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Item 4 (a) of the provisional agenda*
**Implementation of the international drug control treaties: changes in the scope of control of substances**

## Changes in the scope of control of substances**

### Note by the Secretariat

*Summary*

The present document contains a recommendation for action to be taken by the Commission on Narcotic Drugs pursuant to the international drug control treaties. In accordance with article 2 of the Convention on Psychotropic Substances of 1971, the Commission will have before it for consideration a proposal from the World Health Organization concerning a recommendation to move *gamma*-hydroxybutyric acid (GHB) from Schedule IV to Schedule II of the 1971 Convention.

This document also contains information on the outcome of the thirty-fifth meeting of the Expert Committee on Drug Dependence of the World Health Organization concerning the review of dronabinol and its stereoisomers.

* E/CN.7/2013/1.

** The submission of the present document was delayed owing to the deadline of 31 January 2013 for comments by Member States.

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# I. Consideration of a notification from the World Health Organization concerning scheduling under the Convention on Psychotropic Substances of 1971

1. Pursuant to article 2, paragraphs 1, 4 and 6, of the Convention on Psychotropic Substances of 1971,[1] the Director-General of the World Health Organization (WHO), in her correspondence dated 22 October 2012, notified the Secretary-General of the United Nations that WHO recommended that *gamma*-hydroxybutyric acid (GHB) be rescheduled from Schedule IV to Schedule II of the 1971 Convention (see annex).

2. In accordance with the provisions of article 2, paragraph 2, of the 1971 Convention, the Secretary-General transmitted to all Governments notes verbales, dated 9 November and 27 December 2012, annexing the notification and the information submitted by WHO in support of the recommendation to reschedule GHB from Schedule IV to Schedule II of the 1971 Convention.

3. As of 5 February 2013, the following 23 Governments provided comments on economic, social, legal, administrative or other factors relevant to the possible rescheduling of GHB from Schedule IV to Schedule II of the 1971 Convention: Algeria, Armenia, Australia, Austria, Belgium, Bulgaria, Cambodia, China, Croatia, Estonia, Guatemala, Israel, Malta, Mexico, Panama, Poland, Portugal, Qatar, Russian Federation, Slovakia, the United Arab Emirates, the United States of America and Venezuela (Bolivarian Republic of).

4. The Government of Algeria reported that the Department of Pharmacy of the Algerian Ministry of Health, Population and Hospital Reform had no objection to the transfer of GHB from Schedule IV to Schedule II of the 1971 Convention in view of its harmful medical and socioeconomic effects. Furthermore, the Department indicated that the substance was not imported into Algeria and that it was neither sold nor used in Algeria.

5. The Government of Armenia reported that the transfer of *gamma*-hydroxybutyric acid from Schedule IV to Schedule II of the 1971 Convention will not have any economic, social, legal, administrative or other implication for Armenia.

6. The Government of Australia reported the following:

> “Australia supports the rescheduling of GHB from Schedule IV to Schedule II. The scheduling change will not affect existing Australian drug controls. The relevant area of the Department of Health will require a minor administrative amendment for GHB in the ‘Export Regulations’ (a move from table 3 to table 2 in Schedule 8); and GHB is generally not permitted for medical use in Australia, as it is scheduled as a prohibited drug.”

7. The Government of Austria indicated that the current control measures concerning GHB were considered sufficient and that a transfer of GHB to Schedule II of the 1971 Convention was not deemed desirable. Furthermore, the Government of Austria indicated the following:

[1] United Nations, *Treaty Series*, vol. 1019, No. 14956.

"Four medicines that contain GHB are regularly imported into Austria or produced in Austria using imported GHB.

**Development of imports and exports in recent years** *(amounts calculated in grams as a base)*

| *Year* | *Imports (grams)* | *Exports (grams)* |
|---|---|---|
| 2009 | 95 535.91 | 971.10 |
| 2010 | 126 943.52 | 2 913.30 |
| 2011 | 129 455.10 | 6 050.70 |
| 2012 (as of 29 November 2012) | 63 591.71 | 9 785.70 |

"Currently the misuse of GHB seems to play a relatively minor role in Austria; as far as is known, GHB is currently hardly used in the scene.

