United Nations E/CN.7/2014/10

Economic and Social Council

Distr.: General
18 December 2013

Original: English

Commission on Narcotic Drugs
Fifty-seventh session
Vienna, 13-21 March 2014
Item 10 (a) of the provisional agenda*
Implementation of the international drug control treaties: challenges and future work of the Commission on Narcotic Drugs and the World Health Organization in the review of substances for possible scheduling recommendations

Challenges and future work in the review of substances for possible scheduling recommendations

Note by the Secretariat

Summary

The present document provides information on the relevant provisions of the international drug control conventions for possible scheduling of substances, challenges in the review of substances and possible options for the way ahead. The report also contains recommendations for consideration by the Commission on Narcotic Drugs. The procedures for the scheduling of substances under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and under the Convention on Psychotropic Substances of 1971 are described in annex I. The scheduling provisions of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 are summarized in annex II.

* E/CN.7/2014/1.

V.13-88967 (E) 140114 150114

I. Introduction

1. At its fifty-sixth session, the Commission on Narcotic Drugs added a sub-item to the provisional agenda of its fifty-seventh session, entitled "Challenges and future work of the Commission on Narcotic Drugs and the World Health Organization in the review of substances for possible scheduling recommendations", under agenda item 10, entitled "Implementation of the international drug control treaties", in order to assist Member States in applying the existing scheduling procedures set forth in the three international drug control conventions.

2. The present document provides information on challenges related to the review of substances and their possible scheduling, rescheduling or descheduling under the international drug control conventions and makes suggestions for the possible way ahead. Bearing in mind the wording of the new sub-item, the document deals mainly with the scheduling procedures under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971, which are also outlined in annex I. The relevant provisions of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988 are summarized in annex II.

II. Challenges in the control of new substances under the international drug conventions

3. The period when substances were most frequently placed under international control was between the entry into force of the 1961 Convention and of the 1971 Convention, and up to the early 1990s. During that period the Commission on Narcotic Drugs dealt with scheduling matters on a regular, nearly yearly, basis. While recent years have seen less action on the scheduling of narcotic drugs and psychotropic substances, the emergence of new psychoactive substances has renewed the interest in the scheduling process under the international drug control conventions.

4. The present document draws upon the work of the international expert consultations on new psychoactive substances, held in Vienna from 3 to 5 September 2013, and its outcome document, prepared by the Laboratory and Scientific Section of the United Nations Office on Drugs and Crime (UNODC). The experts discussed the fact that States parties had initiated few scheduling notifications since 1961. They also discussed the mechanisms under the conventions regarding provisional control measures, both mandatory and discretionary, which may not have been fully utilized to date. The need for international cooperation in maximizing the use of the tools available under the conventions was noted. The experts recommended the development of simplified guidance for States parties on the scheduling process. The experts identified, among others, the following challenges to the scheduling process:

(a) The rapid proliferation of new psychoactive substances, their rapid turnover and the circulation of different substances in different parts of the world, making prioritization for evaluation difficult;

(b) Obtaining data on potential risks and harms of new substances and other data to carry out the risk assessment;

(c) Efficiency and timeliness of the process, from initiation/notification to recommendation of control measures;

(d) Resource limitations in carrying out the risk assessment of new substances;

(e) Varying degrees of capacity within countries to implement controls while balancing access to substances needed for medical use.

A. Understanding and using the procedures

5. The procedure for the control of new substances that are considered to possibly pose a threat to public health follows a multi-stage structure, provided for in detail in the relevant convention and described in the annexes.

6. The three-stage structure consists of:

(a) Initiation/notification to recommend a new substance for evaluation;

(b) Expert assessment of health risks and dependence potential of the substance;

(c) Decisions on its inclusion in one of the schedules.

1. Notifications

7. Amendments to the scope of control of substances under the 1961 Convention and the 1971 Convention follow a three-stage process, starting when an initiator, either a party to the Convention or the World Health Organization (WHO), notifies the Secretary-General of the United Nations. A note verbale is subsequently transmitted by the Secretary-General to the parties to obtain their comments, and, if the request was initiated by a State party, to WHO, which will undertake a risk assessment. The WHO assessment and recommendations, together with a summary, are provided to the Commission on Narcotic Drugs for its consideration and action.

8. With regard to the notification process, reference is also to be made to Commission resolution 7 (XXVIII) of 22 February 1979, in which the Commission urged States parties to supplement, as required by the 1961 Convention and the 1971 Convention, any notifications with pertinent information in support of the proposed control status of the substance in question, giving special attention to data on the actual or likely nature and magnitude of the public health and social problems warranting the inclusion of a substance in one of the schedules of the 1971 Convention.

9. Only the notification procedure initiates the process of reviewing the scope of control of a substance under the 1961 Convention and the 1971 Convention. For instance, while there have been several Commission resolutions on ketamine,[1] there has been no notification made to the Secretary-General.

[1] Resolutions 49/6, 50/3 and 52/8.

10. As mentioned above, the number of notifications and Commission decisions on the scope of control continues to decline: from 1980 to 1989 there were 79 decisions, from 1990 to 1999 there were 20, from 2000 to 2009 there were 10 and from 2010 to 2013 only 2. Most notifications have been made by WHO and few by Member States. Regarding precursor chemicals under the 1988 Convention, most notifications have been made by the International Narcotics Control Board.[2]

2. Risk assessment and recommendations

11. Pursuant to the 1961 Convention and the 1971 Convention, WHO carries out a risk assessment of the substance under review.[3] That medical and scientific evaluation is carried out by the WHO Expert Committee on Drug Dependence. In general terms, the role of WHO is to undertake an assessment of the medical properties and liability to abuse of any substance and to recommend to the Commission an appropriate level of control under the international drug control conventions, if control is deemed necessary.

