

Expert Committee on the Selection and Use of Essential Medicines: establishment of a subcommittee

Report by the Secretariat

1. Resolution EB120.R13 on better medicines for children requested the Director-General to revise and regularly update the Model List of Essential Medicines in order to include missing essential medicines for children.
2. A number of papers are in preparation as part of the evidence needed to update the Model List in order to meet the needs of children. This process has made it clear that drawing up an updated list of essential medicines for children is likely to require more consultations with appropriate experts than can be accommodated within the agenda of regular meetings of the Expert Committee on the Selection and Use of Essential Medicines for the reasons set out below.
 - The technical scope of the work is broad, including definition of criteria for determining essential medicines for children, formulation of a position statement on the type of dosage forms to be defined as “essential”, review and ratification as essential of all existing dosage forms currently on the list for children, and review of additional products, according to priorities to be established.
 - Review of applications for essential medicines for children requires special expertise that takes account not only of paediatric clinical medicine, but also factors such as the different pharmacokinetics of medicines in children of different ages.
 - A separate process for determining essential medicines for children would provide opportunities for advocacy and for improving access to such products, but should not need to be maintained in the medium term.
3. The regulations governing WHO Expert Advisory Panels and Committees provide a mechanism that can be used for this purpose, namely establishment of a subcommittee of an Expert Committee with specific terms of reference. At its 15th meeting (19 to 23 March 2007) the Expert Committee on the Selection and Use of Essential Medicines, after considering the relevant proposal, recommended that the Executive Board should be requested to consider establishment of a Subcommittee on the Selection and Use of Essential Medicines for Children.

4. The proposed terms of reference are:

- to draw up a WHO model list of essential medicines for children, based on their clinical needs and the burden of disease
- to determine suitability criteria for dosage forms of medicines for children, with particular attention to conditions prevailing in the developing countries
- to review the feasibility of manufacturing appropriate formulations for those priority medicines for which no dosage form for children currently exists, specifically considering requirements for use in resource-limited settings and availability of data on efficacy and safety in the appropriate age groups
- to identify the clinical-research gaps regarding safety and efficacy of essential medicines for children in order to improve suboptimal prescribing and dosing, and to facilitate regulatory approval of paediatric formulations
- to report to the Expert Committee on the Selection and Use of Essential Medicines in 2009.

5. It is expected that the Subcommittee would need to meet twice in order to compile a proposed model list of essential medicines for children. It could report to the meeting of the Expert Committee on the Selection and Use of Essential Medicines scheduled for 2009, and suggest a mechanism for maintaining the list. The Subcommittee could be disbanded once its work was completed.

ACTION BY THE EXECUTIVE BOARD

6. The Executive Board is invited to consider the following draft resolution:

The Executive Board,

Having considered the report by the Secretariat on the establishment of a subcommittee of the Expert Committee on the Selection and Use of Essential Medicines,¹

1. DECIDES to establish as from ... 2007 a temporary subcommittee of the Expert Committee on the Selection and Use of Essential Medicines, of no more than ... members, with the following terms of reference:

- (1) to draw up a WHO model list of essential medicines for children, based on their clinical needs and the burden of disease;
- (2) to determine suitability criteria for dosage forms of medicines for children, with particular attention to conditions prevailing in the developing countries;

¹ Document EB121/8.

(3) to review the feasibility of manufacturing appropriate formulations for those priority medicines for which no dosage form for children currently exists, specifically considering requirements for use in resource-limited settings and availability of data on efficacy and safety in the appropriate age groups;

(4) to identify the clinical-research gaps regarding safety and efficacy of essential medicines for children in order to improve suboptimal prescribing and dosing, and to facilitate regulatory approval of paediatric formulations;

(5) to report to the Expert Committee on the Selection and Use of Essential Medicines in 2009.

2. FURTHER DECIDES that the temporary subcommittee shall terminate in 2009, after its report to the Expert Committee on the Selection and Use of Essential Medicines.

= = =