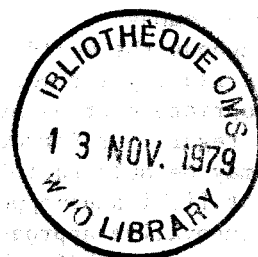




REVIEW OF PSYCHOACTIVE SUBSTANCES
FOR INTERNATIONAL CONTROL

26-28 SEPTEMBER 1979



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1. Introduction

On behalf of Dr H. Mahler, Director-General of WHO, Dr N. Sartorius, Director, Division of Mental Health welcomed the participants and expressed the concern of WHO regarding the process of selecting substances for international control in the future. There was a growing emphasis on psychiatric services and reliance on the use of psychoactive drugs throughout the world and, on the other hand, a rising public reluctance to allow new drugs to be readily introduced onto the market, thus increasing the need for WHO to consider appropriate control measures. Recognizing a limitation in the options available to WHO in this regard, Dr Sartorius asked the reviewers to consider three areas: (1) procedures that WHO may be able to follow in handling these control issues; approaches to resolving scientific issues appear to be much clearer than those regarding legislative procedures; (2) innovative approaches for the assessment of public health and social problems associated with drug use; (3) the roles of the relevant international and national agencies and their interrelationships, especially in the light of a continuing aggregation of national interests into regional ones.

2. Scope of the meeting

At its 28th Session the UN Commission on Narcotic Drugs had accepted the WHO recommendations on the control of nicocodeine and methaqualone as formulated by the preceding Advisory Group and had invited WHO to give attention to any substances for which international control was felt appropriate. Accordingly, WHO has convened this group of advisors to review, as suggested by the preceding WHO Advisory Group in 1978,¹ the pharmacological, medical and epidemiological data relevant to the dependence potential and abuse liability of tilidine, dextropropoxyphene, phencyclidine and mecloqualone and to recommend appropriate measures of control under the Single Convention on Narcotic Drugs, 1961 as amended by the Protocol of 1972² and the Convention on Psychotropic Substances, 1971.³

Sufentanil was added to the agenda in response to a notification from Belgium under Article 3 (1) of the 1961 Convention. No formal notifications had been received from the Federal Republic of Germany on tilidine or from the United States on dextropropoxyphene. In this connection the problem of forwarding notifications was discussed and it was felt that governments should be further encouraged and assisted in meeting their responsibilities to provide for relevant information and notification of the international control organs.

The Representative of the United Nations Division of Narcotic Drugs reviewed the procedures for instituting control under the Conventions of 1961 and 1971, and reported on the replies received from governments in response to the request by the Secretary-General, U.N. for data on dextropropoxyphene, mecloqualone, phencyclidine, sufentanil and tilidine, such as seizures and other data indicating the extent of abuse.

Similarly, the International Criminal Police Organization had requested its members to provide information on how often those substances were identified in seizures. Forty-six countries had replied, twenty-five of which in the negative sense.

¹ Review of Psychotropic Substances, report of a meeting, Geneva, 27-29 September 1978 - MNH/78.25

² hereafter referred to as "The 1961 Convention"

³ hereafter referred to as "The 1971 Convention"

3. Review of drugs for international control

Sufentanil¹

In response to a notification from the Government of Belgium requesting the addition of sufentanil to Schedule I of the 1961 Convention, the Group, in conformity with Article 3, paragraph 3 (iii) and 5 of that Convention, examined relevant evidence and found that:

- a) sufentanil has a pharmacological profile closely resembling that of fentanyl;
- b) sufentanil is, however, about ten times more potent than fentanyl;
- c) in single dose suppression studies in rhesus monkeys, sufentanil completely substitutes for morphine and analogous results have been obtained in dogs;
- d) by chemical and pharmacological analogy the abuse liability of sufentanil in humans can be expected to equal that of fentanyl; and
- e) it has morphine-like effects with much higher potency. Thus, it is potentially attractive for illicit traffic.

For the above reasons and although no data on dependence liability in humans or actual abuse were available, the Group was of the opinion that sufentanil is liable to similar abuse and productive of similar ill effects as fentanyl which is listed in Schedule I of the 1961 Convention and should, therefore, be placed into Schedule I of that Convention, and also in Schedule IV of that Convention because of its higher potency as related to morphine.

