the same time preventing their misuse or abuse.

WHO regional offices

36. Through their contacts with national health authorities, WHO regional offices can obtain reports on governments' plans and programmes, identify types of drugs of abuse warranting international control, and call attention to possible formal notifications in appropriate cases. They may have regular contacts with regional drug control organizations to obtain scientific and other information. Through collaborating centres, country contacts and links with nongovernmental organizations, they can obtain information about new developments in psychopharmacology and results of epidemiological and other studies of relevance to the review procedure. Furthermore, through contacts with national drug regulatory agencies, the regional offices can obtain lists of registered drugs, information about changes in the control of individual drugs and results of clinical trials.

WHO collaborating centres

37. WHO collaborating centres can initiate studies and provide data for the screening process. They are also in a position to coordinate national contributions to the review procedure. Their investigations involve basic and clinical research and the epidemiology of use and abuse of drugs. Each collaborating centre evolves a work plan in cooperation with WHO, in which activities relevant to the WHO review can be clearly identified. The Committee on Problems of Drug Dependence (CPDD), Washington D.C., USA, collaborates in drug testing and information collection.

National health authorities

38. Scientific data produced within health services in Member countries are utilized in the WHO review. The clinical evidence on the dependence-producing capacity of a psychoactive substance is an important part of WHO's evaluation. The clinical trials of psychoactive substances before registration generate important data. Epidemiological studies of drug use and abuse help define the balance between therapeutic usefulness and damage liability in the context of public health and social problems. While evidence of many of these aspects is obtained from the current scientific literature, direct communication with the national drug regulatory agencies is useful. As part of their routine performance of drug authorization procedures, national drug regulatory agencies monitor reports of abuse and misuse of registered medicinal products, and national health authorities are also responsible for monitoring the health consequences of illicit use of psychoactive substances. The information provided by these national authorities in relation to the identification of such substances, and the control measures applied, is therefore of importance to the WHO selection and review procedures.

United Nations Division of Narcotic Drugs

39. The Division of Narcotic Drugs (DND) functions under the direct authority of the Secretary-General of the United Nations. It acts as the secretariat to the CND and performs the functions entrusted to the Secretary-General under the international drug control treaties. It collects, analyses and reviews developments in national drug control activities, illegal drug traffic and drug abuse on the basis of reports from governments.

40. Documents issued by the Division are also concerned with special information on illicit drug traffic and drug abuse collected from governments, pursuant to requests from the Director-General of WHO, for a forthcoming evaluation of a psychoactive substance for possible international control. The reports to the Division from governments on the national drug abuse situation usually originate from national health authorities, which generally rely on local clinical and epidemiological investigations. The International Drug Abuse Assessment System (IDAAS), instituted by the CND, will be an important epidemiological tool.

Other sources

41. Data on illicit traffic and concurrent drug abuse occurring in different contexts are systematically collected for utilization in the review procedure. The International Criminal Police Organization (ICPO/Interpol) is an important collaborating agency in this respect in that its secretariat produces reports concerning international illicit drug trafficking based on information from its member States. Regional and national organizations, which have, for example, both operational and regulatory responsibilities and which assemble and analyse data from large populations, are also requested to transmit relevant information for the WHO review.

42. Other important information, available, for instance, through literature searches, is produced by research conducted in universities and other scientific institutions, during operations of the biochemical and pharmaceutical industry, and in the clinical work of health services and their laboratories. The secretariat maintains contact with these entities; in particular, it contacts known producers of substances selected for review in order to obtain the maximum of relevant information.

43. Material from international congresses and symposia may be especially useful in helping to recognize new trends in psychopharmacology, to facilitate the collection of general information about psychoactive substances, and to identify scientists who might assist in the review procedure.

