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Reports of advisory bodies

Expert committees and study groups[1]

Report by the Secretariat

EXPERT COMMITTEE ON DRUG DEPENDENCE

Thirty-fifth meeting of the Expert Committee on Drug Dependence Hammamet, Tunisia, 4–8 June 2012[2]

1. This meeting of the Expert Committee was the first at which the *Guidance on the WHO review of psychoactive substances for international control* (approved by Executive Board in January 2010)[3] was applied. Eleven substances were evaluated, two of which were subject to critical reviews:[4] γ-hydroxybutyric acid (4-hydroxybutanoic acid) and ketamine.

Main recommendations

2. The Committee recommended that γ-hydroxybutyric acid be moved from Schedule IV to Schedule II of the Convention on Psychotropic Substances of 1971.

3. The Committee decided that bringing ketamine under international control was not appropriate. It did not find that ketamine abuse was a significant global public-health risk, although concerns raised by some countries on its increasing illicit use were acknowledged. Further, the Committee noted that scheduling ketamine would limit access to essential and emergency surgery (because of its use for anaesthesia) and constitute a public-health crisis in countries where no affordable alternative anaesthetic is available.

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[1] The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report of meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken.

[2] WHO Technical Report Series, No.973, in press.

[3] See document EB126/2010/REC/2, summary record of the twelfth meeting, section 1.

[4] **Pre-review**: An initial review to determine whether a critical review is warranted ("the purpose of the pre-review is to determine whether current information justifies an Expert Committee critical review"). **Critical review**: a review to make decisions on scheduling or a change in scheduling ("is to consider whether the Expert Committee should advise the Director-General to recommend the scheduling of, or amending of the scheduling status of, a substance").

4. The Committee recommended critical reviews of the substances tapentadol, *N*-benzylpiperazine, γ-butyrolactone (dihydrofuran-2-one) and butane-1,4-diol for the next meeting of the Expert Committee. It concluded that a critical review of dextromethorphan was not warranted at this time because of its medicinal usefulness and relatively low abuse liability.

5. It also recommended that terminologies for substance evaluation be updated to be consistent with the International Statistical Classification of Diseases and Related Health Problems (10th and 11th revisions). It recommended further exploration of the use of pharmacovigilance data from the Uppsala Monitoring Centre (the WHO Collaborating Centre for International Drug Monitoring). It further recommended that WHO continue to promote the availability of all controlled medicines listed in its model lists of essential medicines.

Significance for public-health policies

6. The recommendation on amending the scheduling of γ-hydroxybutyric acid will be conveyed to the Commission on Narcotic Drugs which is expected to discuss the matter in March 2013. Increasing the control of this substance is unlikely to adversely affect medical availability as it has only limited therapeutic use. Some countries have already increased or are considering increasing the level of control.

7. Although the Expert Committee has not recommended the scheduling of ketamine, in 2009, 48 governments reported to the International Narcotics Control Board that ketamine had already been placed on the list of substances controlled under national legislation. There is a need to monitor developments in this area and make efforts to ensure availability of ketamine for medical purposes.

8. Making the terminologies used in relation to substance abuse, both for diagnostic purposes and for substance evaluation, consistent and appropriately defined, and taking into consideration the sensitivities related to some terms in current use will help to create a better understanding of issues and formulation of public-health policies in this area.

9. Cooperation with the Uppsala Monitoring Centre on pharmacovigilance data could lead to early detection of signals of dependence, especially for newly introduced medicines. Preliminary work in this area appears promising.

10. WHO's work in the area of improving access to controlled medicines such as morphine was appreciated by the Expert Committee. Different stakeholders including national governments, WHO, other international agencies and health-care workers need to join forces to make these medicines accessible to all in need, while ensuring prevention of diversion and abuse.

Implications for the Organization's programmes

11. A Note Verbale to the United Nations Secretary-General, conveying the Expert Committee's recommendation on scheduling of γ-hydroxybutyric acid for decision by the Commission on Narcotic Drugs has been sent.

12. The thirty-sixth meeting of the Expert Committee needs to be organized for 2014; however, the current significant backlog of pending evaluations implies the need for a meeting in 2013. The unresolved state of funding for the Expert Committee requires urgent attention in order to ensure that WHO may fulfil its mandate to review substances for possible scheduling recommendations to the Commission in an uninterrupted manner, as encouraged by the Commission on Narcotic Drugs in its

resolution 55/1 on promoting international cooperation in responding to the challenges posed by new psychoactive substances (March 2012).

13. The Secretariat has to develop documentation as required for those substances that will be pre-reviewed or critically reviewed at the next Expert Committee meeting. They include: the four substances identified at the thirty-fifth meeting for critical review; cannabis, mephedrone and synthetic cannabinoids (pursuant to resolutions of the Commission on Narcotic Drugs); one cathine preparation and six flunitrazepam preparations (pursuant to a notification by the Government of Germany of an exemption from certain provisions under the Convention on Psychotropic Substances of 1971); zolpidem (proposed by an expert); and levacetylmethadol (requested by the Australian National Council on Drugs, not for its status under international control but rather to determine if a recommendation should be made regarding access to this medicine for the management of opioid dependence; it is possible that the availability of levacetylmethadol may improve access to management of opioid dependence).

14. For making consistent the terminologies used in relation to substance abuse for the International Statistical Classification of Diseases and Related Health Problems (11th revision) and for substance evaluation, consistent definitions have to be prepared in a systematic manner ahead of the next meeting of the Expert Committee, with collaboration within WHO and with external stakeholders. This will require additional resources.

15. Collaboration on pharmacovigilance work needs to be expanded to include continuing dependence-related analyses with frequent review of results. This would inform future discussions of the Expert Committee and have the potential to identify medicines that could be misused. This work also requires additional resources.

16. The Expert Committee has recommended that WHO continue its work on improving access to controlled medicines, such as morphine for pain management, and the further development of guidelines for pain treatment. However, after the termination of a secondment in October 2012, no further substantial funding is available and the work may have to be suspended. This requires urgent attention. The Committee also noted that the cross-cutting nature of pain and palliative care, involving many different diseases and conditions such as cancer, HIV/AIDS, extremely-resistant tuberculosis and congenital disease is handicapping the establishment of policies.

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