Tilidine²

After the World Health Organization, in conformity with Article 3, paragraph 1 of the 1961 Convention, had informed the Secretary-General, UN of its opinion that tilidine requires international control, the Group reviewed the relevant data and found that:

- a) in primates tilidine has reinforcing properties and produces mild physical dependence;
- b) in humans tilidine produces objective and subjective opiate effects, and in double-blind studies is identified as opiate-like both by the subject and the observer;
- c) there is published epidemiological evidence for widespread abuse of tilidine in one country, predominantly by subjects already abusing or having abused opiates, and committing criminal acts to obtain tilidine; and
- d) abuse and marked increase in illicit traffic in tilidine had been reported by several countries, two of them suggesting international control; furthermore, tilidine had been included in the narcotics legislation of more than one country and has been denied registration in others because of its abuse potential.

For the above reasons the Group was of the opinion that tilidine is liable to similar abuse and productive of similar ill effects as the drugs in Schedule I of the 1961 Convention and should, therefore, be placed into Schedule I of that Convention.

The recent introduction of a preparation combining tilidine with naloxone prompted a discussion by the Group.

Recommended international non-proprietary name for:

N-/4-(methoxymethyl)-1-/2-(2-thienyl)ethyl/7-4-piperidyl/7propionanilide

Recommended international non-proprietary name for:

(+)-ethyl trans-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate

Dextropropoxyphene¹

In conformity with Article 3, paragraph 3 (iii) of the 1961 Convention, the Group reviewed the data on dextropropoxyphene. Evidence exists that dextropropoxyphene is an effective analgesic for mild to moderate pain; in animals and humans it produces psychological and physical dependence of the opiate type, and has no greater abuse potential than codeine.

Although there is little evidence for widespread street abuse of dextropropoxyphene, there has been an increased incidence of deaths associated with it in the United States of America and Canada. These deaths usually occur in combination with alcohol or other depressant drugs and in individuals with a history of psychiatric problems. Because of this dextropropoxyphene has recently been brought under control by a number of countries. It was also noted that dextropropoxyphene has been subjected to narcotics control in several other countries.

Therefore, the Group recommended that dextropropoxyphene, because of the public health problem created by it, be added to Schedule II of the 1961 Convention.

The Group wished to emphasize that the combined effects of dextropropoxyphene and alcohol or other depressant drugs and the widespread use of dextropropoxyphene as a means of committing suicide, particularly by individuals with a history of psychiatric illness, presented potentially serious public health problems. Since the 1961 Convention does not obligate Parties to require medical prescriptions for dextropropoxyphene, the Group recommended that WHO and the Secretary-General of the United Nations inform Member States of the existence of these problems.

Phencyclidine²

In conformity with Article 2, paragraph 1 of the 1971 Convention, the Group reviewed information pertaining to the past and present control status of phencyclidine.

A significant and widespread abuse of the drug has emerged in North America. Evidence exists that:

- a) phencyclidine produces tolerance as well as psychological and physical dependence;
- b) possesses serious acute and chronic psychological toxicity, including agitation, rage, violent behaviour, hallucinations, recurring psychoses and coma; and
- c) leads to experimentation at all age levels, primarily at school age and in the 18 to 25 year old group. The abuse and long-term health effects of phencyclidine appear to represent a unique drug situation, although some similarities with the abuse of stimulants, depressants and hallucinogens exist.

1 Recommended international non-proprietary name for:

α -(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-butanol propionate ester

2 Recommended international non-proprietary name for:

1-(1-phenylcyclohexyl)piperidine

These observations have been confirmed in both animal experiments and human usage. Because of the growing magnitude of this problem the drug was placed under stricter control in the United States of America.

The Group found little documented evidence for widespread abuse outside North America, nor did it find any evidence of diversion from legitimate veterinary supplies. Large quantities of the drug have been seized that have originated from clandestine manufacture due to its rather facile synthesis and ready availability of starting chemical materials. The Group also noted that a legitimate, but limited demand exists for the continued availability of the drug to veterinarians and others involved in the handling of primates.

In order to maintain the maximum level of international control over phencyclidine as well as its availability for legitimate use, the Group concluded that phencyclidine should remain in Schedule II of the 1971 Convention.