X. EXPERT COMMITTEE ON DRUG DEPENDENCE

Membership

44. The Expert Committee usually has a membership of ten, chosen by the Director-General from WHO expert advisory panels. The experts are known for their integrity and scientific eminence, and the composition of the Expert Committee reflects equitable geographical representation. The expert advisory panels make up fairly large groups whose members are chosen in advance with a view to collaboration with WHO, and come from all WHO regions, and from industrialized and developing countries. WHO at present has four expert advisory panels with directly relevant specialization: those on drug dependence and alcohol problems, on mental health, on neurosciences and on drug evaluation. The register of the panels is open for study by the WHO Executive Board.

Secretariat

45. The Expert Committee is assisted by a secretariat, composed of a secretary and of 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. Consultants and temporary advisers may, as appropriate, be chosen from regional offices and collaborating centres.

Other organizations

46. Representatives of the DND, the International Narcotics Control Board and ICPO/Interpol are invited to attend meetings of the Expert Committee. Representatives of relevant nongovernmental organizations in official relations with WHO may also be invited.

Information meeting

47. Before the start of the Expert Committee's meeting, other representatives of nongovernmental organizations, mentioned in paragraph 35, may be invited to have a meeting with the members of the Committee to present additional information concerning the reviewed substances and to clarify written submissions. Such requests should be submitted at least a week before the start of the Expert Committee's meeting and should be accompanied by reasons for the request and the relevant new information to be submitted. Representatives of the DND, the International Narcotics Control Board and ICPO/Interpol are also invited to this information meeting.

Procedure

48. As a rule the Expert Committee meets annually, preferably during March or the earlier part of April, in order to provide sufficient time to enable the Director-General to transmit notifications incorporating its recommendations to the Secretary-General of the United Nations by about the end of May. WHO has adopted Regulations for Expert Advisory Panels and Expert Committees, as well as Rules of Procedure for Expert Committees.[1]

Functions

49. The function of the Expert Committee is to advise the Director-General of WHO on matters related to its remit under the international drug control treaties. Under the procedures set out in paragraph 14, it is the function of the Expert Committee to review and evaluate information available to it on psychoactive substances under review for international control, and to make recommendations to the Director-General of WHO on such control. The recommendations of the Expert Committee concern scientific, medical and

---

[1] WHO Basic Documents, 37th ed., pp. 95-103, 1988.

public health matters and must comply with the criteria set down in the Conventions. Specific Expert Committee responsibilities within these functions are:

(i) to assess the need to terminate notified exemptions of preparations under the Psychotropic Convention;

(ii) to recommend individual substances for future selection by WHO for a Critical Review (see paragraph 14);

(iii) to make an assessment of each selected substance as to its dependence-producing capability and its liability to cause public health and social problems as well as its usefulness in medical therapy.

50. The Expert Committee bases its deliberations and recommendations mainly on the documents provided by the Secretariat: these consist of the Critical Review Document, and any reply of relevant collaborating information sources concerning the Critical Review (see paragraph 17). They are forwarded to the members of the Expert Committee at least three weeks, if possible, prior to their meeting. In addition, the Expert Committee has for consideration the additional information presented in accordance with the procedure set forth in paragraph 47. All the information on which the Critical Review is based is made available to the Expert Committee members for further evaluation where necessary, keeping the provisions of paragraph 21 in mind.

51. The Expert Committee, when deciding whether to recommend international control after completion of its discussions, first decides, with regard to the Single 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 if the substance:

(1) is liable to similar abuse and productive of similar ill effects as the substances in Schedule I or Schedule II;

(2) is convertible into a substance already in Schedule I or Schedule II.

52. In the case of either (1) or (2) above, the Expert Committee recommends to the Director-General of WHO to communicate that finding to the Secretary-General of the United Nations. If, on the other hand, it finds that the substance cannot be appropriately controlled under the Single Convention, it makes its recommendations in terms of the Psychotropic Convention.

53. In accordance with Article 2, paragraph 4, of the Psychotropic Convention, the Expert Committee determines 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.

54. If either (1) and (3), or (2) and (3) above are found to be the case, the Expert Committee will advise the Director-General to communicate to the Secretary-General of the United Nations a recommendation for international control under the Psychotropic Convention, supported by a summary review, as described below.

