

19th Expert Committee on the Selection and Use of Essential Medicines

The next Expert Committee on the Selection and Use of Essential Medicines is planned for the first half of 2013. Applications for inclusion, change or deletion of a medicine in the next Model List of Essential Medicines should be sent in the prescribed electronic format to the Secretary of the Committee whose address is given below, **before 1 December 2012**. Please note that all applications will be posted on the website for public comment and review **no later than 15 December 2012**.

The Secretary of the 19th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Health Products(EMP)
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

- 1. Summary statement of the proposal for inclusion, change or deletion**
- 2. Name of the focal point in WHO submitting or supporting the application (where relevant)**
- 3. Name of the organization(s) consulted and/or supporting the application**
- 4. International Nonproprietary Name (INN, generic name) of the medicine**
- 5. Formulation proposed for inclusion; including adult and paediatric (if appropriate)**
- 6. International availability - sources, if possible manufacturers and trade names**
- 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 diagnostics, treatment or monitoring 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 cost** 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**

* Excerpts from the unedited report of 18th Expert Committee on the selection and use of essential medicines

"... the Committee reviewed their experience of evaluating the applications that had been submitted. The Committee was concerned that some applications did not provide all relevant published and unpublished data, and noted that at a minimum, application should provide a comprehensive search strategy to identify relevant clinical data and should present all published data or justify fully its exclusion. Some applications considered at the meeting that had been submitted by commercial organizations were clearly too selective and were based on dossiers submitted to regulatory authorities, without appropriate consideration of publicly accessible data from peer-reviewed publications. Further, the Committee was concerned that applications submitted by manufacturers might not include all data available from unpublished studies, and identified several examples where the data that were provided were not presented in formats that allowed correct and complete interpretation (e.g. presentation of point estimates as percentage only, without numbers of confidence intervals). It was also difficult to correctly identify publications based on unpublished trials and sometime only pooled data without the individual study results were provided.

The Committee recommended that it should have access to all data provided to WHO relating to medicines on its agenda, including 'confidential data' provided to other WHO committees. Otherwise it could not fully assess an application and would have no choice but to defer it ... "

** 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