SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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EXPRESSION OF INTEREST: WHO PRE-QUALIFICATION COLLABORATIVE REGISTRATION PROCEDURE

In an effort to support access and affordability to quality, safe and effective medicines in the SADC region, and in South Africa specifically, SAHPRA invites applicants to submit Expressions of Interest (EOIs) for evaluation of applications using the WHO pre-qualification collaborative registration procedure.

The purpose for the CRP:

The WHO Collaborative Registration procedure is a process involving collaboration between NRAs (i.e SAHPRA) and WHO/PQT. It aims to provide a convenient tool for NRAs wishing to enhance their premarketing evaluation and registration system by taking advantage of the scientific assessment work conducted by WHO/PQT. For pharmaceutical products the present procedure is complementary to the WHO/PQT collaborative procedure with NRAs in inspection activities.

Enhanced collaboration and information exchange between NRAs and WHO/PQT benefits all partners. Subject to the agreement of the WHO prequalification (PQ) holders concerned, NRAs have access to assessment outcomes that are not in the public domain and that have been prepared inconformity with the WHO recommended standards on which the *Procedure for prequalification of pharmaceutical products* (*1*) and the *Procedure for assessing the acceptability in*

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principle of vaccines for purchase by United Nations agencies (*2*) are based. Such reports and relevant WHO documents help NRAs to make their decisions and also assist in training national regulatory staff. At the same time, feedback from NRAs on the information and documentation received from WHO/PQT under the Procedure allows WHO/PQT to improve its work and ensures that the outcomes of its assessments are relevant to NRAs. As a consequence, patients benefit from this collaboration by gaining faster access to pharmaceutical products and vaccines that have been found acceptable in principle for procurement by United Nations (UN) agencies. The collaborative registration procedure can be of particular relevance when implemented for pharmaceutical products and vaccines in emergency situations. Depending on available resources, participating authorities have the opportunity to participate in the assessment process and in inspections organized by WHO/PQT. This collaborative procedure also benefits manufacturers of prequalified pharmaceutical products and vaccines through faster and better harmonized regulatory approvals in participating countries. This Procedure, when combined with the WHO/PQT collaborative procedure with NRAs in inspection activities, alleviates the burden of additional national inspections on manufacturers (WHO TRS 966 Annex 08).

More information on the principles and mechanisms of the CRP can be found on the WHO Website under the following link:

https://www.who.int/publications/i/item/WHO_TRS_996

Procedure for the EOI

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Applications for evaluation of medicines via the WHO Collaborative Registration Procedure must be accompanied by a formal agreement that information may be shared by WHO PQT, with SAHPRA. The information will be treated as confidential, in line with applicable legislation and arrangements. In applying for product evaluation through the collaborative mechanism, applicants are requested to submit a covering letter (clearly indicating interest to participate in the CRP), product application in the CTD format, product sample and site master file, according to the SAHPRA requirements, ensuring that regional requirements are adhered to. The country-specific requirements include especially:

- Application fees;
- Statutory forms to be completed;
- Country specific labelling Requirements.
- Country specific Module 3.2.R in accordance with the SAHPGL-PEM-02-Quality-Bioequivalence guideline

Documents to be submitted

1. Covering letter, in English, expressing

    1.1. interest in participating in the CRP.

    1.2. confirmation that the information submitted in the product dossiers is "true and correct";

    1.3. confirmation that the same[1] dossiers and data have been submitted to PQT;

    1.4. consent to sharing of the product related information, during registration and in post-registration period, with staff and with external experts, who support the process and are bound by confidentiality undertakings.

    1.5 Completed and signed Appendix 3 as detailed on the WHO website.

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Further information on the documents and procedures for participation in the CRP may be found on the WHO website using the link below. Focal persons may also be contacted for clarity for information on the process.

https://extranet.who.int/pqweb/medicines/collaborative-procedure-accelerated-registration

Dr Boitumelo Semete-Makokotlela
SAHPRA Chief Executive Officer (CEO)

[1] Specific national administrative documents, labelling and product information texts as submitted in the module 1 of the dossier do not represent a difference between dossiers of the same technical content.