12. One of the core functions of WHO is to ensure access to quality medicines worldwide. When examining the risks of dependence and harm relating to specific substances, WHO considers the therapeutic usefulness of the substance, in accordance with the definitions for appropriate scheduling. Both the 1961 Convention and the 1971 Convention provide for control of substances that are liable to similar abuse and similar ill effects as substances already controlled under those conventions. When considering substances that exhibit abuse characteristics similar to those of substances regulated under both conventions, the Committee will first consider the applicability of the 1961 Convention; if it is found not to apply, then the analysis is made using the criteria of the 1971 Convention.

13. The process for WHO to make such a recommendation is resource-intensive, in terms of both financial and human resources, and requires a substantial amount of time. Steps in the process include:

(a) Circulation of a questionnaire on the substance under review, analysing the data;

(b) Selecting temporary experts to prepare a pre-review or critical review document;

(c) Peer reviews of documents prior to a meeting of the Expert Committee on Drug Dependence;

(d) Convening of that Expert Committee by WHO;

(e) Analysis by the Expert Committee of the need for a change in the status of a substance (new control or change in level of scheduling) based on evidence gathered from literature and data collected directly from Member States using a questionnaire;

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[2] While notifications by member States result in a critical review, notifications by WHO, members of its Expert Committee on Drug Dependence and the International Narcotics Control Board can result in a pre-review.

[3] For scheduling under the 1988 Convention, the International Narcotics Control Board carries out a scientific assessment.

(f) The Expert Committee making a recommendation to the Director General of WHO;

(g) The Director General communicating the recommendation to the Commission through the Secretary-General.

14. The Expert Committee on Drug Dependence is a panel composed of experts chosen by the Director General of WHO from diverse domains. Observers from United Nations agencies are invited to participate. The Expert Committee reviews available information on substances being considered for international control and advises the Director General. The advice of the Expert Committee concerns scientific, medical and public health findings in accordance with the criteria established in the conventions. Its responsibilities are (a) a pre-review to determine whether a substance should be subject to critical review and (b) a critical review to assess the dependence-producing capability of each substance under review, the likelihood of abuse and of causing public health and social problems, and its usefulness in medical therapy, as well as to advise on the appropriate schedule under one of the conventions, if control is needed.[4] A critical review is initiated when (a) there has been notification from a party to the 1961 Convention or the 1971 Convention concerning the scheduling of a substance; (b) there has been an explicit request from the Commission on Narcotic Drugs to review a substance; (c) the pre-review of a substance has resulted in an Expert Committee recommendation for critical review; or (d) information is brought to the attention of WHO indicating that a substance is clandestinely manufactured or is of especially serious risk to public health and society, with no therapeutic use recognized by any party.

15. The WHO secretariat assembles the data on substances for critical review. The critical review document, on which the Expert Committee bases its assessment, includes a summary of medical literature on the substance under review, data collected from international drug control bodies and questionnaire responses from ministers of health in Member States. The draft critical review document, including the report on the questionnaire, is transmitted to requesting governments, institutions, organizations or other interested parties that have collaborated in its preparation, and they may provide comments on the draft. For each substance, the critical review document will be peer-reviewed by two experts from WHO expert advisory panels, including an evaluation of the strength of evidence presented. If there are data limitations or omissions, they are identified and remedied as needed. The critical review document, including the report on the questionnaire, is provided to members of the Expert Committee on Drug Dependence and posted on the WHO website. The information received by WHO for use in the review will be kept confidential if so requested by the provider.

16. The Expert Committee prepares a summary assessment of each substance reviewed and advises the Director General on its assessment and recommendation. The Expert Committee reports are communicated to the Commission on Narcotic Drugs and made available on the WHO website.

[4] A third responsibility is related to exempted preparations under the 1971 Convention.

17. The length of the process and the infrequency of Expert Committee meetings in recent years have posed a challenge for providing the necessary inputs for the Commission's scheduling process.

3. Decisions on control measures

18. Under article 3, paragraph 3 (iii), of the 1961 Convention, the Commission takes decisions to amend the schedules only in accordance with the recommendations of WHO, but it can also decide not to make the amendments.

19. Under the 1971 Convention, the Commission may decide that a substance will be added to a schedule, transferred from one schedule to another or removed from any of the schedules, on the basis of the results of the WHO assessment. The Commission has broad discretionary powers to take into account economic, social, legal, administrative or other factors, but may not act arbitrarily. Article 2, paragraph 5, of the 1971 Convention specifies that the assessments of WHO as to medical and scientific matters shall be determinative, and the Commission cannot base its decisions on other medical or scientific views. However, the Commission's view can be different from that of the Expert Committee, bearing in mind the economic, social, legal administrative and other factors that the Commission may consider relevant.

20. Under both the 1961 Convention and the 1971 Convention, a party can challenge the decision taken by the Commission by filing for review of the decision by the Economic and Social Council. The decision of the Council on the matter is final.[5]

21. Both the 1961 Convention and the 1971 Convention include a possible intermediate step in the scheduling procedure, which provides that the Commission or the parties, after having received all relevant information but pending the assessment by WHO, shall examine the possibility of applying provisional control measures. Under the 1961 Convention there are two different provisions dealing with such measures. Under the discretionary provision, where parties are required to "examine in the light of the available information the possibility" of applying provisional control to a substance, it is left to the judgement of each party to apply the control measures or not. Under the mandatory provision, the Commission, pending its final decision on the matter, may require parties to place the substance under provisional control.[6] The 1971 Convention includes only a discretionary provision,[7] leaving it to the judgement of each party to apply provisional control measures. The possibility of applying provisional mandatory control measures under the 1961 Convention has hardly ever been used in the past: in one case it was considered, but in the end not applied, namely the case of pentazocine in 1981,[8] which in 1984 was added, through normal measures, to Schedule III of the 1971 Convention.[9] Decisions taken by the Commission for provisional scheduling of a substance are final and are not subject to review by the Council.

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[5] Art. 3, paras. 8 and 9, of the 1961 Convention; and art. 2, para. 8, of the 1971 Convention.

[6] Art. 3, para. 3 (i) and (ii), of the 1961 Convention.

