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NOTE

The *Bulletin on Narcotics* seeks to cover all aspects of national and international drugs control; the work of the international bodies responsible in this field; and developments concerning the research, assessment and prevention of drug abuse and the treatment, rehabilitation and social reintegration of persons dependent on drugs. Particular attention is paid to articles presenting national experience in drug abuse control which may be of interest and value to other countries.

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Study on exempted preparations*

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ABSTRACT

The coming into force of the Convention on Psychotropic Substances 1971 has rekindled the interest in the technical and administrative modalities of relaxing the control measures applicable, under that convention and the Single Convention on Narcotic Drugs, 1961, to preparations of substances that are controlled by virtue of those international treaties. Therefore, an analytical review of the principles and procedures laid down in those conventions for the exemption of defined preparations from certain control measures was felt desirable as an adjunct to the ongoing discussions, especially in connection with the provisions of the 1971 Convention. The gradual emergence and development of the relevant principles and procedures embodied in the successive international control treaties since 1912 are highlighted as a background for the review of the actual treaty obligations faced by the parties to the conventions and by the international organizations concerned. Included are some suggestions for possible improvement of the system for exempting preparations under the terms of the 1971 Convention.

Introduction

For over 50 years the number and diversity of dependence-producing substances has grown continuously. This growth is reflected in the increasing complexity of the successive international instruments for the control of such substances. The early control treaties have been generally replaced by the Single Convention on Narcotic Drugs, 1961 (referred to hereafter as the 1961 Convention) and the Convention on Psychotropic Substances, 1971 (referred to hereafter as the 1971 Convention), and the international com-

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munity is now called on to apply two treaties which have a number of similar provisions, but at the same time also present certain differences, in particular in respect of the provisions concerning exempted preparations.

As a contribution to the ongoing discussion of this complex subject, the present paper endeavours to review and compare the concepts and procedures for exempting preparations from control provisions under the existing international treaties. The treaties preceding the 1961 Convention are included in the study as historical background in order to better understand the present systems. Moreover, the provisions of the earlier treaties demonstrate the gradual development of theory and practice of international drug control.

I. The principles of exemption

Early in the deliberations on the international control of what are now regarded as dependence-producing drugs, the questions arose whether preparations containing such drugs might, because of their lower abuse liability, be freed from control measures or subjected to a more lenient regime of control than that applicable to the individual drug(s) contained in such preparations. The basic considerations and criteria regarding the control of drugs were considered pertinent also to the control of their preparations. The emergence of these guiding principles in the successive treaties is briefly reviewed here.

The International Opium Convention, 1912 (referred to hereafter as the 1912 Convention) was aimed both at the gradual suppression of the *"abuse"* of opium, morphine and cocaine and of the drugs prepared from these substances which give rise to "*similar* abuses" (this and all later emphasis is by the author). It differentiated between drugs subject to control and certain preparations not requiring control. Article 14(*b*) and (*c*) stipulated that preparations (including the so-called anti-opium remedies) containing not more than 0.2 per cent of morphine, 0.1 per cent of cocaine or 0.1 per cent of heroin were not subject to the control measures provided for the drugs themselves.

The Agreement Concerning the Suppression of the Manufacture of, International Trade in, and Use of Prepared Opium, 1925 (referred to hereafter as the 1925 Agreement), on the grounds of *"humanity"*, proposed to promote *"social and moral welfare"*. The notion of morality, although referred to in many official statements, did not, however, recur in later international treaty texts.

The International Opium Convention, 1925 (referred to hereafter as the 1925 Convention), concluded as a "humanitarian effort" requires in article 5 that the Contracting Parties "limit exclusively to medical and scientific purposes" the manufacture, transactions in, and use of controlled sub-

stances. The principle of limitation to medical and scientific purposes has been adopted by subsequent treaties. The term *"substances"* in article 4 included preparations since the article listed, under the heading "substances", the drug itself as well as specific preparations, except that preparations of heroin were no longer exempted as was the case under the 1912 Convention. A discretionary exemption was provided for in article 9 of the 1925 Convention which authorized Parties to permit, in urgent cases, the supply by chemists of preparations containing not more than 250 mg of officinal opium. Article 8 of the 1925 Convention stipulated that a preparation may be exempted if the development of a *"drug habit"* (equivalent to drug addiction or drug dependence) was precluded by virtue of the medicaments with which the controlled drug was compounded. The specification that the development of a drug habit should be precluded was in later treaty instruments replaced by the criterion of the need to avoid harm to public health and the society as a whole (see the 1961 and 1971 Conventions). Article 8 of the 1925 Convention further provided for the exemption of a preparation from control if the *"recovery"* of the parent drug from the preparation was in practice also precluded as a consequence of the medicaments with which the preparation was compounded. Later treaty instruments also stipulated the preclusion of recovery without indicating possible methods. For instance, the preclusion of recovery could be achieved by the composition of the preparation as such, i. e. by the addition of any substance, medicinal or inert, or by simple dilution, and not necessarily by the admixture of other medicaments. Article 10 of the 1925 Convention introduced as a criterion for control the capacity of a substance [i. e. also of a preparation (see above)] to bring about *"similar abuse . . ."* and be *"productive of similar ill-effects"* as a substance already controlled by the Convention. The idea of similarity was carried over into subsequent treaties.

The Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, 1931 (referred to hereafter as the 1931 Convention) was formulated to "supplement the provisions of the International Opium Conventions . . . by rendering effective by international agreement the *limitation of the manufacture of narcotic drugs to the world's legitimate requirements for medical and scientific purposes . . .*". Article 6 of the 1931 Convention limited the manufacture of drugs and preparations to the quantities estimated to be required for the medical and scientific needs of a Party. Regarding the criteria and procedures for the exemption of preparations, article 13 of the 1931 Convention referred to article 8 of the 1925 Convention. In addition, the 1931 Convention introduced a new concept: article 11 requires that, with respect to any new product—drug or preparation—obtained from any of the phenanthrene alkaloids of opium or from the ecgonine alkaloids of the coca leaf and intended for manufacture, the Party concerned ascertain the *"medical or scientific value"* of the product in question. This requirement anticipated the now widely accepted principle that no medicinal product be introduced into

the market without proof of its therapeutic efficacy and safety. With regard to the composition of preparations, article 13, paragraph 1 (*b*) of the 1931 Convention distinguished between the addition of another medicinal substance and simple dilution of the controlled drug by mixing it with an *"inert substance, liquid or solid . . . "*. Preparations of the latter type were not fit for exemption because of the ease of recovery of the drugs for illicit purposes [1, p. 173]. In order to exclude the exemption of preparations with an inordinately high drug content which might facilitate illegal transactions and recovery under the guise of legality, article 13, paragraph 2 (*b*) makes the exemption of a preparation contingent upon its ability to be *"adapted to a normal therapeutic use"* [1, p. 176]. This criterion was not adopted by the subsequent treaties. Article 19 stipulated that the labels under which drugs and their preparations were offered for sale should indicate the percentage of the drugs and the name of the drugs as provided for in the national legislation. The latter requirement was a forerunner to the clauses in article 30, paragraph 3, of the 1961 Convention and article 12, paragraph 2 (*a*), (ii) of the 1971 Convention, which stipulate the use of international non-proprietary names.

The Protocol Bringing Under International Control Drugs Outside the Scope of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs as Amended by the Protocol Signed at Lake Success, New York, on 11 December 1946, signed at Paris on 19 November 1948 (hereafter referred to as the 1948 Protocol), extended international control to drugs outside the scope of the 1931 Convention, i.e. to drugs mainly of synthetic origin which had appeared on the market in large numbers after the 1931 Convention had entered into force. Consequently, the criteria and procedures pertaining to the exemption of preparations containing such drugs continued to be those laid down in the preceding conventions.

The 1961 Convention resulted from the general desire to unify and combine the existing international drug control treaties into one single instrument. Beyond that, the 1961 Convention introduced some new concepts. The Technical Committee of the United Nations Plenipotentiary Conference for the Adoption of a Single Convention on Narcotic Drugs, New York, from 24 January to 25 March 1961 (hereafter referred to as the 1961 Plenipotentiary Conference), when placing a substance or its preparation in one of the Schedules, was guided by the assessment of the *"degree of its liability to abuse"* and then ensuing *"risk to public health and social welfare"* [2, p. 110]. The latter criterion, although not embodied in the text of the Convention, has since been a prime determining factor when establishing the need for and degree of, instituting international control of a drug or preparation [3, p. 10; 4].

The 1961 Convention was the first to define a preparation as *"a mixture, solid or liquid, containing a drug"* [article 1, paragraph 1 (s)]. This definition

lacks the indication of any characteristic or condition that might make a preparation eligible for exemption. Therefore, each individual preparation must be assessed with reference to its potential harmfulness to public health and social welfare as a result of the abuse of the preparation as such or of the drug recovered from it (article 3, paragraph 4).

As far as preparations and the policy of their exemption from certain control measures are concerned, the 1961 Convention as amended by the Protocol amending the Single Convention on Narcotic Drugs, 1961, concluded at Geneva on 25 March 1972 (referred to hereafter as the 1972 Protocol), does not differ from the original version adopted by the 1961 Plenipotentiary Conference.

The 1971 Convention is not limited to specific types of psychoactive substances, in contrast to the preceding conventions which were restricted to three distinct types, i.e. those of the morphine-, cocaine- and cannabis-type. Because of the open-ended character of the 1971 Convention with regard to the type of substance coming within its scope, the criteria of dependence (addiction), abuse, and similarity have been supplemented in article 2, paragraph 4 (b), by the prime criterion of an abuse-related *"public health and social problem"*. The other new criterion in article 2, paragraph 4(*b*) of the 1971 Convention is the *"degree of usefulness of the substance in medical therapy, . . ."*. In order not unduly to restrict the availability of a substance for legitimate medical purposes, the extent or likelihood of its abuse, the degree of seriousness of the resulting public health and social problems and the degree of usefulness of the substance in medical therapy must be assessed in relation one to the other.

Article 3, paragraph 2, of the 1971 Convention does not specifically refer to the assessment of the therapeutic usefulness of a preparation, in view of its exemption. The assessment of the therapeutic usefulness of the parent drug will, however, have a bearing on the evaluation of the preparation in this regard.

II. Treaty provisions for exempting preparations

A. Procedures

Treaties preceding the 1961 Convention in respect of procedures

The 1912 Convention was the first to distinguish between individual substances such as opium, morphine, heroin or cocaine and preparations compounded with one of these substances. In article 14 several preparations were specified; for opium or morphine preparations the drug content in the preparation must not exceed 0.2 per cent of morphine or 0.1 per cent of cocaine or heroin respectively. If the content exceeded these limits, the

preparation was no longer considered a preparation and was to be controlled in the same manner as the drug it contained.

The 1925 Convention, in article 4, continued to exempt the preparations listed in article 14 of the 1912 Convention with the exception of heroin preparations. Further, the 1925 Convention introduced a procedure for exempting preparations other than those listed in article 4 for the exempt status of which the drug content was the sole criterion. Under article 8 of the original treaty text, the Health Committee of the League of Nations [under the same article of the later amended version, the World Health Organization (WHO)] was empowered to make a finding as to whether any preparation containing any of the controlled drugs could "give rise to the drug habit on account of the medicaments with which the said drugs are compounded and which in practice preclude the recovery of the said drugs . . .".

The 1931 Convention did not include any detailed provisions relating to the procedures of initiating and implementing the exemption of preparations, but referred in article 13, paragraph 1 (*a*) to the relevant provisions in the 1925 Convention.

