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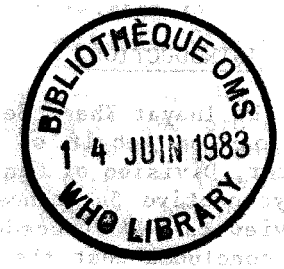

GUIDELINES FOR THE WHO REVIEW OF PSYCHOACTIVE SUBSTANCES

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GUIDELINES FOR THE WHO REVIEW OF PSYCHOACTIVE SUBSTANCES

1. INTRODUCTION

Dr Inayat Khan, Senior Medical Officer of the Division of Mental Health, welcomed the Group on behalf of Dr Halfdan Mahler, Director-General and Dr Norman Sartorius, Director, Division of Mental Health. Dr Khan informed the Group that at the 6th Review of Psychoactive Substances for International Control, Dr Sartorius requested the Group to review the WHO procedures for review of substances for international control. This Group concluded that the working procedures needed to be reviewed in the near future in order to allow the provision of timely and comprehensive advice. Subsequently, the Secretariat solicited, in a letter, suggestions from thirty experts who had in the recent past participated in WHO Review meetings. This letter sought their opinions and suggestions for improvements to the present procedures for reviewing psychoactive substances. In December 1982, Dr Hamid Ghodse, in collaboration with the Secretariat, prepared a working paper on the development of Guidelines for Review of Psychoactive Substances for International Control. The responses of experts to the letter and the working paper served as the basis for discussion.

2. BACKGROUND

2.1 The Group reviewed the responsibilities and mandates given to WHO in the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol and the Convention on Psychotropic Substances 1971. Special note was made of the differing responsibilities mandated by the Conventions. In recent years, the ever-increasing development and therapeutic introduction of psychoactive substances as well as concern over public health and social problems attendant upon the availability of such substances have led to increasing pressure on WHO from the Commission on Narcotic Drugs (CND), Member States, the International Narcotics Control Board (INCB), other bodies and individuals that have or are leading to a greater workload relating to obligations under the Conventions. In 1980 the World Health Assembly (WHA) requested the Director-General of WHO 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 in consultation with UNDND, INCB and other concerned UN agencies (WHA33.27).

2.2 The Group took note of three factors that are having impact on the activities of WHO:

(a) Almost all recommendations for control of single substances under the 1971 Convention have been initiated by WHO

(b) In the case of two recent recommendations based on medical and scientific finding of WHO (one recommending control, the other not recommending control) the Commission requested WHO to further examine the issues with the result that the next two meetings of the Review Groups are primarily devoted to reconsideration of these two recommendations in the light of new data.

(c) The need for resources allocated by WHO to be strengthened and made proportional to the increasing activities and responsibilites.

2.3 The Group next discussed issues of critical concern to the working of the Review Group.

2.4 Since the coming into force of the 1971 Convention, WHO convenes Review Groups instead of Expert Committees. Temporary advisers (the only voting members of the Review Groups) are selected from related Expert Panels in WHO. On occasion, a temporary adviser with special knowledge will be selected on the advice of related Expert Panel Members, representative geographical distribution, advice of Regional Offices and demonstrated performance in WHO activities. The Group also includes participants such as those from UNDND, INCB, NGO's, WHO Collaborating Centres and observers at the request of governments. All Members of the Group are selected in accord with WHO procedures. The Assistant Director-General gives final approval of the list. The Group concluded that this process resolved concern over real or apparent conflicts of interest by Members of the Group. The Group was of the opinion that the Members of the Review Groups should not be members of government delegations to CND.

2.5 The recommendations for substances to be reviewed comes from multiple sources. These include units within WHO such as Regional Offices, INCB, CND, Collaborating Centres, governments, non-governmental organizations and individuals. The Group recognized that absolute priority would be given to review notifications received from governments. Another priority would be given to drugs suggested for review by WHO governing bodies, UNCND and INCB. (In general, Review Groups set the agenda for future reviews). The Group concluded that the large number of psychotropic substances potentially available for review, the limited resources of WHO, the statutory priorities, the need for flexibility, and the circumstances under which WHO obtains scientific data necessitated that a set of criteria be developed for selection of substances for reviews initiated by WHO The Group also concluded from recent experiences that, as a rule, a minimum of eighteen months advance notice was necessary for adequate information to be developed and assembled for review of a substance. With regard to the frequency with which a drug under control should be reviewed, the Group concluded that such a review when initiated by WHO should take place only when new information was available indicating a need for review.

