

Annex 11

Guidelines on submission of documentation for prequalification of innovator¹ finished pharmaceutical products approved by stringent regulatory authorities²

The World Health Organization (WHO) recognizes the scientific evaluation of innovator finished pharmaceutical products (FPPs) by regulatory authorities, which apply similarly stringent standards for quality, safety and efficacy to those recommended by WHO. Where an applicant and a stringent regulatory authority (SRA) can agree to share the following information on an innovator FPP with WHO, WHO will consider such an FPP for inclusion in the list of WHO prequalified products, as and when information about such a product becomes available to WHO and when the applicant in question expresses his or her interest in the product being prequalified by WHO.

The following should be submitted:

1. A covering letter, which should include:
 - a statement indicating that the information submitted is true and correct;
 - a statement confirming that, for WHO prequalification, the product, including composition, formulation, strength, specifications, packaging will at the time of submission be the same in all respects as the product registered with the relevant SRA; and
 - the name of the person responsible for communication with WHO on any issues related to the product.
2. An original or certified copy of the current WHO-type Certificate of a Pharmaceutical Product issued and fully completed, including answers to each question, by the relevant SRA, together with the latest approved summary of product characteristics (SmPC), or an equivalent thereof, as well as the patient information leaflet (PIL) and the labelling.

¹ Generally, the innovator pharmaceutical product is that which was first authorized for marketing, on the basis of documentation of quality, safety and efficacy (WHO Technical Report Series, No. 937, Annex 7, 2006).

² Stringent regulatory authority (SRA): a regulatory authority which is: (a) a member of the International Conference on Harmonisation (ICH) (as specified on www.ich.org); or (b) an ICH observer, being the European Free Trade Association (EFTA), as represented by Swissmedic and Health Canada (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement including Australia, Iceland, Liechtenstein and Norway (as may be updated from time to time).

3. An assessment report issued by the relevant SRA: a publicly available scientific assessment report, such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by the relevant SRA is also acceptable.
4. A certified copy of the marketing authorization issued by the relevant SRA. If applicable a certified copy of the latest renewal of the marketing authorization should also be provided.
5. A list of the SRA-approved manufacturer(s) of the FPP, with the physical address of the manufacturing site(s) (and unit if applicable).
6. A list of the SRA-approved manufacturer(s) of the active pharmaceutical ingredient(s) (API(s)) used in the manufacture of the FPP, with the physical address of the manufacturing site(s) (and unit if applicable).
7. A sample(s) of the product in market packaging(s) should be provided with the submission to enable a visual inspection to be made. The respective certificate of analysis should be attached.

Please note that the submission must be in English, which includes certified English translations of the SmPC and other documents. These documents should be made available both as hard copies and electronically. The SmPC and PIL should be submitted as Word files.

Variations to and renewal of the marketing authorization of a product that has been prequalified by WHO based on the approval by an SRA, remain the responsibility of the relevant SRA.

Once the product has been prequalified, WHO should be provided with a copy of the regulatory acceptance letter of any changes to the main characteristics of the product — such as the labelling for storage, the nature and contents of the container, the shelf-life, manufacturing site(s) of the FPP or API, or any other relevant change to the product information — immediately after the variation has been approved by the relevant SRA. The main characteristics of the product will be listed in the Letter of Prequalification.

The preferred storage condition for WHO prequalified products is “do not store above 30 °C”. If this is not indicated on the SmPC, PIL and labels of the innovator product, applicants are encouraged to apply for a variation in this respect with the relevant SRA. This could also be done after prequalification of the product.

Products that received tentative approval from the United States Food and Drug Administration (FDA) or positive opinions under Article 58 of European Union Regulation (EC) No. 726/2004 or the Canada S.C. 2004, c. 23 (Bill C-9) procedure are not within the scope of this guideline. Such products can be co-listed on the WHO List of Prequalified Products in accordance with mutual agreements between WHO and these regulatory authorities.³

³ Information and the full text of the relevant WHO documents can be found on the web site <http://apps.who.int/prequal/>.