[7] Art. 2, para. 3, of the 1971 Convention.

[8] See E/CN.7/668.

[9] See E/CN.7/1984/13.

B. Challenges related to data collection

22. While challenges to the scheduling process do not apply only to new psychoactive substances, those substances do provide examples of such challenges. The UNODC report entitled *The challenge of new psychoactive substances*[10] revealed the rapid increase in new psychoactive substances in many parts of the world in the last decade. The number of new psychoactive substances reported to UNODC by Member States rose from 166 at the end of 2009 to 251 by mid-2012 and to 354 (including 6 substances to be yet verified) by August 2013. However, one of the main challenges is that there seems to be no clear indication as to which of those are currently circulating and their distribution in different parts of the world or the harm caused by each substance.

23. WHO requires data to evaluate the risks and harm potential of a given substance. When preparing the draft critical review document, WHO should include, where feasible, the following information: (a) substance; (b) chemistry, including general information on synthesis, preparation and properties; (c) ease of convertibility into controlled substances; (d) general pharmacology; (e) toxicology; (f) adverse reactions in humans; (g) dependence potential; (h) abuse potential; (i) therapeutic applications; (j) listing on the WHO Model List of Essential Medicines; (k) marketing authorizations (as medicine); (l) industrial use; (m) non-medical use, abuse and dependence; (n) nature and magnitude of public health problems related to abuse and dependence; (o) licit production, consumption and international trade; (p) illicit manufacture and traffic, and related information; (q) current international controls and their impact; (r) current and past national controls; and (s) other relevant medical and scientific information. Data are often lacking in the areas where they are required.

24. Difficulties arise from countries' differing capacities to collect the data that form the basis for the WHO analysis. Challenges include laboratory capacity for testing and linking events to specific substances; poly-substance abuse, which makes it difficult to attribute effects to a specific substance; social harm data (e.g. related to driving, violence) being difficult to collect; differences in the capacities of archiving systems; and divergent country priorities. Inconsistency of terminology affects basic data-collection tools, and the variance is magnified by translations.

25. The expert consultations discussed the fact that independent publications on risks and harm potential were scarce and often did not contain systematic data. The proliferation of new substances and rapid turnover did not allow sufficient data to evolve on risk and harm. Current control measures also affected research and data collection in clinical situations. Furthermore, for rapidly evolving new psychoactive substances, current clinical and health data were insufficient. The possible new options of generic or analogue scheduling considered chemical similarity or receptor similarity with substances under control, but the clinical effects and risks were not necessarily similar.

26. The expert consultations found that it was useful, in order to identify options for addressing the data-collection problem and improving the functioning of the

[10] Available at www.unodc.org/documents/scientific/NPS_2013_SMART.pdf.

notification and assessment processes, to briefly review monitoring mechanisms currently in place at the national, regional and international levels:

(a) The European Union was the only region with a drug control system that allowed the monitoring and control of new psychoactive substances. The initiative to place a substance under control was the result of regional monitoring of new substances through the European early warning system. Up to June 2013, 12 new psychoactive substances had been subject to a risk assessment, and 9 of them had been placed under control measures by the Council of the European Union;

(b) The International Criminal Police Organization (INTERPOL) carried out intelligence analyses of trends, modi operandi, networks, methods of concealment and routes of criminal activities involving new psychoactive substances. Information was then shared with Member States, whereupon investigations were coordinated;

(c) The World Customs Organization (WCO) aimed to facilitate new psychoactive substance-related operations among its member States. The WCO Customs Enforcement Network represented a central global depositary of enforcement-related information that was accessible to customs administrations. External organizations could access CENcomm, a secure messaging system for cross-border operations;

(d) The UNODC early warning advisory was launched in June 2013 as a response to the emergence of new psychoactive substances at the global level. The early warning advisory was aimed at monitoring, analysing and reporting trends in new psychoactive substances, as a basis for effective evidence-based policy responses. It also served as a repository of information on those substances and a platform for providing technical assistance to Member States;

(e) The International Narcotics Control Board planned to launch a task force focusing on the gathering and sharing of operational intelligence on new psychoactive substances, modelled on its Precursors Task Force mechanism. (The task force has since been launched.)

III. The way forward

27. The present section identifies possible approaches to make the scheduling process more effective, based on findings of the international expert consultations on new psychoactive substances.

1. Facilitating the scheduling procedures

28. The expert consultations found that efforts could be made to prioritize substances by controlling the most harmful ones first. Any approach to accommodate a rapidly growing number of new substances should consider chemical similarities along with the data to quantify misuse in order to prioritize substances for evaluation. It was stressed that all available clinical and public health data and data on medical usefulness needed to be taken into account to make recommendations.

29. WHO had developed a prioritization strategy for risk assessments. It included the use of fast-track expert consultations and the consideration of a critical review without pre-review for substances with proven harm and with no medical use, based on data from forensic laboratories, regional and international organizations, such as the European Monitoring Centre for Drugs and Drug Addiction and UNODC, as well as information from Member States.

30. Notifications by States parties to the conventions could form the basis for prioritization of substances for review, which meant that a critical review could be started immediately, without being preceded by a pre-review.

31. WHO stressed the value of the current system of proper risk evaluation and expressed concern about the possible impact of group control, rapid procedures and temporary control measures, if not based on appropriate scientific evaluations.

32. Many substances not under control showed chemical or receptor similarity with controlled substances. Bringing groups of substances under control would have the advantage of addressing a large number of substances at one time, thereby responding to the rapidly growing number of substances on the market, as well as to the alterations to substances designed to circumvent control measures. However, WHO noted that the clinical effects and risks were not necessarily similar between individual substances. WHO experts stressed that the conventions required the evaluation of the public health and social problems associated with each substance to be brought under control.