The 1948 Protocol did not embody any new definitions or provisions concerning preparations or their exemption from control. Consequently, the provisions of the 1931 Convention and, through them, the provisions of article 9 of the 1925 Convention were applicable to preparations of drugs falling under the scope of the 1948 Protocol. Since article 1 of the 1948 Protocol assigned to a Party the responsibility of initiating the procedure for bringing a drug under international control, this modality would also seem to be applicable to the exemption of a preparation containing such a drug. This, indeed, was the practice followed until the 1961 Convention came into force.

The 1961 Convention in respect of procedures

The 1961 Convention defines a preparation as "a mixture, solid or liquid, containing a drug". This definition is not specific as to the number of controlled drugs in the preparation, or the addition of an uncontrolled medicinal substance, or of an inert ingredient. For an assessment of the exempt status, however, these specifications are covered by the phraseology of article 3, paragraph 4.

The 1961 Convention contains considerably more details than its predecessors regarding the establishment of the exempt status of a preparation.

Schedule III of the Convention lists a number of exempted preparations which were included in that Schedule by the 1961 Plenipotentiary Conference on the recommendation of its Technical Committee. When deciding upon the exempt status of a preparation, i.e. its inclusion in

Schedule III, the Technical Committee considered *(a)* the addiction-producing capacity of the drug and the drug content of the preparation; *(b)* the capacity of the admixtures to (i) diminish or counteract the addiction-producing properties of the drug and (ii) preclude the recovery of the drug from the preparation by readily applicable means; *(c)* the therapeutic value and extent of the legitimate medical use of the preparation; and *(d)* the abuse-related risk to public health and social welfare [2, pp. 102, 110, 112]. Using these criteria, the 1961 Plenipotentiary Conference selected, for example, only one preparation *(pulvis ipecacuanhae et opii compositus)* for inclusion in Schedule III, out of the 56 items listed in the Recapitulatory List of Preparations Exempted from the Provisions of the 1925 Convention by Application of Article 8 of that Convention [5].

Schedule III of the 1961 Convention, as adopted by the 1961 Plenipotentiary Conference, included preparations of all drugs listed in Schedule II at that time. The 1961 Convention does not, however, contain any provisions concerning a global exemption of preparations of Schedule II drugs which would correspond to the provision in article 13, paragraph 2 (*b*) of the 1931 Convention exempting from certain control measures preparations containing drugs included in Group II of that Convention and adapted to a normal therapeutic use.

Apart from the preparations included in Schedule III by decision of the 1961 Plenipotentiary Conference, a number of preparations have been added to that Schedule under the provisions of article 3 since the 1961 Convention entered into force. Under article 3, paragraph 1, if a Party or WHO had information which may require an amendment of Schedule III by adding a preparation to it or deleting one from it, the Party or WHO should notify the Secretary-General of the United Nations accordingly. The Secretary-General transmits this information to the Parties, the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations and to WHO if the notification was made by a Party. Thereupon, WHO must evaluate the case in accordance with article 3, paragraph 4. There is no provision which would invite Parties to comment on the initial notification as is provided for in the 1971 Convention under its article 3, paragraph 4, concerning the termination of an exemption.

The choice of the ways and means of evaluation is left to WHO, in contrast to a provision in earlier treaties which required WHO to act upon the advice of an Expert Committee. Since such Expert Committees must be formally appointed by the Director-General of WHO and in each case authorized by the World Health Assembly, the abolition of this requirement enables WHO to act more speedily by reducing the time lapse between its finding and recommendation and the action by the Commission.

When assessing a preparation, WHO will normally apply the same considerations and criteria which the Technical Committee of the 1961 Plenipotentiary Conference had observed. If WHO, in keeping with article 3,

paragraph 4, finds that the preparation in question is not liable to be abused and the drug which it contains is not readily recoverable, it will transmit this finding to the Secretary-General together with the recommendation that the preparation be added to Schedule III. Conversely, a negative finding will entail the recommendation that the preparation should not be exempted, i.e. not included in Schedule III. In the first case, the Commission may then either act in accordance with the WHO recommendation and decide to place the preparation in Schedule III, or to take no action. If the Commission acts, it is not permitted to take a decision which does not correspond to the recommendation by WHO; a negative recommendation by WHO precludes any further action by the Commission.

The procedure for adding a preparation to Schedule III is equally applicable to the deletion of a preparation from that Schedule [article 3, paragraph 6 (*b*)].

Decisions of the Commission relating to amendments of Schedule III are binding on the Parties immediately after receipt of the notification from the Secretary-General.

The possibility of an appeal against such a decision is provided for in article 3, paragraph 8, of the 1961 Convention. Any Party may, within 90 days, request the Economic and Social Council to review the decision of the Commission. The Council, after having invited comments from the Commission, the other Parties and WHO may confirm, alter or reverse the decision of the Commission. The decision of the Council is final. So far no request for review of a preparation has been filed by a Party.

The 1971 Convention in respect of procedures

The 1971 Convention had to cope with a multitude of psychotropic substances with widely varying properties. This has added to the complexity of the provisions and procedures of exempting preparations containing those substances.

Both the 1961 and the 1971 Conventions define the term "preparation". The definition in the 1961 Convention, "a mixture, solid or liquid, containing a drug", is not specific as to the presence or absence of another drug. The 1971 Convention defines a preparation as "any solution or mixture, in whatever physical state, containing one or more psychotropic substances" or as "one or more psychotropic substances in dosage form". Neither definition refers to the admixture of another medicinal substance or ingredient which may diminish the abuse liability or preclude the recovery of the controlled substance(s) with which the preparation is compounded. These issues are, however, taken care of by the wording of article 3, paragraph 4, of the 1961 Convention and article 3, paragraph 2, of the 1971 Convention.

Article 3, paragraph 2, of the 1971 Convention provides for the exemption of preparations containing substances listed in Schedules II, III, and IV only. This seems to be tenable as long as the substances in Schedule I are generally considered to have no therapeutic value except perhaps under special circumstances and within narrowly defined limits in which cases there would probably be no need for a formulated preparation. There is an analogy to the 1961 Convention which provides, in principle, for the exemption of preparations containing any of the drugs controlled by that Convention. The criteria placing a drug in Schedule IV of the 1961 Convention would, however, hardly seem compatible with exempting a preparation containing a drug in Schedule IV.

