

ATTACHMENT 3



NOV 15 2005

Vladimir Lepakhin M.D., Ph.D.
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Dear Dr. Lepakhin:

On behalf of the United States, I would like clarification on several matters regarding the *Questionnaire for Collection of Information for Review of Dependence-producing Psychoactive Substances*, sent from the World Health Organization (WHO) Secretariat on October 27, 2005.

Critical Review Process for the WHO Expert Committee on Drug Dependence (ECDD). Paragraphs 13-15 of the *Guidelines for the WHO Review of Dependence-Producing Psychoactive Substances for International Control* establish the principles and procedures for selecting substances for consideration by the WHO Expert Committee on Drug Dependence (ECDD). It is my understanding the WHO Secretariat applies the criteria in paragraphs 13 and 15 of the *Guidelines* to determine whether it will collect information for discussion (pre-review), or whether it will develop a "critical review" document that forms the basis for the ECDD to recommend or not recommend control of a substance. The principles and processes set forth by these consensus guidelines help to make the control review process as transparent as possible.

Although the *Guidelines* provide several options for the Committee to consider a substance for critical review, some of the substances on the latest questionnaire, such as dronabinol, gamma-hydroxybutyric acid, and tramadol, underwent WHO ECDD review cycles relatively recently. Therefore, it is unclear whether these substances meet the criteria for critical review again now. The United States would appreciate a detailed explanation, similar to those provided in previous years by the WHO Secretariat, of the reasons why these substances are scheduled for review at this time, so soon after previous reviews.

There are additional items on the draft agenda for the 34th Session of the ECDD that require further explanation and clarification from the Secretariat. For example, why are the *Supplementary Guidelines for Dependence Producing Psychoactive Substances* listed as a pending matter, when the 115th Session of the WHO Executive Board considered them in January 2005 and decided they are not necessary? Why are selective serotonin re-uptake inhibitors (SSRIs) on the draft agenda as a pending matter when the 33rd ECDD reviewed the issue and determined "that there was no evidence of diversion of the drug for abuse," and SSRIs were therefore not subject to further review for a possible change in international control? Please clarify the role of the ECDD in discussing these substances for other purposes.

Buprenorphine

The draft agenda, under "Pending Matters Since Thirty-Third Meeting," indicates the 34th ECDD will render a final decision on oripavine and buprenorphine. Oripavine is not currently controlled; buprenorphine has been controlled in Schedule III of the Convention of Psychotropic Substances since 1988. A decision on both substances was deferred pending the development of additional guidance (*Supplementary Guidelines*) on substances that might meet the criteria for control under more than one Convention. In addition, in the case of buprenorphine, the 33rd ECDD Report noted the need for a stronger justification for recommending a change in control status of a substance from one Convention to another.

The WHO Secretariat should remove buprenorphine from the agenda of the 34th ECDD. As noted above, in January 2005 the WHO Executive Board did not endorse the *Supplementary Guidelines for Dependence Producing Psychoactive Substances*. As such, without any guidance on this issue, it is entirely possible that the 34th ECDD will struggle inappropriately in determining the "more appropriate convention for buprenorphine." Moreover, the 33rd ECDD indicated "additional justification was needed to recommend a change in the control status of a substance from one convention to another." The Circular letter from the Secretariat attaches a one-element question on the impact of transferring buprenorphine to Schedule I of the Single Convention. It is unlikely the response to this one question will provide the information needed for the ECDD to support a recommendation.

If the WHO Secretariat determines to proceed with a re-review of buprenorphine, it should postpone ECDD consideration until it has prepared a complete questionnaire and circulate it to Member States. Parties should have additional time to provide complete, updated information on buprenorphine's expanded availability and use in the treatment of opioid dependence. There are considerably more data and information available to the WHO Secretariat on buprenorphine since the critical review presented to the 33rd ECDD in 2002. There have been significant developments, including the April 2005 addition of buprenorphine to the WHO's list of essential medications as an addiction treatment medication.

Member States' Completion of the Questionnaire. The WHO Secretariat has asked Member States to reply to the *Questionnaire* by January 3, 2006. The *Questionnaire* names seven substances for critical review. Two additional items are listed on the *Questionnaire* for final decision. This is a tremendous amount of data for Member States to provide to the WHO Secretariat in two months. As you are aware, the United States is required by law to publish a notice on the ECDD agenda in our *Federal Register*, with a minimum public comment period of 30 days. Because of this statutory requirement, the ambitious list of items for review that require data collection, and a shorter-than-usual timeframe for providing the requested data, the United States will be unable to reply to the *Questionnaire* before mid-January 2006. I am therefore formally requesting an extension of the deadline until at least January 16, 2006. Extending the deadline for comment will ultimately benefit the WHO Secretariat and the international community by giving Member States more time to collect and review data and commentary, and forward their recommendations to the Secretariat.

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Proposed Date of the ECDD. Given that the ECDD is proposed to meet in mid-March 2006, it would seem the ECDD would not be able to produce results and recommendations from its 34th Session in time for consideration by Member States at the 49th Session (2006) of the United Nations Commission on Narcotic Drugs (CND). Rather, the recommendations of the ECDD 34th Session would be forwarded to the 50th Session of the United Nations Commission on Narcotic Drugs in 2007. Therefore, we are puzzled by the tight timeframe imposed by the Secretariat on Member States to finish the *Questionnaire* by January 3, 2006, and hold the 34th Session of the ECDD in early 2006. We seek clarification from the Secretariat and feedback on this timetable. We would strongly encourage the Secretariat to postpone the meeting of the ECDD until later in 2006 so as to enable maximum flexibility for Member States and adequate time for their preparation and participation.

I appreciate your assistance and consideration in these matters, and look forward to your prompt response. If you have questions, please feel free to contact me on william.steiger@hhs.gov or (202) 690-6174.

Sincerely,



William R. Steiger, Ph.D.
Special Assistant to the Secretary
for International Affairs

cc: Denis Aitken
Lembit Rõgo
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