**Development of police reports in recent years**

| *Year* | *Number of police reports of GHB* |
|---|---|
| 2008 | 1 |
| 2009 | 8 |
| 2010 | 7 |
| 2011 | 5 |
| 2012 | 3 |
| Total | 24 |

"In Austria, substances listed under Schedules I and II of the 1971 Convention are considered as narcotics. Narcotics are subject to stricter rules than the substances listed in Schedules III and IV of the 1971 Convention (referred to as "psychotropic substances").

"A transfer of GHB from Schedule IV to Schedule II of the 1971 Convention would therefore mean that GHB is no longer subject to the milder penalties for psychotropic substances (§§ 30-31b of Narcotics and Psychotropic Substances Act) but to the more stringent penalties for narcotics (§§ 27-28a of the stated Act). Reports by the police would therefore result in more complex and therefore more expensive procedures and lead to higher sentences being both imposed by the courts as well as actually being served by the convicted, in terms of illegal production or trade, as well as of possession for personal consumption.

"Moreover, as to the limited misuse of GHB in Austria, the transfer to Schedule II of the 1971 Convention would also lead to a disproportionate increase in the administrative burden in the field of medical use of GHB and also, to some extent, to an increase in public expenses.

"Not least, the already existing imbalance in the legal status of GHB and *gamma*-butyrolactone (GBL) needs to be considered. Both of the substances have a similar psychoactive potential and may likewise be misused as "liquid ecstasy". Unlike GHB, the broadly commercially used GBL is not subject to

any of the United Nations drug conventions and their control measures.[2] The transfer of GHB to Schedule II of the 1971 Convention would increase the already existing legal imbalance."

8. The Government of Belgium indicated that it would be able to support the reclassification of GHB from Schedule IV to Schedule II of the 1971 Convention. The Government of Belgium furthermore reported the following:

"*gamma*-Hydroxybutyric acid (GHB) is classified in accordance with article 2 §2 of the Belgian Royal Decree of 22 January 1998 governing certain psychotropic substances and relating to risk reduction and treatment advice.[3]

"The above-mentioned article lists:

"• Each substance included in Schedules I (art. 2 §1a in the above Royal Decree) and II (art. 2 §1b of the Royal Decree) of the Convention on Psychotropic Substances of 1971.

"• As well as any substance not covered by the 1971 Convention, or covered by it in less strict terms, for which Belgium has decided that regulatory provision should be as strict as in the case of substances listed in Schedule II of the 1971 Convention (article 2 §2 of the Belgian Royal Decree).

"In Belgium, GHB is already classified as if it were a psychotropic substance included in Schedule II of the 1971 Convention."

9. The Government of Bulgaria indicated that it approved the rescheduling of GHB from Schedule IV to Schedule II of the 1971 Convention.

10. The Government of Cambodia reported that it supported the opinion that GHB should be transferred from Schedule IV to Schedule II of the 1971 Convention.

11. The Government of China indicated that it had no objection to the recommendations of WHO to transfer GHB from Schedule IV to Schedule II of the 1971 Convention.

12. The Government of Croatia indicated that the Ministry of Health, as the competent ministry, had concluded that the transfer of GHB from Schedule IV to Schedule II of the 1971 Convention was entirely well founded and justified.

13. The Government of Estonia reported the following:

"Estonia has solved the problem with GHB in the following manner:

"Sodium oxybate is a controlled substance since 1997 (Schedule IV) in Estonia. Since 2002, *gamma*-hydroxybutyric acid (GHB) is listed in Schedule I (where are substances from the Schedule I and II of the 1971 Convention) with

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[2] In Austria, *gamma*-butyrolactone (GBL) is subject to the Neue-Psychoaktive-Substanzen-Gesetz (New Psychoactive Substances Act) as of 1 January 2012. This new law provides for criminal liability of production and trade of the covered substances for the purpose of misuse.

