Guidance to Applicants for the Registration via the WHO Collaborative Registration Procedure (CRP)

1 INTRODUCTION

1.1. Since 4th October 2024 the Medicines Control Agency (MCA) of The Gambia participates in the World Health Organization (WHO) 'Collaborative Registration Procedure for prequalified medicines and vaccines' and the 'Collaborative Registration Procedure for medicines and vaccines approved by Stringent Regulatory Authorities'.

1.2. This Procedure serves to facilitate and accelerate the registration (marketing authorisation) of products that have already been assessed and listed as prequalified by the WHO Prequalification Team (PQT) or by Stringent Regulatory Authorities (SRAs).

1.3. Detailed information about the CRP for WHO prequalified products can be obtained at https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/collaborative-registration-procedure/procedure-for-prequalified-med-vax, and for SRA approved products at https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/collaborative-registration-procedure/crp-for-medicines-and-vaccines-approved-by-the-stringent-regulatory-authorities.

1.4. The MCA accepts applications for marketing authorisation in line with this procedure (hereinafter referred to as "the Procedure") and all applicants for registration of WHO prequalified products/SRA-approved products in The Gambia are encouraged to use this registration route.

1.5. With this pathway, **finalization of the valid application is expected within 90 days of regulatory time**. Subject to MCA's previous agreement, the Procedure is also applicable to pending WHO prequalified products/SRA-approved products already in national registration for which specific arrangements may be necessary.

1.6. MCA reserves the right to use the standard national registration route or to switch to it during the CRP, in case of specific products (for example, products not included in national treatment/vaccination guidelines) or lack of the applicant's cooperation.

2 APPLICATION PROCESS

Applicants wishing to use this registration route should:

1. Notify WHO/the SRA of their intention to use this Procedure for registration of a particular product by sending the appropriate notification form (Appendix 2/Appendix 3 Part B) to WHO/the SRA, as outlined on the WHO website. If the applicant for national registration is different from the manufacturer with a prequalified product/SRA-approved product, the mutual agreement between the applicant and the manufacturer is necessary and the notification to WHO/the SRA

has to be sent by the manufacturer.

2. Follow the MCA *Guideline for Marketing Authorisation (Registration) of Medicines* available at the MCA website www.mca.gm.

   More important, the following should be considered:

   a. The national application form and requirements on samples and labelling stay in place.

   b. "WHO Collaborative Procedure"/ "SRA Collaborative Procedure" should be indicated as the proposed registration pathway in the national application form or in the covering letter.

   c. The Expression of Interest form (Appendix 3 Part A/Appendix 7 of the Procedure), as outlined on the WHO website, has to be submitted.

   d. The technical content of the dossier has to correspond exactly to that submitted and currently approved by the PQT/SRA and as specified in the corresponding Procedure guidelines. The dossier has to be updated to reflect all post-prequalification variations approved by the PQT/ SRA and accompanied by the appropriate current quality information summary (QIS)/QIS-SRA (CRP). All variations still pending at the PQT/SRA have to be notified, and deviations from the prequalified product have to be clearly declared in the expression of interest form (Appendix 3 Part A/Appendix 7 of the Procedure).

   e. Additional, country specific requirements are the labelling requirements as laid down in the MCA Guideline for Labelling of Medicines for Human Use and the provision of three (3) samples of each product with the Certificate of Analysis for each batch.

3. A fee of currently $300 per product is charged for new applications considered under this procedure.

2.1. In situations where the applicant wishes to apply the Procedure to an application that is already pending with MCA, the applicant should first update the dossier to ensure that the technical part of the information is the same as that currently approved by the PQT/SRA, as applicable.

2.2. The post-prequalification variations should be submitted to MCA within 30 days from the PQT/SRA approval. The PQT/SRA approval letter should be attached.

2.3. In case of questions/requests related to the CRP, the MCA focal person's contact information for medicines and medical devices are as follows: Mariama Simah, msimah@mca.gm, and Abdoukarim Sisoho, ak-sisoho@mca.gm, respectively.