WORLD HEALTH ORGANIZATION

EXECUTIVE BOARD
111th Session
Provisional agenda item 5.6

EB111/8
4 December 2002

International Nonproprietary Names: revised procedure

Report by the Secretariat

BACKGROUND

1. The Executive Board at its 110th session, after discussion of the revised procedure for International Nonproprietary Names,[1] agreed that the proposed revision should be subject to further consultation.

PROGRESS SINCE THE 110TH SESSION OF THE EXECUTIVE BOARD

2. A second consultation process was started in 2002. The draft revised procedure was sent to the International Nonproprietary Names (INN) Expert Group, the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, heads of drug regulatory authorities, pharmacopoeia commissions and the International Federation of Pharmaceutical Manufacturers Associations.

3. In addition to the comments received as a result of the above-mentioned mailing, informal meetings and discussions were held with those Board members who had expressed their concerns regarding the proposed revision and with other parties who would potentially be affected.

4. In line with the suggestion made during the 110th session of the Executive Board, a public information meeting[2] was held on 18 November 2002, in conjunction with the Expert Group meeting, to allow a further exchange of views on the subject.

5. The comments made by a number of parties in the course of the second consultation process require that certain aspects of the proposed revision receive further consideration. These aspects include, in particular, the concept of recommending INN for which there are objections still outstanding and the concept of substituting existing INN. Other opinions expressed in the second consultation phase were generally in favour of the proposed revision.

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[1] Document EB110/3.

[2] Attended by members of the INN Expert Group and representatives from France, the United States of America and the International Federation of Pharmaceutical Manufacturers Associations.

ACTION PLAN

6. On the basis of the preceding paragraphs, the action plan set out below is suggested.

By January 2003. Redraft a new version of the revised procedure considering all comments received during the two consultative phases (in 2001 and 2002) and the public information meeting. Prepare a third mailing to an extended audience as suggested during the second consultative phase, requesting the further input of the INN Expert Group and all parties that have expressed their interest to participate in this endeavour.

April 2003. Evaluate all comments received in the third round of discussion, in consultation with the INN experts, and explore the need for a second public information meeting.

By May 2003. With the assistance of the INN Expert Group, study the feasibility of means to speed up the selection process, including the possibility for more meetings, using modern technology, e.g. electronic voting and teleconferences.

By May 2003. Study means to speed up the process of making newly selected INN known to the public before the "official publication", through a reduced pre-publication on the Web (e.g., including only the proposed INN and a statement on the pharmacological action and therapeutic use of the substance in question).

June 2003. Re-circulate a new version of the revised procedure in a fourth round.

September 2003. Prepare a version of the new procedure and the report to the Executive Board on the feasibility studies proposed above.

January 2004. New procedures to be discussed by the Executive Board at its 113th session.

ACTION BY THE EXECUTIVE BOARD

7. The Executive Board is invited to note the report and the action plan.

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