PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

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GUIDANCE FOR THE REGISTRATION OF HUMAN MEDICINAL PRODUCTS CLASSIFIED FOR FAST TRACK PROCESS

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1-ABBREVIATIONS

FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
ICH	International Conference on Harmonization
SRA	Stringent Regulatory Authority
QIS	Quality Information Summary
WHO	World Health Organization
WHO/PQP	World Health Organization Prequalification of Medicines Programme

2.0 SCOPE

This guideline covers the requirement and processing of medicines classified by the Authority for expedited processing for registration. Currently, the following categories of applications are eligible to be reviewed through fast-track registration;

- World Health Organization (WHO) Prequalified Products
- Public health products (Anti-Retroviral Medicines, Anti-Malaria medicines, Medicines for Tuberculosis, Reproductive health products and Medicines for neglected health products. The Authority may fast-track the review of other products on case by case basis.
- Product Registered by countries within the International Conference on Harmonization (ICH) region.

3.0 GLOSSARY

In the context of this guideline, the following words are defined as follows:

'Authority' means Pharmacy and Medicines Regulatory Authority

'Medicinal purpose' means treating or preventing a disease, diagnosing or ascertaining the presence and extent of a physiological function, contraception, inducing anaesthesia, altering normal physiologic function permanently or temporarily in any way in humans.

'Applicant' means the product owner or licence holder.

'Medicine, medicine or pharmaceutical product' means a substance or mixture of substances prepared, sold or represented for use in -

(a) Diagnosis, treatment, mitigation or prevention of disease, disorders or abnormal physical state or the symptoms of it in human or animal
(b) Restoring, correcting or modifying organic functions in human or animal.

'Finished Pharmaceutical Product (FPP)' means a product that has undergone all stages of production, including packaging in its final container and labelling.

'Manufacture (manufacturing)' means all operations of purchase of materials, production, quality control, release, storage and the related controls.

'Manufacturer' means a person or firm that is engaged in the manufacture of product(s).

'Stringent Regulatory Authority' means a national medicines regulatory authority which is a member, observer or associate of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, as may be updated from time to time.

'Variation' means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labelling and product information.

4.0 REQUIREMENTS

4.1 WHO PREQUALIFIED MEDICINAL PRODUCTS

- This guideline outlines the procedure for the application and registration of WHO prequalified medicines by the Authority.
- This is based on a collaborative procedure between the WHO Prequalification of Medicines Programme (WHO/PQP) and the Authority in the assessment and accelerated registration of WHO prequalified medicines.
- Applicants that have been prequalified by the WHO/PQP can take advantage of this procedure for fast track registration of their prequalified medicinal product by the Authority.

4.1.1 APPLICATION STEPS

1. Applicant should submit the product dossier for a WHO-prequalified pharmaceutical product to the Authority. The dossier submitted should be the same as submitted to the WHO-PQP during the initial prequalification procedure, and subsequent variation documentation where applicable;

The application should include;

a) A completed application form for the registration of the product, including the same technical information as that submitted to WHO/PQP. The technical part of the dossier should be identical to the current version of the WHO/PQP dossier.

b) The following country specific documentation;
   i) Executed batch manufacturing records of one production batch.
   ii) Where applicable, long-term stability studies protocol and report conducted at Zone IVB conditions

Copy of the current version of Quality Information Summary (QIS) submitted to the WHO.

c) Pay the normal product registration fees as per prescribed fee schedule. (access a copy of the fee schedule at www.pmra.mw).

2. In situations where the applicant wishes to apply the Procedure to an application which is already pending with the Authority, the applicant should first update the dossier to ensure that the technical part of the information is the same as that submitted to WHO.

3. Complete and submit an expression of interest form (Part A of Appendix 3) to the Authority through the WHO-PQ collaborative procedure focal person of the Authority.

4. The Authority shall communicate its consent to apply the procedure to the application for registration of the product and to request the WHO-PQ to share product specific information by completing and signing Part B of Appendix 3.

5. Applicant shall then complete and submit an expression of interest form (Part A of Appendix 3) to WHO-PQP directing the PQP to provide full access to the information on the prequalified product to the Authority.

4.1.2 PROCESSING

The Authority shall process the application and communicate its decision on the product to the applicant and WHO within 90 calendar days.

4.1.3 POST APPROVAL

All post-prequalification variations submitted to WHO shall be submitted simultaneously to the Authority after the product has been registered. The variation shall only be approved by the Authority only after a positive response by WHO PQP.

4.2 PUBLIC HEALTH MEDICINES

The applicant shall be required to express an interest to register any product to the Authority with justification of fast-tracking registration of the product. The Authority shall determine if the product qualifies to be registered through fast tract registration.

4.2.1 APPLICATION STEPS

1. Submit full application as per the Authority's requirement for the registration of medicines.
2. Pay the required fast-track application fees for the registration of medicines as per the fee schedule of the Authority. (access a copy of the fee schedule at www.pmra.mw).
3. Submit the required number of samples of the product as per the Authority's sample guideline.
4. Fast tract registration shall only apply to medicines manufactured at sites that are good manufacturing practices (GMP) compliant with the Authority.

4.2.2 PROCESSING

Products submitted through this route will be processed without following principle of first in first evaluated. The Authority will assess the application and communicate its decision on the product to the applicant within 180 calendar days. In cases where the applicant does not provide additional information in time as requested by the Authority, the 90-day timeline may be extended further.

4.3. SRA REGISTERED MEDICINES

All products with valid marketing authorization issued by SRA countries or region will be eligible for fast-tract registration. This will include countries that were members of the ICH prior to 2015.

4.3.1 APPLICATION STEPS

Applicant for the registration of medicines under this category shall:

1. Submit full application as per the Authority's requirement for the registration of medicines.
2. Pay the required application fees for the registration of allopathic medicines as per the fee schedule of the Authority. (access a copy of the fee schedule at www.pmra.mw).
3. Submit the required number of samples of the product as per the Authority's sample schedule.
4. Evidence that the product is registered in SRA country, evaluation reports by reference SRA country(ies) and responses by the applicant. The report from reference SRA need to be signed by response person at the reference SRA.

4.3.2 PROCESSING

Products submitted through this route will be processed without following principle of first in first evaluated. The Authority will assess the application and communicate its decision on the product to the applicant within 90 calendar days. In cases where the applicant does not provide additional information in time as requested by the Authority, the 90-day timeline may be extended further.