33. The expert consultations discussed ways to better synchronize meetings of the Expert Committee on Drug Dependence with sessions of the Commission on Narcotic Drugs, including by aligning the meetings of the Expert Committee with the schedule of the Commission in order to avoid extended delays. The “Guidance on the WHO review of psychoactive substances for international control”[11] mentioned that the schedule for the review procedure should be set by the secretariat, bearing in mind the calendar of the Commission and its procedural requirements. WHO indicated that the Expert Committee review cycle could be adapted to the sessions of the Commission. In addition, the reconvened sessions of the Commission could consider urgent scheduling issues, if necessary.

34. It was recalled that Commission resolution 2 (S-VII) of 1982, entitled “Procedure to be followed by the Commission on Narcotic Drugs in matters of scheduling of narcotic drugs and psychotropic substances”, was aimed at establishing clearer timelines for the Commission’s scheduling functions. In that resolution WHO was requested to forward its recommendations and assessments to the Secretary-General at least three months prior to the Commission’s session, and the Secretary-General was requested to forward the assessment and other relevant information to the States parties at least two months prior to the session.[12]

35. The fact that in 1984 the Commission made 35 scheduling decisions, including 33 regarding types of benzodiazepines for control in Schedule IV of the 1971 Convention, showed that there was no limitation on the number of scheduling decisions taken by the Commission during a single session.

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[11] Available at http://apps.who.int/medicinedocs/en/d/Js17538en/.

[12] See also Commission resolution 4 (XXX).

2. Enhancing the availability of data

36. It was found that data-collection methods might need to be reviewed in order to strengthen coordination at the national, regional and international levels. Improved access to national authorities with relevant information might be needed in order to obtain the required data. Other needs included further standardization of terminology; addressing disparities in national capacities, e.g. in forensics and toxicology; mechanisms to collect data from the health-care sector; guidance on the development of national early warning systems; definitions of minimum criteria and indicators; and a determination of the scope of information disclosure when issuing early warnings.

37. There was also a need for enhanced cooperation and collaboration between various monitoring systems, particularly in the collection and sharing of information at the regional and international levels. This would facilitate more efficient data collection and alleviate the burden on countries in reporting similar data to multiple organizations. It was proposed that the UNODC early warning advisory could broaden its scope, in collaboration with WHO, to collect health-related data that could contribute to the risk-assessment activities of WHO. It could be used as a platform to collate existing information, ensure effective coordination at the global level and subsequently simplify the reporting burden on governments. UNODC and WHO could consider working together on the development of an inter-agency mechanism to improve the collection of relevant data on health. Data could possibly also be shared by other organizations, including data from the European early warning system.

38. WHO was in the process of revisiting its mechanisms for data collection with the aim of establishing more proactive approaches to data collection. A more vigorous effort to collect data from Member States could include a revised questionnaire and tapping into more sources to acquire data, including the data made available by actors such as UNODC and the International Narcotics Control Board through their reports. The "Guidance on the WHO review of psychoactive substances for international control" provided that WHO should routinely collect data related to psychoactive substances that are being abused or might have abuse potential, as well as substances convertible into such substances. The UNODC early warning advisory would continue to provide a platform for sharing legislative information as a knowledge hub.

3. Raising awareness of the scheduling procedures

39. One of the challenges highlighted during the expert consultations was States parties' lack of awareness of the procedural options provided under the conventions. Raising awareness of those options, as well as of practical steps to facilitate the scheduling process, could help States parties to make fuller use of the existing legal framework.

40. Several experts suggested that there was a need for simplified guidance for States parties on the scheduling process and emphasized the importance of providing UNODC and WHO with adequate resources to pursue that work.

4. Increasing resources and capacities

41. Another issue stressed during the expert consultations was the importance of Member States' developing the technical capacity to identify substances as they emerged on the illegal drug market, including identification techniques, technical capacity, equipment and reference standards for that purpose. Capacity needs in the health-care sector to deal with rapidly emerging substances included those relating to diagnostics and substance identification from body samples, and timely sharing of information on the threat, as well as prevention and treatment options. Data-archiving systems and mechanisms for sharing such data also needed further development and strengthening.

42. Member States could consider collaborating by sharing experience in assay development and techniques to test substances. Member States could explore the design, development and implementation of online training courses on specific laboratory identification techniques and/or enhanced bilateral or subregional collaboration in order to facilitate capacity-building to use such techniques.

43. UNODC, through its early warning advisory and the international collaborative exercise, would continue to support laboratories in the identification of substances through the sharing of analytical methods and data. Sufficient resources should be made available for that purpose.

IV. Conclusions and recommendations

44. The ability to schedule substances with potential for misuse or harm is a central element of a well-functioning international drug control system; thus, any hindrance to the scheduling procedures can affect the system at its core. Facilitating the procedures should be made a priority by all actors involved.

45. In that regard, the Commission may wish to consider taking the following actions:

(a) Continue to focus attention on the consideration of its treaty-based functions, including those related to scheduling, during its upcoming sessions;

(b) Explore options to facilitate the use of the scheduling procedures;

(c) Explore the possibility of establishing mechanisms for collecting and sharing data more efficiently and for avoiding duplication of efforts in data collection at the national, regional and international levels;

(d) Request the Secretariat, in collaboration with other United Nations agencies, to continue to conduct in-depth research with reference to relevant official United Nations records and to develop, subject to the availability of extrabudgetary resources, guidance material for publication on the scheduling processes under the international drug control conventions, for the reference of Member States and other interested parties;

(e) Explore options to build the capacity of Member States to fully participate in the identification of substances, from both law enforcement and management-of-health perspectives, and to strengthen data availability, also from both perspectives. In order to do so, call upon donor countries to provide

extrabudgetary resources for that purpose and urge the relevant United Nations agencies to allocate sufficient resources to fulfil their respective roles;

(f) Explore options for improved international cooperation and coordination of research activities aimed at generating, collecting and disseminating the pharmacological and toxicological data in support of the risk assessments of new psychoactive substances by WHO and regional and national bodies;

(g) Explore the possibility of clarifying procedures, including by setting a timetable for the scheduling process, by eventually revitalizing or updating the provisions of Commission on Narcotic Drugs resolution 2 (S-VII);

(h) Urge Member States to undertake resource mobilization for United Nations agencies to perform their mandated functions.