2.6 The Group reviewed the participation of the pharmaceutical manufactureers in the Review Procedures and found that the manufacturers had provided information that was useful and unobtainable from other sources. The Group expressed concerns relating to undue influences and apparent conflicts of interest. They noted that at its Sixty-ninth session (EB69.R9), the Executive Board requested the Director-General to continue to provide drug manufacturers and other interested parties with appropriate opportunity to make written and oral presentations on medical and scientific matters to WHO concerning drugs for possible control under the Conventions. It was also noted that WHO had established a Committee to develop guidelines and direction regarding dialogue between the parmaceutical manufacturers and WHO (IC/82/97). The Group conferred with the Secretary of that Committee. After extensive discussion the Group concluded that a relationship between WHO and the IFPMA, a non-governmental organization, might be helpful. Individual manufacturers should be invited to provide written summaries of required informations well in advance of the meeting. Scientists representing individual manufacturers should be invited to make a presentation to all temporary advisers. The time and manner of such presentations will be dictated by the time available and the number of drugs involved. Other members of the Group, if they wish, may attend these presentations. Manufacturers of individual drugs would not be allowed to attend other presentations; however, a representative of the IFPMA may be invited to attend the entire session of pre-review hearings. The Group concluded that a formalized procedure for interactions between the Group and the Pharmaceutical Manufacturers is required.

2.7 The Group found that the frequency of meetings would be dictated by available resources, availability and assembling of information and need for review notifications. Further, concern was expressed that frequent meetings taxed not only WHO but also the members of the Group. Temporary advisers spend many weeks preparing for and attending meetings at the cost of their primary activity. Similar constraints were placed upon the participation of Collaborating Centres and non-governmental organization. The Group concluded that, except under extraordinary circumstances, meetings should be at minimum yearly intervals. The Group concluded that the format of meeting could be changed to allow more efficient utilization of time.

2.8 With regard to review of exempt preparations, the Group concluded that procedures would be contingent upon acceptance by CND of the guidelines developed in the WHO consultations on Development of further Guidelines for the Exemption of Preparations under Article 3 of the Convention on Psychotropic Substances, 1971 (MNH/82.51).

2.9 The Group extensively discussed the availability of background documents to parties outside the Review Group. They noted that the background documents were working papers prepared only for information and discussion, that information was contributed and developed during discussion, and that time and resource restraints precluded preparation of a scholarly document indicating which portions of background papers had been used. These facts led the Group to conclude that backgorund papers not be made available by WHO nor that a list of background papers be published. The Group recognized that the originator of the background paper is free to distribute his or her paper.

2.10 The Group concluded that further reports of the Review Group should primarily contain recommendations addressed only to the statutory requirements relating to the determinative responsibilties of WHO.

2.11 The Group discussed the procedures for deciding the appropriate Convention when WHO initiates a recommendation for control. Because of the complexity of the issue, the Group decided to extend the discussion. Subsequently, the issue was further discussed during the 7th Review. This Group reviewed the Commentaries on the Conventions, previous decisions of Expert Committees and Review Groups and discussed the complexity of making such decisions from pharmacologic data since most psychoactive agents have varying degrees of similarity to prototypic drugs in both Conventions. With regard to the Single Convention on Narcotic Drugs, 1961, the Group concluded that operational decisions to control substances is defined as determining whether a drug was morphine-like, cocaine-like or cannabis-like. This procedure is in accord with the commentaries and previous practices of the Review Group. At times, previous Groups have come to consensus on these questions with regard to review of notification for control under the Single Convention, 1961. With regard to the Psychotorpic Convention, the Group recognized the less restrictive criteria required for control.

The Group concluded that a formal procedure should be utilized to decide which Convention is appropriate once a decision is made that control of a drug is required.

3. RECOMMENDATIONS

3.1 Selection of Substances

The Group recommends that WHO use the following criteria to establish priorities for review of substances for international control when such reviews are initiated by WHO not in response to notifications from governments. Such substances should be:

(a) Substances which are available licitly or illicitly.

(b) The substance has been abused with evidence that domestic controls failed to deter illicit distribution of drugs.

(c) There is evidence of public health and social problems in more that one part of the world.

(d) There is illicit manufacture or diversion of a drug at an international level

(e) Studies indicate high dependence potential on substances that are available or will become available.

3.2 Participation of Pharmaceutical Industry

The Group recommends that the following procedure be initiated:

Substance is identified for review by WHO

WHO staff and Review Committee to determine (a) concern(s) regarding the substance and (b) information needed for assessment of substance vis a vis international control

IFPMA notified, regarding intent to review:

(a) to advise relevant manufacturers of the review process

(b) to invite submissions by manufacturers concerning specific information about the substances in three forms:

First, detailed background information include non referenced material to WHO;

Second, provide a summary report dealing with specific questions raised by WHO Committee;

Third, Raise additional points by industry.

Report from pharmaceutical manufacurers to be sent to WHO twelve weeks in advance of the meeting for forwarding by WHO to participants of the meeting.

Pre-review hearing with Pharmaceutical Manufacturers

To have a dialogue with scientific representatives. This must be time-limited with IFPMA representation and closed to other drug company manufacturers.

