

WHO Pilot Procedure for Prequalification of Biotherapeutic Products

WHO PQ specific addendum to the RMP

A WHO prequalification specific addendum to the RMP (Risk Management Plan) should be provided for biotherapeutic products (BTPs), or their corresponding similar biotherapeutic products (SBPs), that have been approved by stringent regulatory authorities (SRAs) and which will be assessed via an abridged assessment pathway.

The proposed structure for the WHO PQ specific addendum to the RMP can be found here. If you still have questions please submit them using the email address prequalbiosimilar@who.int or PQ-insulin@who.int

Background

The RMP addendum should include a summary of the risks of the product together with the measures to monitor and minimize such risks, taking into consideration potential differences in the healthcare setting that may change the benefit/risk profile defined within the SRA settings. Changes in the risk/benefit profile would indeed impose the need of further pharmacovigilance activities and/or risk minimisation measures not foreseen for the SRA settings. The following points in the proposed structure below are not intended to be exhaustive or to contain country-specific data or information. The WHO PQ-specific addendum should contain rather a generalized discussion for each of the points below to illustrate how the company will address, after product prequalification, potential differences, compared to SRAs, in healthcare settings that may require a revision of the adequacy of the safety concerns, pharmacovigilance activities, risk minimisation measures and traceability of the product.

The RMP should include:

General

- The invited indications, posology and a summary table of the safety concerns, pharmacovigilance activities and risk minimisation measures proposed for WHO prequalification.
- A commitment from the Applicant that they acknowledge healthcare settings and infrastructure may vary between countries, and following prequalification, they will evaluate the adequacy of the safety concerns, Pharmacovigilance (PV) activities, risk minimization measures and traceability of the product at a national level. Furthermore that the Applicant will implement sufficient pharmacovigilance, risk minimization measures and product traceability following product prequalification even if differences, compared to SRAs, in healthcare settings and/or infrastructure are found at a national level.

The RMP addendum should further include a summary of the proposed methodology concepts that the company will employ following prequalification to evaluate the adequacy of the safety concerns, Pharmacovigilance activities, risk minimisation measures and traceability of the product at a national level for country specific RMPs. This summary should cover the below:

Safety concerns

- A generalised description of what assessment the applicant will undertake at a national level to ensure no additional safety concerns are identified based on local practices or specificities (e.g. epidemiology) in the area where the product is intended for use.

Pharmacovigilance activities

- A generalised description of how the company will ensure that the agreed routine and additional PV activities and PV requirements for the product will be met at a national level. This description should include confirmation that the company will establish contact with a PV focal person at the national PV centre or National Regulatory Authority (NRA) of the country for all safety issues and what the company will do in countries where a focal PV point is not present. A flow chart/communication plan should also be provided summarising how the company currently shares/plans to share information with NRAs.
- A generalised description of what assessment the applicant will undertake at a national level to see whether any additional pharmacovigilance activities are required to address local specificities that may change the benefit/risk profile defined within the SRA settings. This description should include confirmation that the local specificities considered for the assessment of a need for additional pharmacovigilance activities will cover epidemiology (e.g. infection), healthcare infrastructure, clinical practice, social, economic and other.
- A statement confirming that Periodic Safety Update Reports (PSURs) will be prepared and submitted in accordance with the national requirements

Risk Minimisation Measures

- A generalized discussion setting out how the company will ensure each of the risk minimisation measures agreed for the product with the SRA can be implemented nationally and whether any additional Risk Minimisation Measure (RMM) are required, taking into consideration how familiar healthcare professionals are with the product/type of product, current clinical practice and the healthcare setting/infrastructure in that country. This should include ensuring healthcare professionals (HCPs) have access to the Summary of Product Characteristics (SmPC), that non-promotional education material is provided where required and the product is only used where there are adequate facilities to implement the RMMs for example, it may be that close supervision by an experienced HCP is required in an environment where full resuscitation facilities are immediately available. This could take the form of a checklist for each of the safety concerns and the proposed actions that may be required. This would subsequently be completed and implemented on a national level.
- A description of how the company will monitor whether the risk minimisation measures are being implemented and whether they are effective at a national level.

Product traceability

A generalised discussion on product traceability. This should take into consideration the need for this to be fully integrated in different healthcare settings, acknowledging the fact that the infrastructure may vary between countries. The discussion should also list possible actions the company will take to ensure traceability in the countries where the local systems may be found inadequate.