55. The Expert Committee prepares a summary assessment of each substance reviewed, giving a succinct 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 recommendations on the control measures, if any, that would be appropriate in the light of its assessment.

XI. EXPERTS COLLABORATING IN THE WHO REVIEW

56. The selection of members of the Expert Committee is described in paragraph 44.

57. All experts collaborating in the review have a well-documented scientific career at a high level and professional background of international repute, and they represent all relevant behavioural, pharmacological, pharmaceutical, medical, biological and epidemiological disciplines, as well as public health and administrative science. Scientists in industrial research units may be asked to collaborate as consultants and as experts in WHO ad hoc working groups, as appropriate, for their special knowledge, but they are not invited to become members of the Expert Committee.

58. The selection of experts to collaborate in the WHO review is given careful consideration so as to avoid conflict of interests. In this connection, the experts invited to participate in the WHO review and, in particular, in the work of the Expert Committee, sign a statement confirming that no conflict of interest shall affect their participation.

Appendix 1

1. CONVENTION ON PSYCHOTROPIC SUBSTANCES, 1971 (EXTRACT)[1]

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.

Article 3

SPECIAL PROVISIONS REGARDING THE CONTROL OF PREPARATIONS

1. Except as provided in the following paragraphs of this article, a preparation is subject to the same measures of control as the psychotropic substance which it contains, and, if it contains more than one such substance, to the measures applicable to the most strictly controlled of those substances.

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

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

---

[1] Convention on Psychotropic Substances, 1971. New York, United Nations, 1977, pp. 9 and 12-13.

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

A Party shall notify the Secretary-General of any such decision, of the name and composition of the exempt preparation, and of the measures of control from which it is exempted. The Secretary-General shall transmit the notification to the other Parties, to the World Health Organization and to the 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 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 matter, 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 questions within 180 days of the date of the Secretary-General's communication.

2. THE SINGLE CONVENTION, 1961 AS AMENDED BY THE 1972 PROTOCOL

(EXTRACT)[1]

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,

---

[1] Single Convention on Narcotic Drugs, 1961. New York, United Nations, 1977, pp. 17-18.

(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:

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

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

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

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

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

Appendix 2

TIME SCHEDULE FOR THE WHO REVIEW PROCEDURE

Year 1.	Notification by a Party or WHO	----------
	Ongoing information collection	SECRETARIAT
Year 2.	Selection for Critical Review	March-April ECDD
	Critical Review finished	November-December SECRETARIAT
Year 2 - 3.	Circulation of Critical Review to relevant collaborating information sources	December-January SECRETARIAT
Year 3.	Assessment and recommendations	March-April ECDD
	ECDD report; communication of recommendations to Secretary-General	May-June DIRECTOR-GENERAL of WHO
Year 3.	Circulation of WHO communication to States Parties to Conventions	July-December DND SECRETARIAT
Year 4.	Decision on international control	February CND

Appendix 3

ABBREVIATIONS

CND	United Nations Commission on Narcotic Drugs
DND	United Nations Division of Narcotic Drugs
ECDD	WHO Expert Committee on Drug Dependence
ICPO (Interpol)	International Criminal Police Organization
INCB	International Narcotics Control Board
DMP	WHO Division of Drug Management and Policies
MNH	WHO Division of Mental Health
Review procedure	Procedure for the WHO review of dependence-producing psychoactive substances for international control

