Annex 5

General background notes on the list of international comparator pharmaceutical products

1. List of international comparator products

The list of international comparator products provides tabulated information about pharmaceutical products on the World Health Organization (WHO) Model List of Essential Medicines (EML) (1), specific finished pharmaceutical products that can be selected as comparators (column headed ‘International comparator product’ ) and the markets where the product’s quality, safety and efficacy is considered as best documented (column headed ‘Market’ ). Comparator products recommended by the WHO Prequalification Team – Medicines (PQTm) are included in the list of international comparator products (column headed ‘PQ comparator product’ ). PQTm prequalifies pharmaceutical products included in the Expressions of Interest for priority medicines such as those used for HIV/AIDS, malaria and tuberculosis as well as for reproductive health. For more information regarding comparator products in the context of prequalification, please see the PQTm guidance documents (2).

1.1 Selection criteria for the international comparator product

The international comparator products that are listed in the table are selected according to the following criteria.

1. A product from a stringent regulatory authority (SRA) is listed where the same product is marketed worldwide by the same marketing authorization holder (MAH).

2. Products from the United States of America (USA) and/or the European Union (EU) are listed (if available in those markets) where the same product is not marketed worldwide by the same MAH.

3. A specific product, the MAH and the respective market is listed where the comparator product is not available in the markets of the USA or widely in the EU.

4. In order to select a specific product, preference is given to products marketed by MAHs from countries with SRAs.
5. Comparator products marketed in other countries are selected in those cases where a comparator product is not available in markets with SRAs.

The list of international comparator products is to be used in conjunction with the *Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability* and the *Guidance on the selection of comparator pharmaceutical products for equivalence assessment of interchangeable multisource (generic) products*. Please consult the WHO website for the most recent version of these guidance texts (3).

The list of international comparator products is published as a living document and will be revised and regularly adapted to the newest version of the EML on the following website: [http://www.who.int/medicines/areas/quality_safety/quality_assurance/regulatory_standards/en/](http://www.who.int/medicines/areas/quality_safety/quality_assurance/regulatory_standards/en/).

WHO relies on the support of medicines regulatory authorities and information provided by manufacturers. If an international comparator product is no longer available or is being replaced, please contact QAS@who.int.

**References**