The 1971 Convention empowers a Party to exempt individual preparations from certain control measures on its own initiative if, in accordance with article 3, paragraph 2, it finds that a preparation containing a controlled psychotropic substance does not give rise to a public health and social problem because the manner in which the preparation is compounded abolishes or renders negligible its abuse liability and precludes the recovery of the controlled substance by readily applicable means in a quantity liable to abuse.

Further, article 2, paragraph 7, allows a Party not to apply certain control measures to a substance which the Commission has added to one of the Schedules if the Party, in view of exceptional circumstances, is not in a position to give effect to all of the control measures applicable to that substance. This possibility of a partial exemption from control applies also to a preparation of the substance in question since article 3, paragraph 1 stipulates that a preparation is subject to the same control measures as the psychotropic substance(s) which it contains. Consequently, it can be argued that a Party can indirectly "exempt" a preparation by envoking article 2, paragraph 7, and that that "exemption" cannot be terminated by the Commission.

The fundamental difference between the provisions of the 1961 Convention and those of the 1971 Convention is that the former entrusts WHO with making, either on its own initiative or on request by a Party, a finding and a corresponding recommendation which the Commission may transform into a decision binding all Parties; whereas under article 3 of the 1971 Convention a Party is empowered to make the finding and take the decision to exempt a preparation, the exemption being valid in its country if not terminated by decision of the Commission. Any such decision must be notified to the Secretary-General who invites the other Parties and WHO to submit such information as in their opinion may require the total or partial termination of the exemption. Following the Secretary-General's transmittal of the information received to the Parties, the Commission and WHO, the latter organization must then examine whether the exemption is justified and must accordingly recommend to the Commission whether or not the

exemption should be terminated either as a whole or with respect to certain control measures. In considering the WHO recommendation, the Commission may decide to terminate the exemption of the preparation as a whole or in part, i.e. to re-establish all or certain control measures. Those Parties which have exempted the preparation in question from control measures to which the terminating decision of the Commission applies, are bound to implement that decision within 180 days. Thus, inasmuch as the termination is required because of an existing or possible risk with international ramifications, the procedure under article 3, although initiated by a Party, will have a certain protective or preventive effect on the international level. Decisions of the Commission to terminate exemptions are not subject to the right of non-acceptance by Parties under article 2, paragraph 7, nor to review by the Council as are the Commission's decisions amending a schedule.

It is noteworthy that article 3, paragraph 7, of the 1961 Convention does not allow for any time lag in the implementation by Parties of a comparable decision of the Commission to remove a preparation from Schedule III of that Convention. This difference might find its explanation in the perceived greater abuse liability of preparations of drugs controlled by the 1961 Convention as compared to preparations of psychotropic substances. The same logic would, however, not apply to the difference between the two Conventions regarding the possibility of an appeal against the Commission's decisions relative to exemptions. The 1961 Convention provides in article 3, paragraph 8, for a review of those decisions by the Council in the same context as all decisions concerning scheduling. The 1971 Convention does not have an equivalent provision.

Another difference between the 1961 Convention and the 1971 Convention concerns the degree of freedom of the Commission vis-à-vis the recommendation of WHO relative to the exemption of a preparation. According to article 3, paragraph 4 and article 3, paragraph 6 *(b)* of the 1961 Convention, the Commission may either act in accordance with the WHO recommendation and decide to add the preparation to Schedule III or to delete it from that Schedule, or it may take no action; but the Commission cannot decide on any other course of action. In taking no action the Commission would most probably only consider arguments of a socio-economic or administrative and not of a medical or scientific nature.

Article 3, paragraph 4, of the 1971 Convention also leaves the Commission free to act or not to act on the recommendation of WHO. Under the provisions of the 1971 Convention however, the Commission may also adopt a position different from the recommendation of WHO in respect of the termination of certain control measures. It can do so only for economic, social, legal or other reasons, while the assessment of WHO must be considered determinative as to medical and scientific matters.

B. Control regimes

The conditions for the exemption of preparations must be seen in the light of the control measures from which they are exempted. The "exempt" status does not mean freedom from any control, except for preparations exempted under the terms of the 1912 Convention and the unamended 1925 Convention which were, however, later subjected to some control by the 1931 Convention. The treaties following the 1925 Convention stipulated control measures for exempted preparations which were less strict than those for the drug substances they contained.

Treaties prior to the 1961 Convention in respect of control regimes

The 1912 and 1925 Conventions were the only treaties which exempted certain designated preparations from any control. Such preparations were specified in article 14 of the 1912 Convention, and in article 4 *(d)* (preparations containing 0.2 per cent or less of morphine or 0.1 per cent or less of cocaine) and in article 9 (three opium preparations at a maximum single dose of 250 mg of officinal opium for use in urgent cases) of the 1925 Convention. Other preparations were exempted by a decision of the Health Committee of the League of Nations [5] or of WHO under article 8 of the amended 1925 Convention.

The 1931 Convention dealt with the following exempted preparations: *(a)* preparations exempted from the provisions of the 1925 Convention under its Articles 4 *(d)*, and 9; *(b)* preparations of drugs in Group II of the 1931 Convention – and by extension, of the 1948 Protocol – which are "adapted to a normal therapeutic use"; and *(c)* preparations exempted from the 1925 Convention by a decision of the Health Committee of the League of Nations (under article 8 of the original text) or by a decision of WHO (under article 8 as amended by the 1946 Protocol).

The preparations under *(a)* and *(c)* were subject to only a few provisions of the 1931 Convention: inclusion in the estimates of the quantity of drugs required for manufacture of these preparations; wholesalers to report the amount of the drug(s) contained in preparations imported or exported; and inclusion in the annual statistics of the amount of drugs used for the manufacture of these preparations. The labels under which all preparations mentioned were offered for sale must show the percentage of the drugs which they contained.