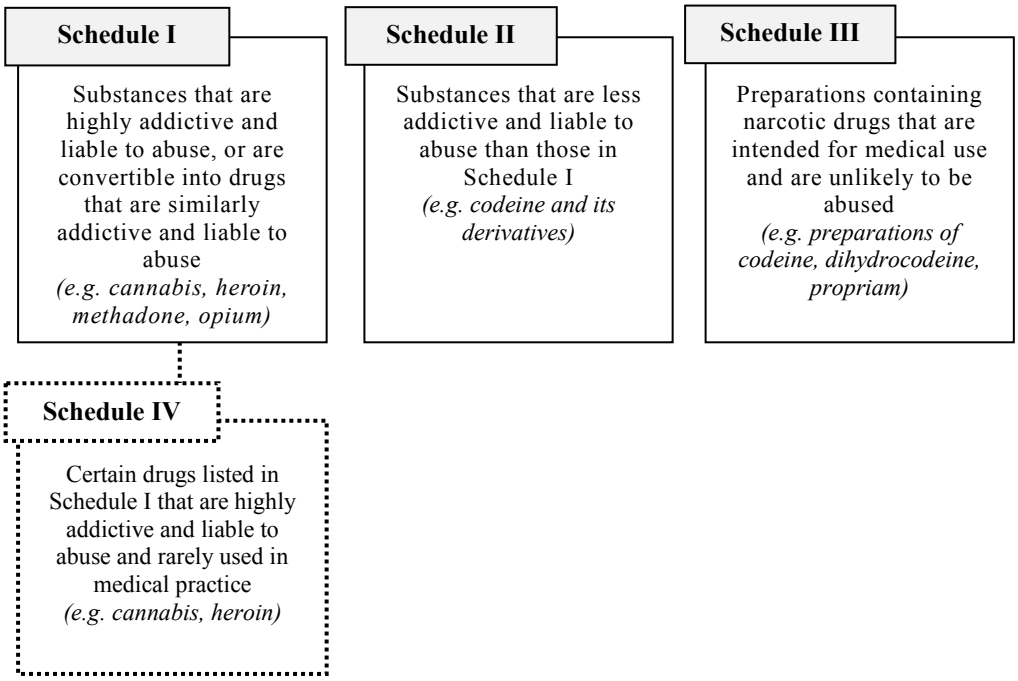
Annex I

Procedure to change the scope of control of substances under the 1961 Convention and the 1971 Convention

I. Structure of schedules under the 1961 Convention and the 1971 Convention

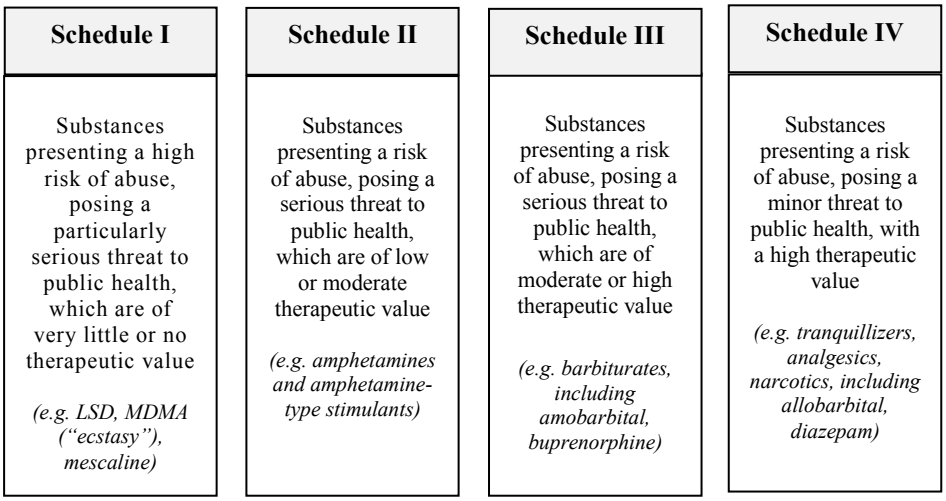
1. In the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, narcotic drugs and their preparations are listed in four schedules according to their dependence potential, abuse liability and therapeutic usefulness (see figure I).

Figure I
1961 Convention



2. Substances in Schedule I are highly addictive and liable to abuse. Schedule II consists of drugs that are considered to be less liable to abuse and that are more widely used in medicine. Schedule III consists of preparations that contain narcotic drugs, but that are intended for medical use and are unlikely to be abused. These preparations are exempt from certain control measures because of their consumption. Schedule IV consists of certain drugs listed in Schedule I (all drugs in Schedule IV must be included in Schedule I) that are considered to be particularly harmful, meaning highly addictive and liable to abuse. Substances in Schedule IV are rarely used in medical practice.