DEFINITIONS

Dependence-producing substance	A narcotic drug, a psychotropic substance or a psychoactive substance liable to induce repeated use as a result of a psychological and/or physiological state of want or need.
International control	The various control measures applicable to substances scheduled under the international drug control conventions.
International drug control conventions (or treaties)	The Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol; and the 1971 Convention on Psychotropic Substances.
International Narcotics Control Board	A control organ entrusted with functions assigned to it by international drug control treaties, one of these functions being the monitoring of licit trade of drugs brought under international control.
Narcotic drug	Any of the substances in Schedules I and II of the Single Convention on Narcotic Drugs, 1961, and that Convention as amended by the 1972 Protocol.
Notification	A formal communication addressed to the Secretary-General of the United Nations by a State Party to an international drug control treaty or by WHO pursuant to a provision of that treaty requiring the communication, or such a communication from the Secretary-General of the United Nations to a State Party or to WHO. In the context of the present Guidelines, reference to a notification means a notification relating to the scheduling of a substance either under the provisions of Article 3 of the Single Convention or Articles 2 and 3 of the Convention on Psychotropic Substances.
Psychoactive substance	Any substance, natural or synthetic, or any natural substance material, which has psychoactive properties. In this Annex 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, or any natural material in Schedule I, II, III or IV of the 1971 Convention on Psychotropic Substances.
State Party	A State which has become a Party to an international drug control treaty, through signature, ratification, accession, or succession.

Appendix 4

RESOLUTION OF THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS

2(S-IX) Commendation of World Health Organization procedures for the review of dependence-producing psychoactive substances for international control under the international drug control Conventions[1]

The Commission on Narcotic Drugs,

Recalling its resolutions 2 (S-VII), 4 (XXX) and 2 (S-VIII),

Noting with appreciation the World Health Organization's response to the suggestions contained in those resolutions,

Recognizing the complexities associated with the review and evaluation of the diversion, abuse and abuse liability of psychoactive substances.

Recognizing also that both the Single Convention on Narcotic Drugs, 1961, and the 1971 Convention on Psychotropic Substances stress the concept of applying rigorous measures to restrict the use of psychoactive substances to legitimate purposes while recognizing that the use of psychoactive substances for medical and scientific purposes is indispensable and that the availability of those substances for such purposes should not be unduly restricted.

Further recognizing that public health and social problems caused by some psychoactive substances have required governments to undertake actions to limit the use of these substances to legitimate purposes.

Acknowledging the highly commendable efforts of the World Health Organization to develop and implement effective guidelines for the full and open review of psychoactive substances, as most recently discussed at the seventy-seventh session of that Organization's Executive Board.

Noting with pleasure that the World Health Organization intends to re-evaluate carefully its criteria and plans for the selection of substances for future review.

Bearing in mind that the resources available to review substances adequately are limited and that World Health Organization reviews ought to focus on priority needs.

Noting the importance of assisting the Secretary-General to fully document drug scheduling recommendations conveyed to Member States of the Commission on Narcotic Drugs.

1. Commends the World Health Organization for its efforts to re-evaluate and refine its guidelines for the review of dependence-producing psychoactive substances for international control, and to develop further an efficient and effective mechanism to fulfil its role as specified in the international drug control Conventions;

2. Endorses, in principle, the guidelines for the review of dependence-producing psychoactive substances, taking into account the amendments proposed in the discussion at the seventy-seventh session of the World Health Organization Executive Board in January 1986;

---

[1] Extract from United Nations document E/CN.7/1986/13 (1986).

3. Endorses, in particular, the ongoing efforts of the World Health Organization to clarify the procedures, criteria and plans for the selection of substances for future review;

4. Endorses also the World Health Organization's continuing efforts to document fully all recommendations forwarded to the Secretary-General, for presentation to Member States of the Commission on Narcotic Drugs, giving particular attention to the degree of seriousness of the public health and social problems, so that those Member States may be fully informed concerning the rationale for the World Health Organization's recommendations, including the recommendations on the need for international controls;

5. Urges all Governments and other interested parties to assist the Secretary-General and the World Health Organization by providing full and accurate information on substances under consideration by the World Health Organization, both prior to and during the review process.

Appendix 5

RESOLUTION 1(S-VIII) OF THE UNITED NATIONS COMMISSION ON NARCOTIC DRUGS[1]

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 II 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;

---

[1] Extract from United Nations document E/CN.7/1984/13 (1984).

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

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

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

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

Guidelines proposed for use by the World Health Organization

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

- - -