The 1961 Convention in respect of control regimes

The 1961 Convention provides for two categories of exempted preparations which differ in the extent of control measures to which those preparations are subjected:

(a) Preparations which were exempted by decision of the 1961 Plenipotentiary Conference or by a special procedure similar to that placing drugs under control are listed in Schedule III, together with the pharmaceutical formulation. The following measures must be applied to preparations in Schedule III:

(i) Licensing of manufacture and trade (including export and import) except when carried out by a State enterprise (article 29, paragraph 1; article 30, paragraph 1 *(a)*; article 31, paragraph 3 *(a)*);
(ii) Control under licence of the premises of manufacture (article 29, paragraph 2 *(b)*);
(iii) Control of all persons and enterprises engaged in manufacture, trade or distribution (article 29, paragraph 2 *(a)*; article 30, paragraph 1 *(b)*);
(iv) Detailed records to be kept by manufacturers and traders (article 34 *(b)*);
(v) Limitation to medical and scientific purposes of manufacture, trade, possession and use (article 4 *(c)*).

Medical prescriptions are not required for preparations in Schedule III.

(b) Article 2, paragraph 3, refers to preparations of drugs in Schedules I and II other than those in Schedule III. For these preparations no specification as to composition, lack of abuse liability, or recovery is required. This category of preparations is subject to the same measures of control as the drugs they contain except that:

(i) Estimates and statistics are not required (since they are included in the comprehensive estimates and statistics for the drugs);
(ii) A periodical permit for manufacturers of the preparation is not required (article 29, paragraph 2 *(c)*);
(iii) Control of establishments and premises for trade or distribution is not required [article 30, paragraph 1 *(b)* (ii)].

The 1971 Convention in respect of control regimes

The 1971 Convention does not provide for the exemption of preparations containing a substance in Schedule I.

Whereas a non-exempt preparation is subject to the same control measures as the most strictly controlled substance it contains, exempted preparations must be subjected only to the following measures.

(a) Manufacturers must be licensed (article 8, paragraph 1) and must keep records of the quantity of each substance used in the manufacture of the preparation, and of the nature, total quantity, and initial disposal of the exempt preparation manufactured (article 11, paragraph 6);

(b) Inspection of the premises, stocks, and records of the manufacturer (article 15);

(c) Substances of Schedules II and III used in the manufacture of the preparation must be reported to the INCB (article 16, paragraph 4 *(c)*);

(d) Prohibition of export to a Party having prohibited the import of any of the substances in preparation (article 13, paragraph 2);

(e) Penal provisions against violation of the foregoing obligations (article 22, paragraph 1).

III. Review of cases of exemption

A. Exemptions effected under article 3, paragraph 4 of the 1961 Convention

At the time of its adoption by the 1961 Plenipotentiary Conference, Schedule III of the 1961 Convention included preparations which the Technical Committee of the Conference had selected, *inter alia*, on the basis of a list proposed by the WHO Expert Committee on Addiction-Producing Drugs [3, p. 13]. With the exception of three opium preparations, the Technical Committee had rejected all preparations in the Recapitulatory List of preparations exempted from the provisions of the 1925 Convention because they were toxic or lacked therapeutic efficacy and were, therefore, considered obsolete [2].

Schedule III as adopted by the 1961 Plenipotentiary Conference comprised:

(a) Preparations of the seven drugs then listed in Schedule II, provided they were:

(i) Compounded with one or more other ingredients (not controlled) in such a way that the preparation had no, or a negligible, risk of abuse and in such a way that the drug could not be recovered by readily applicable means or in a yield which would constitute a risk to public health and

(ii) Their drug content did not exceed a defined limit which was the same in all seven cases.

For this group of preparations it was, indeed, possible to lay down a common limit of drug content since the drugs in question had a similar therapeutic dose range. Clause (i) regarding risk of abuse and recoverability is, however, open to more or less strict interpretation by Parties. Therefore, the Commission, on the recommendation of WHO, later decided to remove this clause. Since the entry into force of the 1961 Convention, the Commission has added to this first group the preparations of nicocodine and nicodicodine, both of which are congeners of codeine and, therefore, subject to the common limit of drug content in these preparations. Upon entry into force of the 1961 Convention, dextropropoxyphene was removed from Schedule II and its preparations were consequently deleted from Schedule III. They were added again to the latter Schedule after the parent

drug had been reintroduced in Schedule II in 1980. This time the drug content in the preparation was set at a higher level and the preparation could not, therefore, be included in the list in paragraph 1 of Schedule III. The restriction was added that exempted preparations of dextropropoxyphene must not contain any substance controlled under the 1971 Convention. This was deemed necessary by WHO in view of an increased abuse of such combinations.

(b) Preparations of cocaine, opium, and morphine with a limited drug content which were specified for each preparation in relation to the therapeutic dose of the drug. As for the group of preparations in paragraph 1 of Schedule III, the reference to "no, or a negligible risk of abuse" was later removed by decision of the Commission on the recommendation of WHO. The proviso regarding recovery of the drugs was, however, retained in view of their greater abuse potential compared to that of the drugs contained in the preparations listed in paragraph 1 of Schedule III:

(c) Preparations of diphenoxylate with a maximum content of diphenoxylate and a minimum content of atropine;

(d) Pulvis ipecacuanhae et opii compositus (Dover's powder) with a maximum content of opium;

(e) Since the entry into force of the 1961 Convention, preparations of propiram and difenoxin have further been added to Schedule III, both with a maximum drug content and the latter with the addition of a minimum content of atropine.

All the amendments in Schedule III after its adoption by the 1961 Plenipotentiary Conference were, in conformity with Article 3, paragraph 4, decided upon by the Commission acting on the relevant recommendations of WHO.