[3] Available from www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1998012251&table_name=loi.

an exception for medicinal products containing sodium oxybate. Sodium oxybate is listed in schedule IV.[4]

"In Estonia, sodium oxybate (N01AX11) is used as a general anesthetic in hospitals (Natrii oxybutyras, inj. 20 5 200 mg/ml 10 ml N10).

"According to Regulation No. 30 of the Minister of Social Affairs of 18 February 2005, entitled "The Conditions and Procedure for the Issue of Prescriptions for Medicinal Products and for the Dispensing of Medicinal Products by Pharmacies and the Format of Prescriptions" (§2 section 7), it is not permitted to issue prescriptions for injectable pharmaceutical forms containing ketamine, fentanyl, thiopental, sodium oxybate, alfentanil, sufentanil and remifentanil and oral pharmaceutical forms of buprenorphine.

"There is the preparation Xyrem oral solution 500 mg/ml 180 ml (N07XX04) in the Community register for treatment of cataplexy in adult patients with narcolepsy. This preparation is not currently marketed/available in Estonia. There has been established a limit for the maximum amount of a medicinal product prescribed on the basis of one prescription: 90 grams.

14. The Government of Guatemala indicated that in Guatemala there were no registered pharmaceutical products that contained *gamma*-hydroxybutyric acid (GHB) as an active ingredient in their formulas, for which reason the Department of Regulation and Control of Pharmaceutical and Similar Products had no objection to the possible transfer of GHB from Schedule IV to Schedule II of the 1971 Convention.

15. The Government of Israel reported that it had no objection to the rescheduling of GHB as proposed by WHO. Furthermore, the Government indicated the following:

"Israel's Dangerous Drugs Ordinance does not differentiate between the different drugs by schedules, but all drugs in the ordinance have the same status. GHB has been considered an illicit drug in Israel since 2003, when it was added to the Dangerous Drugs Ordinance. In 2007, GBL was added to the Ordinance. There have not been many cases of seizures of these substances. The customs authorities managed to successfully seize most shipments entering the country. Although GHB is also known as the "rape drug", there has been no evidence of such cases in Israel.

16. The Government of Malta reported that it supported the rescheduling of GHB from Schedule IV to Schedule II of the 1971 Convention.

17. The Government of Mexico indicated the following:

"The National Center for Planning, Analysis and Information for Combating Crime (CENAPI), through the Attorney General's Office (PGR), communicated that, while no seizures of GHB have been made in Mexico, the proposal of WHO to transfer the substance to Schedule II of the 1971 Convention is considered convenient, as this measure of control would

[4] The list of controlled substances in Estonia is available from www.riigiteataja.ee/aktilisa/1301/1201/1014/Lisa1.pdf.

contribute to preventing Mexico from becoming a route for the smuggling of this drug towards the United States, where its illicit consumption exists.

"Meanwhile, the Federal Commission for Protection against Sanitary Risk (COFEPRIS), through the Department of Health (SSA), undertook consultations on the matter with its Executive Directorate for Regulation of Drugs and Psychotropic and Chemical Substances, which in turn emphasized that the agreement which establishes the classification and codification of goods and products whose import, export and permitted entry and exit are subject to sanitary regulation by the Department of Health, classifies the substance *gamma*-hydroxybutyric acid (GHB) with the customs code 2918.19.99, thereby obligating all companies wishing to import the substance to request an import permit from COFEPRIS.

"In addition, after a search in the internal database, it was found that, from 2008 to date, import permits have been granted for this substance only as a standard, which means that the quantity authorized to enter the country is minimal.

"Even though the import of GHB in Mexico is not high, it is important to highlight the potent effect that the molecule presents, causing in those who consume it a sedative effect, for which reason COFEPRIS considers that the reclassification from Schedule IV to Schedule II is appropriate, in order to have a tighter control of the substance."

18. The Government of Panama indicated that GHB should be moved from Schedule IV to Schedule II of the 1971 Convention, in line with the recommendation made by the WHO Expert Committee on Drug Dependence.