Figure II
1971 Convention



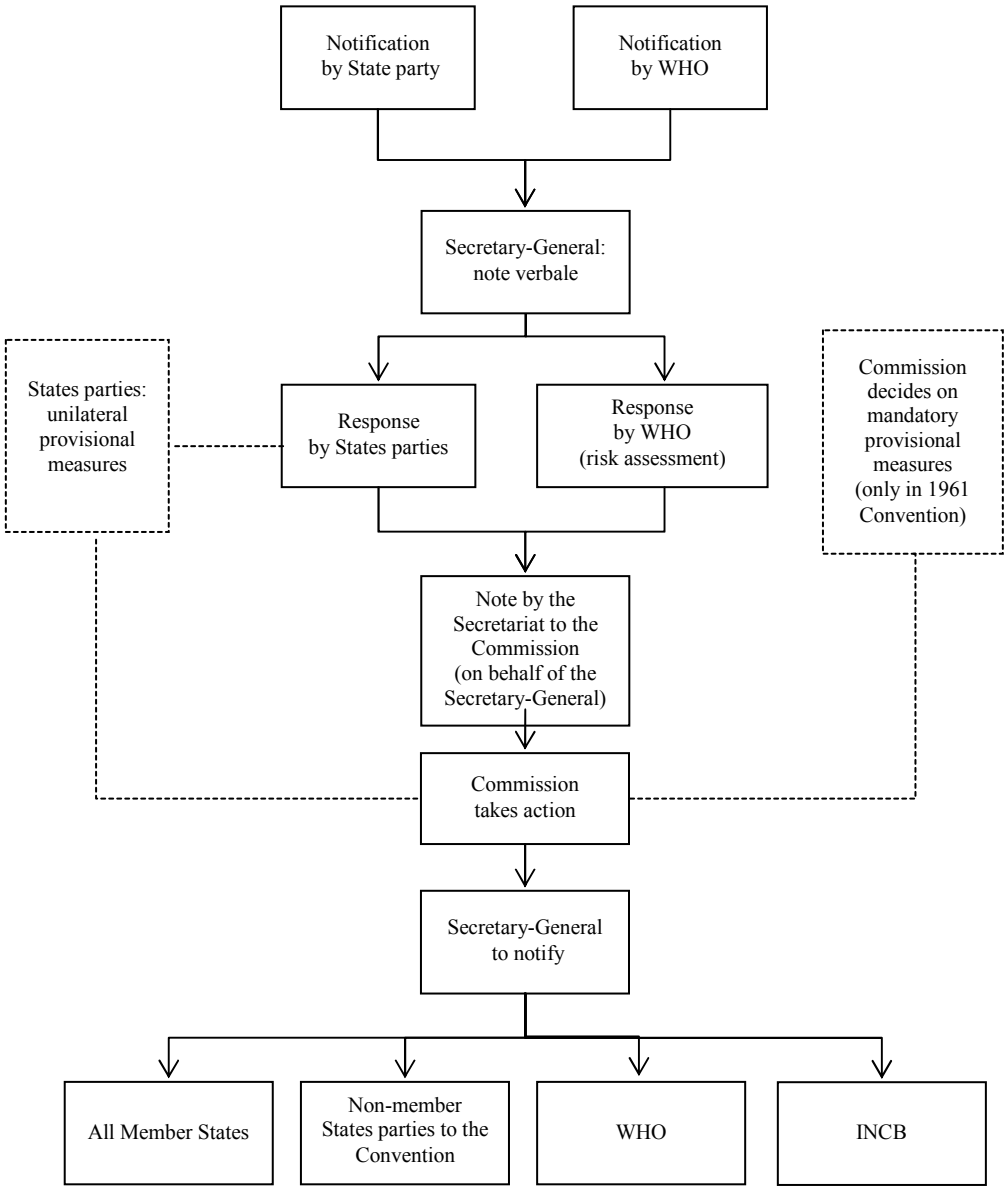
3. In the Convention on Psychotropic Substances of 1971, control measures are categorized in four schedules, depending on the relationship between the therapeutic usefulness and the public health risk of the substances. The four schedules use a sliding scale of those two variables: inclusion of Schedule I implies high public health risk and low therapeutic utility, and therefore the strictest control measures, whereas inclusion in Schedule IV implies the opposite, lower public health risk and higher therapeutic utility (see figure II).

II. Scheduling procedures

4. The procedures to change the scope of control are established by article 3 of the 1961 Convention and article 2 of the 1971 Convention. Figure III gives a simplified overview of the scheduling process under the conventions.[a]

[a] It does not include the option of notifications by Expert Committee on Drug Dependence members and the International Narcotics Control Board leading to a pre-review.

Figure III
Scheduling process



5. The Commission on Narcotic Drugs may decide, on the basis of recommendations of the World Health Organization (WHO), to place narcotic drugs and psychotropic substances under international control or to amend the schedules. The discretion of the Commission on Narcotic Drugs differs between the 1961 Convention and the 1971 Convention. A number of substances were included in the original list when the two conventions entered into force.

1. Notification

6. Under both conventions, a party to the convention or WHO can send a notification to the Secretary-General regarding an amendment to the schedules. An amendment could involve:

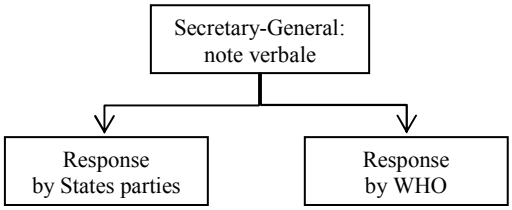
(a) Placing a substance under international control (by adding it to one of the schedules);

(b) Transferring a substance from one schedule to another;

(c) Exempting a preparation from certain controls or freeing a drug from international control.

7. The notification should contain the chemical formula of the substance and its known names. It can be sent to the Secretary-General in any of the official languages of the United Nations. Information in support of the notification should include all relevant data (data on research or clinical experiments, etc.), which enables WHO to initiate the scientific assessment and assists the Commission on Narcotic Drugs in performing its scheduling functions.

Figure IV
Notification



8. The Secretary-General transmits the notification and all relevant information to the parties and, if the notification is made by a State party, also to WHO (see figure IV).

9. With the transmission of the notification, the Secretary-General invites parties to the Convention to provide additional relevant information and comments on the substance in question, and simultaneously initiates the review and assessment process of the substance by WHO, in the event that the process has been initiated by a Member State. The Expert Committee on Drug Dependence considers the notification and determines whether the substance has harmful effects that justify international control.[b] WHO then makes a recommendation to the Commission on Narcotic Drugs as to whether the substance should be scheduled and in which schedule of the 1961 Convention or the 1971 Convention it should be placed.[c]

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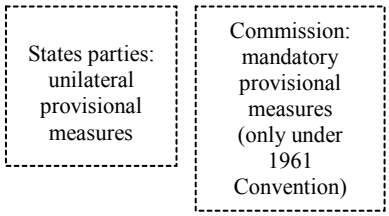
[b] WHO must determine whether the substance is liable to similar abuse and productive of similar ill effects as the drugs in Schedule I and II or is convertible into a drug (art. 3, para. 3 (iii), of the 1961 Convention and art. 2, para. 4, of the 1971 Convention).