Some considerations concerning the composition of preparations in Schedule III

The limitation of the drug content in a preparation refers to the amount of drug per individual dosage unit (tablet, capsule, ampoule, suppository) or the concentration of the drug in an undivided preparation in solid or liquid form (powder, solution, suspension) as the case may be. For preparations of propiram, difenoxin and diphenoxylate, exemption had been granted only in the form of subdivided dosage units whereas the exemption of other preparations in Schedule III is applicable to the undivided form as well as to dosage units.

A number of preparations in Schedule III contain ingredients which are apt to preclude intentional abuse. For example, the atropine content of the difenoxin and diphenoxylate preparations and the toxic effects of the ipecacuanhae root in Dover's powder should prevent the administration of increased quantities.

Except for preparations of cocaine, morphine and opium the composition of the preparations as specified in Schedule III is deemed to preclude recovery by readily applicable means or in a yield which would constitute a risk of abuse. Only preparations of cocaine, morphine and opium must be "compounded with one or more ingredients and in such a way that the drug cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health". These provisions have been carried over, in part, from article 8 of the 1925 Convention.

A certain diversity in the formulation of preparations in Schedule III (e. g. the addition of an antidote in some cases but not in others) results also from the fact that, as a rule, the exemption procedure is initiated by Parties to the Convention that are responsible for the formulation of a preparation proposed for exemption.

With respect to the list of preparations in Schedule III it can be seen that for all drugs in Schedule II an exemption has been granted, in contrast to only five drugs out of 82 controlled in Schedule I, and this for valid reasons: the dependence and abuse potential of the latter is by far greater than that of Schedule II drugs. Furthermore, the legitimate consumption of the drugs in Schedule II and their preparations exceeds by far the consumption of Schedule I drugs and their preparations.

B. Exemptions effected under article 3 of the 1971 Convention

Over a period of 18 years since the entry into force of the 1961 Convention, only four preparations have been added to its Schedule III. During the six years since the entry into force of the 1971 Convention, approximately one thousand preparations have been notified by eight countries for review and decision of their exempt status under article 3 of that Convention. This remarkable discrepancy reflects the larger number of preparations of psychotropic substances coming within the purview of the 1971 Convention, the greater variety of their therapeutic applications and, hence, much wider distribution and consumption, including self-medication.

The accompanying table presents a survey of the notifications from Parties under article 3 and of the action taken by WHO, the Commission and the Secretary-General under paragraph 4 of article 3. It will be recalled that the draft of the 1971 Convention did not include a list of exempted preparations and that, therefore, the United Nations Plenipotentiary Conference for the Adoption of a Protocol on Psychotropic Substances, Vienna from 11 January to 21 February 1971 (referred to hereafter as the 1971 Plenipotentiary Conference), did not deal with individual preparations as did the 1961 Conference when establishing Schedule III of the 1961 Convention.

Notifications under Article 3, paragraphs 3 and 4 of the 1971 Convention

Party notification			*WHO recommendation*			*Commission decision*			*Secretary-General transmittal*	
Date	*Party*	*No. of prep.*	*Date*	*Term.*	*Deferred*	*Date*	*Term.*	*Deferred*	*Date*	*NAR/CL*
18 October 1979	Mexico[a]	6	16 October 1980	5	0	4 February 1981	5	0	15 April 1981	15/1981
16 April 1980	Bulgaria	11	16 October 1980	3	0	4 February 1981	3	0	14 April 1981	14/1981
7 July 1980	Chile	3	8 October 1981	1	0			1[b]		
24 September 1980	Sweden[a]	30	26 October 1981	7	8[c]		[d]			
29 October 1980	Hungary	21	8 October 1981	4	2[c]			1[b]		
23 July 1981	United States	32	18 September 1981	—	32[e]					
18 September 1981	France	112	10 September 1982	64	12[c]					
13 November 1981	Finland[a]	59	10 September 1982	28	4[c]					

[a] Notification made on model form.
[b] Pending availability of WHO guidelines.
[c] Additional information requested.
[d] No action since preparations notified have been either withdrawn from the market or their exemption terminated by the notifying Party.
[e] Pursuant to a request from the USA for postponement of consideration pending their review of their list of preparations (NAR/CL.19/1982 of 1 June 1982).

Speedy action on notifications under article 3 is essential. Nevertheless, a certain time lag between the receipt of a notification from a Party and the conclusion of the findings and formulations of the recommendation by WHO is inevitable.

As the table shows, the notifications from Bulgaria and Mexico were dealt with within 12 months and 18 months, respectively, from their receipt by the Secretary-General until his final notification to the Parties of the Commission's decision. In both cases the interval between the transmittal of the WHO recommendation and the Commission's decision was 15 weeks.

The cases notified by Chile, Hungary and Sweden were considered by WHO within a maximum of 15 months. With respect to the notifications from Hungary and Sweden however, WHO had to defer a recommendation in regard to two and eight preparations, respectively, until further information requested from the notifying Parties was available. The Commission, moreover, decided to defer action on the recommendations from WHO concerning the notifications from Chile and Hungary until criteria for the exemption of preparations which the Commission had requested WHO to formulate became available and, hopefully, provided a useful basis for decision.

The Commission did not have to act on the notification from the Government of Sweden, since that Government had in the meantime withdrawn the marketing licence or the exempt status for all the preparations in question after WHO had transmitted its respective recommendations to the Commission. Also, Hungary had since withdrawn from the market three of the four preparations in respect of which WHO had recommended that the exemption be terminated.

The consideration by WHO of a notification from the United States of America (NAR/CL. 19/1982 of 1 June 1982) was postponed on the request of the notifying Party since the latter was in the process of reviewing its list of exempted preparations [6, p. 24].

The notifications from Finland (concerning 59 preparations) and from France (concerning 112 preparations) were dealt with by WHO within 10 and 12 months, respectively. In these cases the time-lapse between the formulation of the relevant recommendations by WHO [6] and their transmittal for action by the Commission was five months.