Further, WHO should inform its Member States of the dangers associated with this drug.

Phencyclidine analogues

The Group considered the following PCP analogues:

1-[1-(2-thienyl)cyclohexyl]piperidine "TCP"

1-[1-phenylcyclohexyl]pyrrolidine "PHP or PCPY"

N-ethyl-1-phenylcyclohexylamine "PCE"

These three compounds are chemically and pharmacologically very similar to phencyclidine (PCP). They have CNS depressant effects as indicated by rotarod studies and are all more potent than PCP. All are discriminated by rats as PCP. They have been shown to be self-administered in either the dog or the monkey or both, and all appear to be more potent than PCP. There is good evidence for their illicit production and street use in the United States of America and Canada.

Therefore, the Group was of the opinion that the above named substances be placed on Schedule I of the 1971 Convention because of their capacity to produce a state of dependence; CNS stimulation resulting in hallucinations and disturbances in thinking, behaviour or mood; and similar abuse and similar ill effects as a substance in Schedule I of the 1971 Convention; and because there is sufficient evidence that the three substances are likely to be abused so as to constitute severe public health and social problems warranting international control.

Mecloqualone¹

In accordance with Article 2, paragraph 1 of the 1971 Convention, the Group examined evidence relative to mecloqualone.

Recommended international non-proprietary name for:

3-(o-chlorophenyl)-2-methyl-4(3H)-quinazolinone

Mecloqualone is a sedative-hypnotic agent chemically and pharmacologically similar to methaqualone. The latter is controlled under Schedule II in the 1971 Convention. Mecloqualone shares with methaqualone the ability to produce CNS depression resulting in disturbances in motor function, behaviour, perception and mood. Although no studies or clinical observations of dependence on mecloqualone have been reported, its chemical and pharmacological similarity to methaqualone strongly suggests that it would produce both psychological and physical dependence. The Group concluded that, because of its similarity to methaqualone, mecloqualone was likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. There is no evidence of a therapeutic use for mecloqualone which cannot be met by other widely available drugs, some of which have less abuse potential.

Therefore, the Group recommended that mecloqualone, because it fulfils the criteria enumerated in Article 2, paragraph (a) (i) and (ii) and paragraph (b), of the 1971 Convention be added to Schedule II of that Convention.

4. Selection of further substances requiring control

In order to allow for a judicious approach to selecting drugs as candidates for control and to permit more time to properly prepare needed background documentation, WHO should act in response to or as a result of, notifications by Parties under Articles 3 and 4 of the 1961 and 1971 Conventions respectively; enquiries from WHO Member States; recommendations by the WHO Advisory Group; or reviews, in collaboration with the UN Division of Narcotic Drugs, of national decisions re control.

Whenever possible, a class of substances should be reviewed rather than any single drug. In the next two years the following classes might be considered:

Anxiolytics (especially diazepam, chlordiazepoxide, flurazepam, nitrazepam and meprobamate).

Non-barbiturate hypnotics (especially ethchlorvynol, glutethimide, methyprylon, ethinamate, chloral hydrate and paraldehyde).

Anorectics (especially phenmetrazine, phentermine, amfepramone, phendimetrazine, benzphetamine, mazindol, chlorphentermine, chlortermine, and fenfluramine).

Agonist/antagonist opiate analgesics (pentazocine, butorphanol, nalbuphine, buprenorphine, and perhaps cyclazocine).

5. The need for more and better information

The Group suggested that a formal request by WHO should be sent to the WHO Collaborating Centres to provide all documents and data available to them concerning the drugs listed above. Furthermore, enquiries should be channelled in an appropriate manner to the manufacturer(s) in question to give them the opportunity of supplying relevant data. The Group also urged the need for continued cooperation with the UN Division of Narcotic Drugs, International Narcotics Control Board and such groups as the Committee on Problems of Drug Dependence and the International Council on Alcohol and Addictions. The Group recognized that the burden of assembling and reviewing the documents and data submitted would fall on WHO staff and the members of the Advisory Group.

Data on psychotropic drug utilization was essential for evaluating the benefit/risk ratio of a substance as required by the 1971 Convention. Such data can also help to identify users and prescribing doctors.

The Group strongly recommended that the facilities of the WHO Drug Monitoring Programme should be further strengthened in order to identify as early as possible any association of abuse or drug dependence with products moving in the international market.