19. The Government of Poland transmitted the following comments:

"The rescheduling will require a change in internal legislation, specifically, in the Act of 29 July 2005 on Counteracting Drug Addiction. Furthermore, it will have economic consequences in the form of fees levied on enterprises in connection with the ensuing need to apply for a change in the scope of licences for production and wholesale trade. There are currently 360 Polish enterprises that are licensed for wholesale trade as well as to produce narcotic drugs, psychotropic substances and category 1 drug precursors. The change of the licensing would cost each enterprise 300 zlotys (73 euros).

20. The Government of Portugal reported the following:

"Portugal endorses the opinion of the Director-General of the World Health Organization that *gamma*-hydroxybutyric acid (GHB) should be transferred from Schedule IV to Schedule II of the 1971 Convention."

21. The Government of Qatar indicated that the possible rescheduling of GHB has no effect in the economic, social, legal, administrative or other areas in the State of Qatar because it is not registered or circulated in Qatar.

22. The Government of the Russian Federation has indicated that, in its territory, the psychotropic substance *gamma*-hydroxybutyric acid (GHB) is included in Schedule III of the list of narcotic drugs, psychotropic substances and their precursors subject to control in the Russian Federation. The Government further

reported that it was not in possession of any information indicating that, in the event that the Commission on Narcotic Drugs adopted a decision on transferring GHB from Schedule IV to Schedule II of the 1971 Convention, there would be any restriction on trade in derivatives of this substance on the internal market.

23. The Government of Slovakia indicated that it accepts the recommendation of the WHO Expert Committee on Drug Dependence on the rescheduling of GHB. Slovakia further indicated that the substance would have to be rescheduled, respectively, in Act No. 139/1998 entitled "Collection of laws on narcotic drugs, psychotropic substances and preparations" and that legislative revision would require some time.

24. The United Arab Emirates reported that, pursuant to article 2 of the 1971 Psychotropic Convention, and in accordance with the provisions of article 2 of the Registration and Drug Control Department of the Ministry of Health, the Government agreed and supported the WHO Expert Committee's recommendation to move *gamma*-hydroxybutyric acid from Schedule IV to Schedule II of the 1971 Convention. The Government further reported that so far, no abuse of GHB had been reported, and it was not registered or used as a pharmaceutical preparation in the United Arab Emirates.

25. The Government of the United States reported the following:

> "The United States notes the report of the World Health Organization and the Expert Committee on Drug Dependence efforts to review substances in conformity with the process outlined in the 1971 Convention on Psychotropic Substances. WHO has an important treaty function in providing recommendations based on best evidence on substances not yet under control.
>
> "The United States appreciates the Expert Committee's efforts to conduct a critical review of *gamma*-hydroxybutyric acid, known as GHB, and ketamine and notes the recommendation that GHB be moved from Schedule IV to Schedule II of the 1971 Convention on Psychotropic Substances. The domestic consultative process is ongoing in the United States. However, the United States has domestic controls on this substance very similar to those proposed by the Expert Committee."

26. The Government of the Bolivarian Republic of Venezuela indicated that it supported the recommendation of WHO for the rescheduling of GHB. The Government further reported that the Ministry of People's Power for Health had carried out relevant consultations and communicated that there was sufficient evidence that GHB causes dependency in humans and is susceptible to abuse, which represents a public health problem.

## Action by the Commission on Narcotic Drugs

27. The notification from WHO is before the Commission for its consideration, in accordance with the provisions of article 2, paragraphs 5 and 6, of the 1971 Convention, which read as follows:

> "5. The Commission, taking into account the communication from the World Health Organization, whose assessments shall be determinative as to

medical and scientific matters, and bearing in mind the economic, social, legal, administrative and other factors it may consider relevant, may add the substance to Schedule I, II, III or IV. The Commission may seek further information from the World Health Organization or from other appropriate sources.

"6. If a notification under paragraph 1 relates to a substance already listed in one of the Schedules, the World Health Organization shall communicate to the Commission its new findings, any new assessment of the substance it may make in accordance with paragraph 4 and any new recommendations on control measures it may find appropriate in the light of that assessment. The Commission, taking into account the communication from the World Health Organization as under paragraph 5 and bearing in mind the factors referred to in that paragraph, may decide to transfer the substance from one Schedule to another or to delete it from the Schedules."