At its sixth special session the Commission recommended in resolution 2(S-VI) of 19 February 1980 that Governments consider the exemption of *in vitro* diagnostic reagents, buffers and analytical standards containing substances in Schedules II, III and IV of the 1971 Convention. In formulating this recommendation the Commission was satisfied as to the absence of any risk to the community of these laboratory agents which would fall under the term (i) of the definition of a preparation given in article 1 of the 1971 Convention. This recommendation does not liberate a

Party from notifying the exemption of these reagents under article 3. One wonders why only the exemption from the provisions of article 12 was recommended by the Commission and why diagnostic reagents could not, in accordance with article 4 *(b)* be considered as being "in such a condition that they will not in practice be abused or recovered".

General remarks

The terminations recommended by WHO and decided upon by the Commission under article 3, paragraph 4 have so far been total ones, i. e. restoring all the control provisions which the Party had removed.

In one half of the notifications referred to above and listed in the table, use was made of the model form which the Secretariat had circulated to the Parties in 1978 in order to facilitate the procedure under article 3 of the 1971 Convention.

IV. The question of guidelines for the exemption of preparations under the 1971 Convention

The preceding survey of the action so far taken by WHO under the provisions of article 3 did not deal with the specific reasons why WHO recommended the termination of an exemption. This leads me to consider the basis on which WHO predicates its recommendations.

As we have seen, the 1971 Convention provides that Parties can, on their own authority, exempt preparations containing psychotropic substances from certain control measures and that every such exemption should be examined by WHO with a view to the possible termination of the exemption by decision of the Commission if so recommended by WHO. During the 1971 Plenipotentiary Conference, neither of its two main committees (Technical Committee and Committee on Control Measures) was called upon to consider in detail the scientific, technical, or administrative implications of this arrangement, which attempts to combine the unilateral activity of a Party with the supervisory function of two international bodies. Soon after the entry into force of the 1971 Convention it was realized that the differences between Parties regarding the number and variety of preparations being marketed and their attitude towards exemption might render difficult the harmonization of national control efforts under the international agreement. At its twenty-seventh session in 1977 the Commission, therefore, requested the Secretariat to study the matter in close collaboration with WHO and to formulate recommendations regarding the exemption of preparations from control measures and the conditions under which exemptions could be effected. In response to this request, a group of WHO consultants prepared a set of guidelines [7] consisting of four criteria as an administrative basis for granting exemptions and a series of

considerations for the assessment of the risk of abuse of a preparation and of its availability without medical prescription.

The WHO guidelines were first discussed at the fifth special session of the Commission in 1978 and further discussed at all subsequent sessions of the Commission. While there was general agreement with the "considerations" in paragraphs 11–13 of the WHO guidelines, the debate reflected the wish of delegations to have a clear statement of generally applicable criteria for exemption. It was, perhaps, not sufficiently realized that the variety of psychotropic substances, even of those listed in the same Schedule, did not permit measuring them by one yardstick as was possible with the drugs in Schedule II of the 1961 Convention.

At its sixth special session the Commission again requested the Secretariat and WHO to collect such information from Governments as would enable them to continue the elaboration of further guidelines. In response to several Notes Verbales [11] by the Secretary-General, 30 replies were received. Some of them were mere acknowledgements, two accepted and eleven indicated general agreement with the WHO guidelines, though raising points calling for clarification. Two replies mentioned the possibility of establishing for each individual psychotropic substance its maximum content in a preparation, which might be a more acceptable criterion than setting the same limit for all substances listed in one Schedule.

In the meantime, WHO had initiated a study [12] on the problems of exempting preparations. The study used the situation in Sweden as an example. The authors came to the conclusion that they were unable to suggest better guidelines than had been proposed by WHO.

At the request of WHO and in order to enable it adequately to discharge its functions under article 3, paragraph 4, Parties were invited, by Note Verbale NAR/CL.16/1982 of 19 May 1982 of the Secretary-General to furnish, in addition to information on the composition of the exempted preparation, the following data: *(a)* Specification of the total package dispensed; *(b)* Description of the formulation; *(c)* Therapeutic indications; *(d)* Summaries of the pharmacology of active constituents not under international control; *(e)* Pharmaceutic form (tablets, ampoules etc.); and *(f)* Quantity in each package dispensed (10-ampoule package, 100-tablet package etc.).

Whichever criteria will eventually be adopted, a solution to the problem is desirable because the concern has been expressed that broader adherence to the 1971 Convention might be compromised by the difficulties faced by countries engaged in the international commerce of preparations as long as generally recognized criteria for their exemption from certain control measures are lacking.

V. General observations and conclusions

The difference between the 1961 and 1971 Conventions regarding the provisions for exempting preparations have been presented in preceding sections. In the following discussion an examination is undertaken of some of the consequences of those differences for the implementation of the relevant provisions of the 1971 Convention, also in the light of past experience with the 1961 Convention.

Sound medical practice requires a readily available supply of effective and safe medicaments, an important segment of which are internationally controlled. With the increasing number of such medicaments, the effectiveness of the control system is likely to diminish. Keeping the number of controlled medicaments, especially preparations, within manageable limits will assist sound medical practice as well as the effective administration of control.

From the point of view of the preceding observations, the system for the exemption of preparations under the 1961 Convention is sound. The assessment of a preparation with respect to its possible exemption is guided by the same principles, considerations and criteria that are applicable to the assessment of a substance for its possible classification under the schedules. There has been no reason or desire to change this approach. The administrative procedure for initiating and implementing an exemption is uncomplicated and has not given rise to criticism, though there is room for doubt whether shifting the power of decision from WHO to a functional Commission of the Economic and Social Council is always commensurate with serving the best interests of protecting public health and safety. Previously, the Health Committee of the League of Nations was entrusted with the decision on the control status of a drug or preparation.

