

## Additional information for applicants

**1. Minimum criteria for acceptance of an application for consideration by the Expert Committee:**

- the application must present scientific evidence on comparative safety and efficacy. Summary evidence tables of key trials should be included in the application and the original data should be available in the public domain
- the application must include information on the public health need for the medicine
- the medicine being proposed for inclusion must have a composition of product defined in a way that is reproducible

**2. Where appropriate evidence of comparative effectiveness and safety should be presented in tabular form using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) tables.**

For further information regarding GRADE tables refer to the following presentation and website:

[http://intranet.who.int/homes/rpc/documents/grade\\_workshop\\_quality\\_march\\_20091.pdf](http://intranet.who.int/homes/rpc/documents/grade_workshop_quality_march_20091.pdf)

<http://www.gradeworkinggroup.org/>

Software for producing GRADE tables can be downloaded from the following website:

<http://www.ims.cochrane.org/revman/other-resources/gradepr>

Copies of the key trials included in the application to support the comparative safety and efficacy of the proposed medicine(s) should be provided electronically in a portable document format (PDF) to the Secretariat

**3. All applications must evaluate data for both adults and children. If data for certain populations (e.g. children, pregnant women) are not available this must be clearly stated in the application**

**4. The application should provide a detailed specification of the active pharmaceutical ingredient, dosage forms and strength for the proposed medicine for inclusion**

- the medicine(s) for inclusion must be described by its International Nonproprietary Name

*International Nonproprietary Names (INN) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name*

- the application must demonstrate that the dosage form(s) and strength(s) of the proposed medicine(s) do exist and are available somewhere in the world. The Expert Committee will only list available dosage forms and strengths.

**5. The application must provide a summary of the regulatory status of the medicine(s) proposed for inclusion. This should include the regulatory status in the country of origin and preferably other countries as well. The summary should also specify the indications that the medicine is licensed for.**

Useful web links for further information regarding the regulatory status of medicines:

- US Food and Drug Administration  
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>
- European Medicines Agency  
<http://www.emea.europa.eu/>
- Australian Government, Department of Health and Ageing, Therapeutic Goods Administration  
<http://www.tga.gov.au/>

The WHO List of Prequalified Medicinal Products is a list that contains medicinal products used for HIV/AIDS, tuberculosis, malaria and other diseases, and for reproductive health, which have been assessed as part of the WHO Prequalification Programme and found to be acceptable, in principle, for procurement by UN agencies.

- the list of WHO prequalified medicines can be found at:  
[http://apps.who.int/prequal/info\\_general/notes.htm](http://apps.who.int/prequal/info_general/notes.htm)

**6. For the purposes of listing, the application must clarify if the inclusion of the medicine is as an individual medicine or an individual medicine with a square box symbol.**

*The square box symbol (□) is primarily intended to indicate similar clinical performance within a pharmacological class. The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety. In some cases, this may be the first medicine that is licensed for marketing; in other instances, subsequently licensed compounds may be safer or more effective. Where there is no difference in terms of efficacy and safety data, the listed medicine should be the one that is generally available at the lowest price, based on international drug price information sources.*

If a square box is being requested for the medicine, a review of the therapeutic alternatives that may be considered under the square box needs to be included in the application.