Procedure to enable national registration of products prequalified based on SRA approval utilizing WHO's Collaborative Registration Procedure for prequalified products

Introduction

According to WHO's *Procedure for prequalification of pharmaceutical products* (TRS 961, Annex 10) the role of the PQ programme is to provide "United Nations agencies with advice on the acceptability, in principle, of pharmaceutical products for procurement by such agencies… The pharmaceutical products found to meet the WHO-recommended quality standards are included in the list of medicines, as manufactured at the specified manufacturing sites, which are considered to be acceptable, in principle, for procurement by United Nations agencies." TRS 961, Annex 10 furthermore states that "WHO recognizes the evaluation of relevant products by SRAs which apply standards for quality equivalent to those recommended by WHO."

Since the start of WHO's Prequalification Programme, products could be prequalified based on their SRA status. In fact, the initial products prequalified came mainly through the abridged (SRA) route. The current requirements for prequalification via the abridged route are outlined in WHO's *Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities*[1] (SRA guideline).. The current SRA guideline and its abridged procedure however does not support facilitation of national registrations through WHO's collaborative registration procedure (CRP) due to the absence of full PQT/MED assessment and inspection reports for sharing in the context of CRP.

Following comments from stakeholders, PQT/MED aims to expand the current abridged prequalification procedure for products approved by SRAs, initially as a pilot[2]. This expansion aims to make these products eligible for CRP as prequalified products, thereby facilitating their national registrations. This will be feasible if the reference SRA provides PQT/MED with its unredacted assessment and inspection reports and permits PQT/MED to share these reports with countries through the CRP for prequalified products.

Scope

The pilot is applicable only to products that have been approved by the reference SRA since the beginning of 2012[3].

[1] WHO Technical Report Series No. 986, Annex 5, 2014. All SRAs are being transited to the WHO Listed Authorities (WLA) list based on abbreviated performance evaluation such that the term SRA is replaced with WLA.

[2] Initially applicable only for products approved by SRAs/WLAs that have supported prequalification of products over a long time based on the abridged procedure (i.e., EMA, BfArM, MHRA, MPA, CBG/MEB, Swissmedic, TGA, FAMHP or USFDA). A draft guidance regarding prequalification of products approved by other WLAs is to be published.

[3] 2012 is the year when WHO's *Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability* (full assessment route) were published and implemented. This will ensure that the dossier format and assessment requirements of the different SRAs and WHO PQT/MED are current and sufficiently similar.

Expanded abridged procedure

Products that received marketing authorisation from an SRA since the beginning of 2012 can be prequalified as before according to WHO's *Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities*[1] (SRA guideline, but now with the option to participate in the CRP following prequalification of the product.

For participation in this pilot procedure, the following should be provided in new applications for prequalification via the abridged route in addition to the requirements outlined in the current SRA guideline:

1. A statement in the cover letter indicating the applicant's intention to participate in the CRP.

2. A list of variations allowed by the reference SRA post approval, with proof of acceptability of such variations where applicable.

3. Any variations accepted by the reference SRA while the application is under PQT/MED assessment should be submitted to PQT/MED on a rolling basis as part of a response submission. Information on pending variations should be provided.

4. A letter from the reference SRA indicating that it is willing to share with WHO PQT/MED the unredacted assessment and inspection reports underlying the SRA approval of the product and any subsequent variations. In the letter the reference SRA should also authorize WHO PQT/MED to further share the unredacted assessment and inspection reports with countries participating in the WHO CRP. WHO PQT/MED will request the unredacted assessment reports directly from the reference SRA for sharing with NRAs that are participating in the CRP.

Once a product is prequalified via this pilot procedure, it will be listed under a new "Basis of listing" to distinguish it from the current 'Prequalification – Abridged', namely: 'Prequalification – Abridged – WHO CRP - A'

Products that were approved by an SRA since the beginning of 2012 and that are currently listed under the abridged (SRA) procedure ('Prequalification – Abridged') will be eligible for participation in the CRP. The additional information as listed above should be provided with the application to participate in the CRP. The basis of listing will then be changed to 'Prequalification – Abridged – WHO CRP - A'.

For products listed under 'Prequalification – Abridged' that do not qualify for the pilot procedure the current abridged procedure will remain in place. The same applies to a currently listed product that does qualify or for a new application submitted for prequalification relying on SRA approval, where the applicant does not intend to proceed with national registration of the product through the CRP[4].

[4] This option will remain open only for products approved by SRAs/WLAs that have supported prequalification of products over a long time based on the abridged procedure (i.e., EMA, BfArM, MHRA, MPA, CBG/MEB,

Collaborative registration procedure (CRP)

The national registration of a product that has been prequalified via the above abridged procedure can be facilitated according to WHO's

> *Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines*[5]

For this purpose, WHO will provide the NRA with the reference SRA's unredacted assessment reports, a list of variations accepted by the SRA and the relevant PQT/MED summary assessment reports.

Swissmedic, TGA, FAMHP and USFDA). PQT/MED has issued a separate guidance regarding prequalification of products approved by other WLAs (xxxxx).

[5] WHO Technical Report Series No. 996, Annex 8, 2016