There are 82 drugs in Schedule I of the 1961 Convention and 10 in Schedule II; Schedule III includes preparations of altogether 14 drugs. For the 1971 Convention, the relation between the number of psychotropic substances in Schedules II—IV and the number of exempted preparations so far notified and not terminated is the numerical inverse of the situation with the 1961 Convention. The reason for this contrast lies in the greater variety of preparations containing psychotropic substances and the extent of their therapeutic use. The difference is also explained by the long-standing control of dependence-producing drugs as opposed to the recent date of instituting control over psychotropic substances. The relative absence of control has favoured a large increase in the number of preparations containing psychotropic substances.

Over a period of almost two decades, only four preparations were added to Schedule III of the 1961 Convention. They had been assessed by generally recognized, clear criteria. Those in charge of exempting preparations under the 1971 Convention find themselves in the reverse situation. Innumerable

preparations have been granted or are being proposed for an exempt status in the absence of universally adopted criteria for exemption: the situation is conducive to tailoring the criteria to fit the exempt status.

The challenge posed by the 1971 Convention is to cope efficiently with *(a)* the multitude of preparations already marketed and *(b)* new preparations to be marketed in the future, as follows:

(a) In coping with the bulk of preparations already on the market, a reasonable approach towards adjusting their control status (exempt or not) might be one comparable to the mutual recognition between a number of Governments of their national registration of new drugs under application of mutually recognized basic principles and criteria, not necessarily by mandatory application of the same measures or methods. The variety of psychotropic substances and the possible variation of their effects in preparations compounded in different ways set a limit to the detailed specification of such criteria. The principles and criteria such as those offered in the WHO guidelines, if properly applied, should satisfy the need for conformity and mutual recognition among Parties to the 1971 Convention;

(b) New combination products (i.e. preparations) containing psychotropic substances should be subjected to the national registration procedure for new psychoactive drugs as was advocated by the WHO Expert Committee of Addiction-Producing Drugs as long ago as 1961 [8]. The abuse potential of the preparation would be assessed by appropriate methods [9, 10]. Only a product with no, or a negligible, abuse potential could be considered for exemption under national authority. Such screening might also have a limiting effect on the output of preparations without any new therapeutic effects.

There is an analogous experience regarding the development of strong analgesics of the morphine type. When early screening had revealed the dependence-producing potential of these substances and had led to their international control, the further development of these drugs for commercialization was often abandoned – witness the large number of drugs in Schedule I of the 1961 Convention which do not appear in the statistics of the International Narcotics Control Board.

Finally, subjecting preparations containing psychotropic substances to the national registration procedure for drugs in general might foster the much needed co-operation between the national special administration for the control of psychotropic substances and the national health agency.

So far, the number of notifications made under article 3, paragraph 3, of the 1971 Convention has been rather low. It is not likely that in the foreseeable future the present system will be capable of coping with all preparations exempted by the Parties. The application of the national drug registration scheme may improve the situation.

It is somewhat surprising to note speedy action at all levels on the first two occasions regarding the notifications from Bulgaria and Mexico under article 3, paragraph 3, and then considerable delays on subsequent occasions. Factors delaying action include the WHO need for supplementary information from the notifying Party and other sources; time to be allowed for replies from Parties to the Secretary-General's Note Verbale requesting observations relevant to the exemption of a preparation by another Party; prolonged discussion of the guidelines for the exemption of preparations; the difficulty of adapting the timetable of WHO activities under article 3, paragraph 4, to the date of the nearest session of the Commission. Parties should in any case notify their exemptions immediately to the Secretary-General regardless of the date of a WHO review meeting or a session of the Commission.

Only the 1961 Convention provides WHO with the possibility of initiating the procedure of exempting a preparation. So far, WHO has not taken such action and is unlikely to do so in the future because there remains a residue of risk of abuse with respect to any preparation containing a drug controlled by the 1961 Convention as long as such a preparation is available without prescription. Other things being equal it seems reasonable that under the 1971 Convention, WHO has been assigned a supervisory function over exemptions enacted by Parties.

The two Conventions differ as regards the procedure of voting on the exempt status of a preparation. A decision by the Commission to remove a preparation from Schedule III under the 1961 Convention requires the simple majority of the members of the Commission present and voting. For a decision to terminate an exemption under the 1971 Convention, which in principle is comparable to removing a preparation from Schedule III of the 1961 Convention, article 17, paragraph 2, of the 1971 Convention requires a two-thirds majority of the Commission members, no matter how many members may be absent, abstain or do not participate in the vote. This may be interpreted as an expression of a more liberal attitude of the 1971 Plenipotentiary Conference, perhaps because of the perceived lower risk potential of preparations containing psychotropic substances, as compared to those containing drugs controlled under the 1961 Convention.

The number of exemptions so far notified by Parties under article 3, paragraph 3, has varied between three (Chile) and several hundred (United States of America). It might be asked whether the number of exemptions would reflect a more or less liberal attitude of the notifying Party or the magnitude of the number of preparations existing in its country. The material available does not permit the attempt of such an analysis.

Under article 3, paragraph 4, of the 1971 Convention a Party shall communicate to the Secretary-General such information as in its opinion may require the termination of an exemption authorized by another Party. This safeguard against a possibly too liberal practice of exemption has so far

been activated only by one Party (United States of America) which commented on the exemptions notified by three other Parties (Chile, Hungary, Sweden).

A different matter is the gathering of information by the Commission from both Parties and non-parties on their practices in exempting preparations[1]. This is a further example of the Commission's wish to foster wider adherence to the 1971 Convention and, by appropriate recommendations, to improve its implementation by Parties.

The control of dependence-producing drugs and psychotropic substances, and especially the preparations of the latter, places a considerable administrative burden on the Parties to the Conventions. The assessment of preparations as well as that of the drugs and psychotropic substances they contain might be facilitated if it could be linked with the national scheme for the registration of medical substances. Such schemes have been developed to a remarkable degree. It would be logical and expedient to perceive the control of dependence-producing drugs and psychotropic substances within the broad framework of "drug and chemical safety". A by-product of this concept might be an approach free of emotional determinants which have sometimes tended to interfere with rational solutions to problems of drug abuse.

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