

Expert Consultation on Essential Medicines for Children

An Expert Consultation on Essential Medicines for Children will be held in Geneva from **9 to 13 July 2007**. Applications for inclusion, change or deletion of a medicine in the Model List of Essential Medicines for Children should be sent to the Secretary of the Expert Consultation whose address is below before **15 May 2007**.

The Secretary of the Expert Consultation on Essential Medicines for Children
Policy, Access and Rational Use
Department of Medicines Policy and Standards
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
email: emlsecretariat@who.int

Information to be included with an application for inclusion, change or deletion of a medicine in the WHO Model List of Essential Medicines for Children

1. Summary statement of the proposal for inclusion, change or deletion
2. Name of the focal point in WHO submitting or supporting the application
3. Name of the organization(s) consulted and/or supporting the application
4. International Nonproprietary Name (INN, generic name) of the medicine
5. Dosage form or strength proposed for inclusion
6. International availability - sources, if possible manufacturers
7. Whether listing is requested as an individual medicine or as an example of a therapeutic group
8. Information supporting the public health relevance (epidemiological information on disease burden, assessment of current use, target population)
9. Treatment details (dosage regimen, duration; reference to existing WHO and other clinical guidelines; need for special diagnostic or treatment facilities and skills)
10. Summary of comparative effectiveness in a variety of clinical settings:
 - Identification of clinical evidence (search strategy, systematic reviews identified, reasons for selection/exclusion of particular data)
 - Summary of available data (appraisal of quality, outcome measures, summary of results)
 - Summary of available estimates of comparative effectiveness
11. Summary of comparative evidence on safety:
 - Estimate of total patient exposure to date
 - Description of adverse effects/reactions
 - Identification of variation in safety due to health systems and patient factors
 - Summary of comparative safety against comparators
12. Summary of available data on comparative cost¹ and cost-effectiveness within the pharmacological class or therapeutic group:
 - Range of costs of the proposed medicine
 - Comparative cost-effectiveness presented as range of cost per routine outcome (e.g. cost per case, cost per cure, cost per month of treatment, cost per case prevented, cost per clinical event prevented, or, if possible and relevant, cost per quality-adjusted life year gained)
13. Summary of regulatory status of the medicine (in country of origin, and preferably in other countries as well)
14. Availability of pharmacopoeial standards (British Pharmacopoeia, International Pharmacopoeia, United States Pharmacopoeia)
15. Proposed (new/adapted) text for the WHO Model Formulary

¹ Information on cost and cost-effectiveness should preferably refer to average generic world market prices as listed in the *International Drug Price Indicator Guide*, an essential medicines pricing service provided by WHO and maintained by Management Sciences for Health. If this information is not available, other international sources, such as the WHO, UNICEF and *Médecins sans Frontières* price information service, can be used. All cost analyses should specify the source of the price information.