[c] If WHO recommends that the substance be placed in Schedule I, it may also recommend that it be placed in Schedule IV of the 1961 Convention.

2. Provisional control

Figure V
Provisional control measures



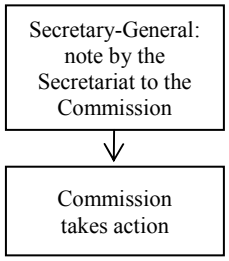
10. Since the procedure set forth in article 3 of the 1961 Convention and article 2 of the 1971 Convention may in some cases be too time-consuming to prevent widespread abuse before bringing a substance under control, both conventions include a possible intermediate step in which the Commission on Narcotic Drugs, after having received all relevant information but pending the WHO assessment, examines the possibility of applying provisional control measures (see figure V). The provisions for such measures differ in the two conventions.

11. Under the 1961 Convention there are two provisions dealing with such measures. Under the discretionary provision, parties to the Convention are required to "examine in the light of the available information the possibility" of applying provisional control to a substance. It is left to the judgement of each party to apply the control measures or not. Under the mandatory provision, the Commission, pending its final decision on the matter, may require parties to place the substance under provisional control. The possibility of applying provisional mandatory control measures has been pursued only once according to the information available and in the end was not applied by the Commission in 1981.[d]

12. The 1971 Convention includes only a discretionary provision, in article 2, paragraph 3, leaving it to the judgement of each party to the Convention whether or not to apply provisional control measures.

3. Action by the Commission

Figure VI
Action by the Commission



[d] See E/1981/24-E/CN.7/668.

13. The Commission considers scheduling at its session, under the agenda item entitled, “Implementation of the international drug control treaties: changes in the scope of control of substances”, on the basis of a note by the Secretariat containing any notification and supplementary information transmitted by a party or WHO to the Secretary-General, the recommendation of WHO, and additional information on the proposed changes provided by Member States (see figure VI).

14. Under the 1961 Convention, the Commission can make changes in the Schedules only in accordance with recommendations of WHO, but it can also decide not to make the changes recommended. Under the 1971 Convention, the Commission may decide (even contrary to the recommendation of WHO) to place a substance under international control, to not place a substance under international control or to place it out of international control. The Commission can place a substance in a different schedule from that recommended by WHO. The Commission has broad discretionary powers to take into account economic, social, legal, administrative or other factors, but may not act arbitrarily. Article 2, paragraph 5, of the 1971 Convention specifies that the assessments of WHO as to medical and scientific matters are determinative, meaning that the findings of WHO have to be accepted and the Commission cannot base its decisions on other medical or scientific views. The Commission, however, can make a decision based on other factors. If WHO finds that a substance has significant therapeutic usefulness, the Commission cannot place the substance in Schedule I, which would restrict the availability of the substance for medical and scientific purposes.

4. Commission on Narcotic Drugs voting procedure

15. The Commission may, before taking a vote to place the substance in question under international control, or to reschedule the substance according to the recommendation, decide not to vote and rather to seek more information from WHO.[e]

16. Article 17, paragraph 2, of the 1971 Convention provides that decisions of the Commission shall be taken by a two-thirds majority of the Commission’s total membership. Decisions of the Commission to change the scope of control of substances under the 1961 Convention are taken by a majority of its “members present and voting”.[f] In practice, votes have been taken by show of hands. Member States may request a roll-call vote.[g]

17. The Commission may decide on a recommendation through voting by mail. Its resolution 1 (XX) of 1965 provides that if WHO notifies the Secretary-General and recommends the scheduling of a substance and the Commission will not be in session for the following three months, a decision should be taken by the Commission before its next session. The Secretary-General is requested, for that purpose, to arrange in these exceptional circumstances for a decision of the Commission to be taken by a vote of its members by mail or telegram, and for a

[e] See e.g. Commission on Narcotic Drugs decision 50/2.

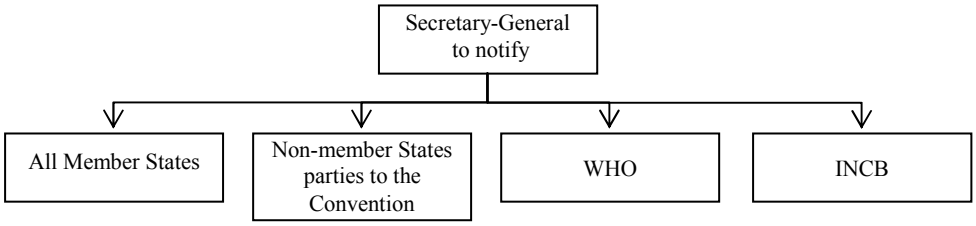
[f] Rules of procedure of the functional commissions of the Economic and Social Council, rule 58.

[g] Ibid., rule 59.

report to be made to the Commission at its next session. The application of this procedure is generally feasible only in respect of non-controversial questions.[h]

5. Implementation of Commission decisions

Figure VII
Communication of Commission decisions



18. As shown in figure VII, the Secretary-General is required to communicate the decisions taken by the Commission to the Members of the United Nations, non-member States that are parties to the Convention, WHO and INCB.[i]

19. Decisions of the Commission become effective on the date of the receipt of the communication for the 1961 Convention and 180 days after the date of the communication for the 1971 Convention. Under the 1971 Convention, a State party may transmit to the Secretary-General, within that period of 180 days, a written notice (right of non-acceptance) citing the exceptional circumstances and reasons why it is not in a position to implement all provisions of the decision.[j]

20. The right of non-acceptance refers to any decision adding or transferring a substance to a schedule of the 1971 Convention.[k] However, if the International Narcotics Control Board concluded that the aims of the Convention were endangered as a result of a party's non-acceptance of a decision, it would have the possibility of applying the sanctions foreseen in article 19 of the 1971 Convention. States parties can withdraw their notification of non-acceptance at any time. The 1961 Convention does not provide for a right of non-acceptance.