In these efforts, the Multilingual List of Drugs Controlled by the 1971 Convention, currently being prepared by the UN Narcotics Laboratory, would be helpful.

In order to facilitate the review process the report format proposed at the Group's previous meeting, for the presentation of the background information, should be used as much as possible.

As the complexities of assessing the health consequences expand, new approaches need to be devised for the input of data from the social and economic areas. In addition to the need for obtaining such information from Member States, these disciplines should be presented in the WHO Advisory Group.

In their recent resolutions, the WHO Executive Board¹ and the UN Commission on Narcotic Drugs² had invited governments to provide the much needed information on their domestic public health and social problems connected with drug abuse. The Group concurred that such information was essential for the proper evaluation of the need for international drug control.

The Group was especially concerned about the general lack of data from developing countries on their public health and social problems associated with the use of narcotic and psychotropic substances. The lack of such data cannot mean that the problems do not exist. On the contrary, the frequent absence of systematic assessment and regulatory machinery in developing countries can make them more vulnerable to the free marketing of drugs that might be tightly controlled in other settings.

There is a pressing need for WHO to find the resources necessary to establish additional centres in developing countries to develop the expertise as well as the means suitable to their circumstances for the assessment of their drug problems.

¹ Resolution EB63. R29 of 25 January 1979

² Resolution 7 (XXVIII) of 22 February 1979
UN Commission on Narcotic Drugs - Report of the 28th Session, 12-23 February 1979
E/1979/35. E/CN7/638

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LIST OF BACKGROUND DOCUMENTS

1. MNH/78.25 - Review of meeting to Review Psychotropic Substances, Geneva, 27-29 September 1978
2. Decisions on methaqualone and nicocodeine taken by the UN Commission on Narcotic Drugs, Twenty-eighth Session, 12-23 February 1979, Document E/1979/35, E/CN.7/638
3. Procedures for International Control of Psychoactive Substances Paper prepared by the UNDND for the Expert Committee on Drug Dependence, 26 September-1 October 1977, MNH/DDC/77.6
4. Review of replies received from Governments to Secretary-General of the United Nations about illicit traffic in substances under review
5. MNH/79.23 - Paper prepared by INTERPOL on appearances of certain psychoactive substances in illicit traffic
6. Copy of official notification from the Government of Belgium to the Secretary-General of the United Nations on Sufentanil
7. MNH/79.21 - Literature Review on Sufentanil by Dr P. Kalix and Dr I. Khan
8. Report on Sufentanil Citrate by the Committee on Problems of Drug Dependence
9. Report by the Addiction Research Center, Lexington, Kentucky on Sufentanil by Dr P. Gilbert
10. Miksic, S., Shearman, G. & Lal, H. Generalization Study with some Narcotic and Non-narcotic Drugs in Rats trained for Morphine-Saline Discrimination. Psychopharmacology, 60, 103-104 (1978)
11. MNH/79.19 - Tilidine: A Review on Pharmacology, Dependence Liability and Abuse by Dr P. Kalix and Dr I. Khan
12. MNH/79.20 - Decisions and Statements regarding the Control Status of Dextropropoxyphene by Dr P. Kalix
13. MNH/79.27 - Propoxyphene Review by Professor L. Harris
14. Report on Phencyclidine by Dr R. Willette
15. Progress Report on Phencyclidine and its Analogues from the NIDA Research Center by Dr D. Jasinski Etal
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SUMMARY OF THE DISCUSSION ON
INVESTIGATION OF THE STIMULANT AND REINFORCING PROPERTIES OF
SELF-ADMINISTRATION OF PHENYLETHYLAMINE DERIVATIVES ISOLATED FROM CATHA ed. (KHAT)

25 SEPTEMBER 1979

The findings collected during the last year's research were briefly summarized. The pharmacological effects of (-) Cathinone, the main phenylalkylamine compound of freeze-dried khat was compared mainly to amphetamine and partly to (+) Cathine, (+) Cathinone and norephedrine in different in vivo and in vitro tests.

Self-administration studies in monkeys revealed the high reinforcing capacity of (-) Cathinone.

