

**FIRST MEETING OF THE SUBCOMMITTEE OF THE EXPERT COMMITTEE ON
THE SELECTION AND USE OF ESSENTIAL MEDICINES**

Room M-505, WHO headquarters

Geneva, 9-13 July 2007

DRAFT AGENDA

Opening: by Dr Howard A. Zucker
Assistant Director-General, Health Technology and Pharmaceuticals

Review of Terms of Reference for Subcommittee:

(1) To prepare a list of medicines for children, based on their clinical needs and the burden of disease, that the WHO Expert Committee on the Selection and Use of Essential Medicines can use to revise and regularly update the WHO Model List of Essential Medicines to include missing essential medicines for children:

- Criteria for the selection of essential medicines for children
- Review of the 1st draft of model list for essential medicines for children
- Review of other medicines listed in WHO treatment guidelines for children

Proposals for additional medicines to be considered:

- Abacavir (scored tablet: 300 mg)
- Antifungal medicines
- Artemether (20 mg/ml for intramuscular administration)
- Artemether/lumefantrine (paediatric powder for oral liquid)
- Artesunate (rectal capsules containing 50 mg and 200 mg sodium artesunate)
- Fixed-dose combination artesunate + amodiaquine
(25 mg/67.5 mg, 50 mg/135 mg and 100 mg/270 mg)
- Fixed-dose combination artesunate 50 mg + mefloquine 125 mg
- Fixed-dose combination lamivudine + stavudine + nevirapine
(tablet for oral liquid: 40 mg + 10 mg + 70 mg; 20 mg + 5 mg + 35 mg)
- Fixed-dose combination lamivudine 30 mg + zidovudine 60 mg + nevirapine 60 mg
(tablet for oral liquid)
- Fixed-dose combination zidovudine + lamivudine (scored tablet: 300 mg + 150 mg)
- Lamivudine (scored tablet: 150 mg)
- Racecadotril
- Medicines for respiratory tract infections, especially in children with HIV

Review of existing medicines:

- Review of chloramphenicol injection
 - Subcutaneous immunoglobulin
 - Update on oral rehydration solution constituents
- (2) To determine suitability criteria for dosage forms of medicines for children, with particular attention to conditions prevailing in the developing countries:**
- Paediatric age categories for essential medicines for children
 - Preferred dosage forms for essential medicines for children

- (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:**
- Criteria for the selection of fixed-dose combinations for essential medicines for children
- (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:**
- Position paper on off-label use of essential medicines for children
 - Report on adherence to medications in children
 - Review of regulatory initiatives designed to improve access to registered paediatric medicines
- (5) **To report to the Expert Committee on the Selection and Use of Essential Medicines in 2009:**
- Preparation of draft report

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