21. The right to request a review of the decision provides that parties to the 1971 Convention have the possibility of requesting, within 180 days of receipt of notification of the decision, that the Economic and Social Council review a decision of the Commission. The request must be transmitted to the Secretary-General.[l] The 1961 Convention also provides that any party can file a request within 90 days of receipt of notification of the decision. The Secretary-General transmits copies of the request for review to the Commission, WHO and all States parties to the Convention and invites the parties to submit comments within 90 days. A decision of the

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[h] In 1966 the procedure worked for acetorphine and etorphine and in 1968 for codoxime, but its use has become increasingly challenging. For example, in 1971 it did not prove possible to reach a conclusion regarding propiram, and in 1973 regarding nicodicodine preparations and drotebanol, and the Commission took a vote at its session.

[i] Art. 3, para. 7, of the 1961 Convention; art. 2, para. 7, of the 1971 Convention.

[j] Art. 2, para. 7, of the 1971 Convention.

[k] Ibid.

[l] Art. 2, para. 8, of the 1971 Convention.

Commission not to take action on a WHO recommendation is not subject to review by the Economic and Social Council.

22. The Council may confirm, alter or reverse the decision of the Commission under both conventions, guided by the purpose of protecting public health. The Council is not bound to the WHO assessment and has broad discretion in selecting the reasons for its decision. While the review is pending, the original decision of the Commission remains in effect.

23. There are rare cases where Member States have made use of the possibility of requesting the Council to review a decision of the Commission.[m]

24. Under both conventions, the process is completed with the Secretary-General transmitting the decision of the Council to all States Members of the United Nations, non-member States parties to the Conventions, WHO and the Commission.

[m] For example, the notification by the Government of Spain to the Secretary-General requesting that the Economic and Social Council review and reverse the decision taken by the Commission on the inclusion of dextropropoxyphene in Schedule II of the 1961 Convention (decision 1 (S-VI) of 14 February 1980). The Council decided to confirm decision 1 (S-VI).

Annex II

Procedure to change the scope of control of substances under the 1988 Convention[a]

1. Notification/initiation

1. Under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, a request to change the scope of control of substances can be initiated either by a party or by the International Narcotics Control Board.[b] An amendment could involve:

(a) Placing a non-scheduled substance under international control (by adding it to Table I or Table II of the Convention);

(b) Deleting a substance from Table I or Table II; or

(c) Transferring a substance from one table to another.

2. The initiator notifies the Secretary-General and furnishes him with information in support of the notification. Upon receipt, the Secretary-General transmits that notification and any relevant information to the parties (in the form of a note verbale), to the Commission (in the form of a note by the Secretariat) and, when the notification is made by a party, to the International Narcotics Control Board.[c]

3. The parties then communicate their comments concerning the notification to the Secretary-General, together with all supplementary information that could assist the Board in making an assessment and the Commission in reaching a decision. The format for the communication of comments is a questionnaire that is disseminated by the Secretary-General as part of the note verbale.

Notifications initiated by the International Narcotics Control Board

To date, with the exception of a notification concerning a set of 10 substances in 1991 and a notification concerning norephedrine in 1997, all other scheduling decisions by the Commission have been based on notifications initiated by the International Narcotics Control Board. A recommendation by the Board for the scheduling of *alpha*-phenylacetoacetonitrile will be before the Commission at its fifty-seventh session.

2. Assessment

4. Under the 1988 Convention, the assessment of a substance for possible inclusion in, deletion from or transfer between the tables of that Convention is conducted by the International Narcotics Control Board. Taking into account the extent, importance and diversity of the licit use of the substance, and the possibility and ease of using alternate substances both for licit purposes and for illicit drug manufacture, the Board determines whether a substance is frequently used in the illicit manufacture of a narcotic drug or psychotropic substance and whether the

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[a] The procedure is detailed in art. 12, paras. 2 to 7, of the Convention.

[b] Art. 12, para. 2.

[c] Art. 12, para. 3.

volume and extent of the illicit manufacture of a narcotic drug or psychotropic substance creates serious public or social problems, so as to warrant international action.[d]

3. Action by the Commission

5. To enable the Commission to take a decision on these matters, it has before it a note by the Secretariat on the changes in the scope of control of substances. Such a note contains the assessment of the substance by the Board, including the likely effect of adding the substance to either Table I or Table II on both licit use and illicit manufacture, together with recommendations on monitoring measures.[e] The note also contains the notification and supplementary information transmitted by the party or by the Board to the Secretary-General, as well as additional information on the proposed changes in the scope of control of substances provided by Member States, in response to the note verbale transmitted by the Secretary-General to Member States.

6. In the case of changes in the scope of control, the Commission, when taking a decision, takes into account the assessment of the Board, which shall be determinative as to scientific matters, and takes into due consideration any other relevant factors.[f]

7. Pursuant to article 12, paragraph 5, of the Convention, the Commission may decide on changes to the scope of control by a two-thirds majority of its members.

4. Implementation of the decisions of the Commission

8. Once the Commission has taken a decision concerning the scope of control of substances, it is communicated by the Secretary-General to the International Narcotics Control Board and to all States and other entities that are, or that are entitled to become, parties to the 1988 Convention.[g]

9. Decisions taken concerning the scope of control of substances in the tables of the 1988 Convention become fully effective with respect to each party 180 days after the date of communication of the decision.[h]

10. Decisions taken by the Commission concerning the scope of control of substances are subject to review by the Economic and Social Council, upon the request of any party filed within 180 days of receipt of notification of the decision. In that case, the Council may confirm or reverse the decision of the Commission.[i]

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[d] Art. 12, para. 4.
[e] Ibid.
[f] Art. 12, paras. 4 and 5.
[g] Art. 12, para. 6.
[h] Ibid.
[i] Art. 12, para. 7.