(-) Cathinone proved to enhance motility in mice and rats, increase oxygen consumption and reduce food intake in the rat as potently as amphetamine. It also acted like amphetamine in the hot plate and in a one way avoidance test in the rat.

(-) Cathinone and amphetamine exerted similar cardiovascular effects. They raised blood pressure in the cat, facilitated electrically stimulated contractions in the perfused central ear artery of the rabbit and in the rabbit pulmonary artery strip and exerted positive inotropic and chronotropic effects in the guinea pig atrium.

Like amphetamine, (-) Cathinone was found to facilitate neuromuscular transmission in the nictating membrane of the cat in vivo and in vitro. It acted similarly on the isolated guinea pig vas deferens and on the isolated rat vas deferens. (-) Cathinone was also found to be as potent as amphetamine in stimulating the flexor reflex of the hind limb of the spinal rat. This reflex is controlled by noradrenergic neurotransmission and is regarded as a good model for studying the action of drugs on central noradrenergic neurons.

Putting together all the findings of the in vivo and in vitro experiments, it was concluded that the main acute effect of (-) Cathinone is the facilitation of noradrenergic neurotransmission.

Regarding the mechanism of this effect, it is supposed that (-) Cathinone and (+) Cathinone are taken up by the noradrenergic nerve terminals, like amphetamine, and they enhance the release of the transmitter.

Amphetamine and (-) Cathinone seem to act at the same site as cross tolerance between the two substances was found on the cat nictating membrane in vivo and in vitro. Cross tolerance between the two substances could also be demonstrated in food intake studies.

Some differences between the central effects of (-) Cathinone and amphetamine were also detected. (-) Cathinone was found to be much less potent than amphetamine in producing stereotype behaviour, showing its low effectiveness on dopaminergic neurotransmission.

To study the similarities and differences between amphetamine and (-) Cathinone, the following studies were recommended:

1. Analysis of the pharmacological effects of (-) Cathinone during long term administration of the compound.
- 2.1 Comparison of the effects of amphetamine and (-) Cathinone on dopaminergic and serotonergic neurotransmission.
- 3.1 Comparison of the effects of (-) Cathinone and amphetamine on levels, turnover, release and uptake of biogenic amines in the brain.

The Committee appreciated the close collaboration between the World Health Organization and the United Nations Narcotics Laboratory and supported the recommendations made at the meeting in Madagascar in 1978 by the Expert Group on the Botany and Chemistry of Khat.¹

In stressing the importance of pharmacological studies, the Committee hoped that the United Nations Narcotics Laboratory would prepare adequate amounts of khat components for such studies. In addition, extracts containing all the components should be prepared from the main types of khat.

The Committee also emphasized the importance of determining the amounts of the various components present in khat and hoped that the United Nations Narcotics Laboratory would undertake this research.

The need for detailed studies of the public health and social problems associated with khat chewing in the affected countries was discussed. A review of research on khat being carried out in Somalia showed that out of the 2,000 subjects interviewed in the Northern City of Hargeisa, 80% chewed khat at least once a week. A similar survey of 2,000 men in Mogadishu found 30% chewing khat at least once a week. It would be desirable to have funds to cover the salary of khat using subjects if they were admitted to hospitals for purposes of monitoring them during the withdrawal and post-withdrawal phase.

¹ The Botany and Chemistry of Khat, Report of an Expert Group, Antananarivo, 27 November - 1 December 1978 MNAR/3/1979, GE.79.10365

The Group was informed about WHO's plans to carry out studies on the public health and social problems associated with problems associated with khat use in at least three countries with support from the United Nations Fund for Drug Abuse Control.

No less important however, is the assessment of the socio-economic implications of the habitual consumption of khat. This issue is indeed, of paramount importance for instituting national and trans-national controls.

The publication policy regarding the new data collected through the WHO project was a matter of discussion and the following decisions were made:

1. Unpublished data and expected new results from experiments in progress seem to be sufficient for a second symposium on khat research, which is proposed to be held at the next Committee on Problems of Drug Dependence in Cape Cod in June 1980.
2. The whole material which accumulated during the last years should be published in a NIDA Monograph.
3. A summary of the pharmacological findings should be included in that issue of the "Bulletin on Narcotics", which will be devoted to the khat problem.
4. A survey on khat research for "Pharmacological Reviews" should be prepared by a competent scientist.

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