

Note with respect to WHO PQT/MED Recommended Product

Information additional to the SRA Approved Product Information for Products Prequalified via the Abridged (SRA) Route

According WHO's *Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities* (SRA guideline) the SRA-approved product information will not be changed, but is published either in WHOPAR part 3 (PIL), part 4 (SmPC) and part 5 (labelling) or, where applicable, a link to the product information on the website of the reference SRA is provided in WHOPAR part 1.

The SRA guideline furthermore makes provision for “additional information, relevant for use of the product within the scope of the Prequalification Programme ... in the WHO public assessment report (WHOPAR) as a separate piece of information”. In accordance with this provision, the WHOPARs for products prequalified based on SRA approval will be supplemented by a “WHO-PQ recommended patient information leaflet” (as part 3a), a “WHO-PQ recommended summary of product characteristics” (as part 4a) and “WHO-PQ recommended labelling” (as part 5a), as applicable. Parts 3a and 4a will be based on the relevant current WHO treatment guidelines and are regarded necessary for the use of the product in populations, settings or regions relevant for distribution of the product based on its prequalification status. Parts 3a, 4a and 5a will include the WHO recommended storage condition with shelf life where appropriate.

Note that WHOPAR parts 3a, 4a and 5a will not replace the SRA approved product information, but will be provided as supplemental information.

WHO PQT/MED is responsible for drafting WHOPAR parts 3a, 4a and 5a in a similar way as is currently done for multisource (generic) products prequalified via the full assessment route. In cases where assessment of the SRA approved product information proves to be in line with the relevant current WHO guidelines, posting of parts 3a, 4a and / or 5a may be waived.

When supplying a WHO prequalified medicine to a country, and if requested by that country's national medicines regulatory authority, the supplier should use the WHO recommended text for the medicine's summary of product characteristics and patient information leaflet as the basis for local product information.

This procedure will be applied with immediate effect to:

- All new applications submitted for prequalification of products via the SRA route, once such products have been prequalified. When submitting the application, the applicant should agree in writing to this procedure;
- All products subject to verification of the SRA status. The letter requesting such verification will include a paragraph referring to the procedure.

Suppliers of products currently prequalified via the SRA route are not required to take any action with respect to this note. If a supplier of a prequalified product wishes to have WHOPAR parts 3a, 4a and 5a published, the WHO PQT/MED Team Lead, Medicines Assessment can be contacted at stahlm@who.int.

WHO PQT/MED may request publication of parts 3a, 4a, 5a for any product prequalified via the SRA route at any time, when major differences between SRA-approved and WHO PQT/MED recommended texts are evident, for example with respect to the therapeutic indications or target population, and when withholding this information could result in a risk with respect to the use of the product in populations, settings or regions relevant for distribution of the product based on its prequalification status.