WHO Review Group

Convened to decide action to be taken concerning
the need to advise the Director-General to
recommend control at the International line

Decision of the Director-General communicated to IFPMA representative

3.3 Frequency of meeting

The Group recommends that, except under extraordinary circumstances, that meetings be at minimum one year intervals and the review of a substance initiated by WHO be done at a minimum of two years after WHO makes its intention known to review a substance.

3.4 Format of recommendations

The Group recommends that after completion of discussions, the deliberation to recommend for control will follow a formal format and that the results of their deliberation be communicated only in terms of this format. First, the Group will vote to recommend International Control. If international control is recommended, the Group will first vote.

With regard to the 1961 Convention

The Group will initially determine if a substance is morphine-like, cocaine-like or cannabis-like. If so, the Group will then determine if the substances

1. ...are liable to similar abuse and productive of similar ill effects as the drugs in Schedule I or Schedule II.

2. ...are convertible into a drug (i.e. a substance in Schedule I or Schedule II).

If either 1 or 2 is found, the Group will recommend to the World Health Organization to communicate that finding to the Secretary-General of the United Nations.

If the Group finds that substance cannot be appropriately controlled under the Single Convetnion, they will then vote.

With regard to the 1971 Convention

The Group will determine if a substance...

1(a) ...has the capacity to produce similar abuse and similar ill effects as a substance in Schedule I, II, III or IV.

or

1(b) ...has the capacity to produce (a) a state of dependence, and (b) central nervous system stimulation or depression, resulting in hallucinations or distrubances in motor functions or thinking or behaviour or preception or mood.

and

2. ...is being or is or is not likely to be abused so as to constitute a public health and social problem arranging the placing of the substance under international control.

If either 1(a) and/or 1(b) and 2 are found, the Group will make a recommendation to the World Health Organization to communicate to the UN Commission on Narcotic Drugs its 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.

The Group recommends that their decision be made as the basis of chemical properties, pharmacologic properties, therapeutic indications and efficacy and the degree of seriousness of public health and social problems.

3.5 Review of exempt preparations

The Group deferred further consideration of exempt preparations pending the review by CND of proposed WHO Guidelines for such review.

3.6 Structure of Meeting

The Group recommends that the first working day be devoted to review all documents submitted or obtained for the review and to briefing in order to acquaint the participants with the task. The second day will be devoted to hearing with the Pharmaceutical Manufacturers, if any. On subsequent days, the Group would conduct reivews according to the agenda. The Group also recommends that certain reviews (i.e. exempt preparations) take place with small Working Groups prior to the meeting such that the Review Group would deliberate primarily on critical issues raised by the working groups in makings its recommendations.

3.7 Review of substances previously controlled or previously reviewed

The Group recommends that such reviews take place only when sufficient information is available to WHO that indicate a need for review.

ANNEX I

List of participants - 3 and 4 March Meeting

Dr A. Anumonye, Professor & Head Department of Psychiatry, University of Lagos, Lagos, Nigeria

Mr Paul Bailey, Chief, Treaty Implementation and Commission Secretariat Section, United National Division of Narcotic Drugs, Vienna International Centre, Vienna, Austria

Dr Philip H. Connell, Director, Drug Dependence Clinical Research & Treatment Unit, The Maudsley Hospital, London, England

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Dr Awni Arif, Senior Medical Officer, Division of Mental Health, WHO, Geneva, Switzerland

*Invited but unable to attend.

ANNEX II

List of participants - 7th Review Meeting

Dr A. Anumonye, Professor and Head Department of Psychiatry, University of Lagos Lagos, Nigeria (Co-Rapporteur)

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Dr A. Hamid Ghodse, Consultant Psychiatrist in charge of Drug Dependence Treatment Unit, Blackshaw Road, London, England (Chairman)

Dr H.I. Maghazaji, Assistant Professor, Baghdad University, Head of Neuropsychiatric Unit, Medical City Hospital, Baghdad, Iraq

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Dr J. Woods, Department of Pharmacology, Medical School University of Michigan, Ann Arbor, USA (Co-Rapporteur)

Dr T. Yanagita, Director, Preclinical Research Laboratories, Central Institute for Experimental Animals, Kawasaki, Japan (Vice-Chairman)

Representatives of other organizations

United Nations

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International Narcotics Control Board

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*Institute Mexicano de Psiquiatria, Mexico

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Mr R.J. Gallagher, Legal Officer, Office of the Legal Counsel, WHO, Geneva

Dr I. Khan, Senior Medical Officer, Division of Mental Health, WHO, Geneva (Secretary)

Dr N. Sartorius, Director, Division of Mental Health, WHO, Geneva

Dr M. Swerdlow, Consultant, Cancer Unit, Division of Noncommunicable Diseases, Geneva

Observers

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