28. With regard to the decision-making process, the attention of the Commission is drawn to article 17, paragraph 2, of the 1971 Convention, which stipulates that the "decisions of the Commission provided for in articles 2 and 3 shall be taken by a two-thirds majority of the members of the Commission". From a practical point of view, that means that, for a decision to be adopted, an affirmative vote of at least 35 members of the Commission is required.

29. The Commission should therefore decide whether it wishes to reschedule GHB from Schedule IV to Schedule II of the 1971 Convention or, if not, what other action, if any, might be required.

# II. Review of dronabinol and its stereoisomers

30. At its fiftieth session, the Commission adopted decision 50/2, entitled "Review of dronabinol and its stereoisomers", in which it decided by consensus: "(a) not to vote on the recommendation of the World Health Organization to transfer dronabinol and its stereoisomers from Schedule II to Schedule III of the Convention on Psychotropic Substances of 1971; (b) to request the World Health Organization, in consultation with the International Narcotics Control Board, as appropriate, to undertake, for consideration by the Commission, a review of dronabinol and its stereoisomers when additional information became available."

31. In her communication to the Secretary-General dated 22 October 2012, the Director-General of the World Health Organization further mentioned that, following the request from the Commission on Narcotic Drugs at its fiftieth session, in March 2007, that WHO reconsider its recommendation to move dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention, the Expert Committee on Drug Dependence had discussed whether it should revisit its recommendation on dronabinol. As the Committee was unaware of any new evidence that was likely to materially alter the scheduling recommendation made at its thirty-fourth meeting, it had decided that the decision to move dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention should stand.

32. In addition, the Government of Croatia indicated that it considered that the recommendation of WHO to transfer dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention should stand.

33. The Government of Slovakia indicated that it had no reservations to moving dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention, and that it was not aware of any clinical evidence that would impede the rescheduling. Slovakia further indicated that the substance would have to be rescheduled, respectively, in its Act No. 139/1998, entitled “Collection of laws on narcotic drugs, psychotropic substances and preparations”, and that this revision of legislation would require some time.

# Annex

## Notification from the Director-General of the World Health Organization to the Secretary-General dated 22 October 2012 concerning the recommendation to reschedule *gamma*-hydroxybutyric acid from Schedule IV to Schedule II of the Convention on Psychotropic Substances of 1971, including the relevant extract from the thirty-fifth report of the Expert Committee on Drug Dependence

1. With reference to article 2 of the Convention on Psychotropic Substances of 1971, article 2, paragraphs 1, 4 and 6, I am pleased to submit the recommendations of the World Health Organization (WHO), concerning the international control of γ-hydroxybutyric acid (GHB). The recommendation is that GHB be rescheduled from Schedule IV to Schedule II of the 1971 Convention. The basis for this recommendation is set out in an extract from the report of the Expert Committee on Drug Dependence (ECDD), which advises on these issues, attached in annex 1 to this letter.

2. ECDD was informed that the WHO recommendation to move dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention was rejected by the Commission on Narcotic Drugs at its fiftieth session in March 2007. The Expert Committee noted that the Conventions allow the CND to decide differently from a WHO recommendation, based on considerations other than the medical and scientific ones considered by ECDD. Following the request from the Commission on Narcotic Drugs that WHO reconsider this issue, ECDD discussed whether it should revisit the recommendation on dronabinol. However, the Committee was unaware of any new evidence that was likely to materially alter the scheduling recommendation made at its thirty-fourth meeting. The Expert Committee therefore decided that the decision to move dronabinol and its stereoisomers from Schedule II to Schedule III of the 1971 Convention should stand.

### Annex 1

### Extract from the thirty-fifth report of the Expert Committee on Drug Dependence

### Recommendation on γ-hydroxybutyric acid (GHB)

This section provides information additional to the information presented in the report of the thirty-fourth meeting.[a] The Expert Committee discussed GHB in the context of γ-butyrolactone (GBL) and 1,4-butanediol (1,4-BD), precursors of GHB (see sections 4.4 and 4.5).

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[a] *WHO Expert Committee on Drug Dependence: Thirty-fourth Report*, WHO Technical Report Series, No. 942 (Geneva, World Health Organization, 2006). Available from http://whqlibdoc.who.int/trs/WHO_TRS_942_eng.pdf. (accessed 15 July 2012).

**Substance identification and pharmacodynamics**

γ-Hydroxybutyric acid (GHB), also known as 4-hydroxybutanoic acid and sodium oxybate, is a naturally occurring substance found in low concentrations in mammalian tissues. It is considered to act by binding to GHB-specific receptors and γ-aminobutyric acid B (GABAB) receptors. At pharmacological doses it acts as a central nervous system depressant.

**Previous reviews**

GHB was pre-reviewed during the thirty-first[b] and thirty-second[c] meetings, held in 1998 and 2000, respectively. In 2001, GHB was placed in Schedule IV of the 1971 Convention by a decision of the Commission on Narcotic Drugs. It was again pre-reviewed at the thirty-fourth ECDD meeting in 2006,[a] at which time the Expert Committee recommended a new critical review to consider its possible rescheduling.

**Evidence on dependence potential**

The Expert Committee examined additional information from the updated critical review report and peer-review reports. The Expert Committee noted that there is compelling evidence that dependence on GHB exists in humans and noted withdrawal syndromes and withdrawal seizures.

**Actual abuse**

The Expert Committee noted that at present, GHB appears to be mainly used and abused in the United States of America, Europe and Australia. Most GHB used illicitly originates from clandestine manufacture.

In their discussions, the Expert Committee and advisers agreed on the narrow margin of safety of GHB. There have been numerous reports from Europe and the United States of accidental fatal and non-fatal overdoses where GHB was implicated, both when used alone and with other substances.

The Expert Committee also noted there have been reports of GHB being used to facilitate sexual assault.

**Therapeutic usefulness**

GHB is used as a medicine in some countries on a small scale for various indications. GHB is not included in the World Health Organization Model List of Essential Medicines.[d]

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[b] *WHO Expert Committee on Drug Dependence: Thirty-first Report*, WHO Technical Report Series, No. 887 (Geneva, World Health Organization, 1999). Available from http://whqlibdoc.who.int/trs/WHO_TRS_887.pdf (accessed 15 July 2012).

[c] *WHO Expert Committee on Drug Dependence: Thirty-second Report*, WHO Technical Report Series, No. 903 (Geneva, World Health Organization, 2001). Available from http://whqlibdoc.who.int/trs/WHO_TRS_903.pdf (accessed 15 July 2012).

[d] World Health Organization, Model List of Essential Medicines, 17th ed. (Geneva, World Health Organization, 2011). Available from http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf (accessed 15 July 2012).

**Need for the substance for other purposes (e.g., industrial)**

The Expert Committee acknowledged the use of GHB in the production of a wide variety of industrial polymers.

**Measures taken by countries to curb abuse**

The Expert Committee was made aware of measures taken by 30 out of the 51 countries that responded to the questionnaire circulated by WHO in 2008 in preparation for the meeting. For example, Norway is planning to implement legal limits for driving under the influence of non-alcohol drugs including GHB. In the United States, GHB (Xyrem®) is available for the treatment of narcolepsy in association with an extensive risk management programme. Post-marketing data from this programme show minimal abuse or diversion of this product. The Netherlands recently re-assessed the risk potential of GHB and found it to be moderate to high. On this basis GHB was upgraded to List I (hard drugs) of the Opium Act of the Netherlands.

**Recommendation**

The Expert Committee considered the implications of rescheduling this substance. On the basis of available data on its toxicity and dependence potential, the Committee rated the abuse liability of GHB to be substantial, whereas the therapeutic usefulness is little to moderate. The Committee therefore came to the conclusion that GHB should be moved from Schedule IV to Schedule II of the 1971 Convention.