Pharmacy and Medicines Regulatory Authority (PMRA)

REGISTRATION PROCEDURE FOR MEDICINES RECOMMENDED FOR REGISTRATION BY ZAZIBONA

Registration procedure for medicines recommended for registration by ZAZIBONA

Once the product is recommended for registration by the ZAZIBONA Central Office, the applicant is expected to submit the application to the Pharmacy and Medicines Regulatory Authority (PMRA), Malawi, within one-year post registration recommendation. The applicant is expected submit a complete application consisting the following:

1. Expression of interest letter to register a product which has been recommended for registration by the ZAZIBONA within one year.
2. A completed application form
3. The dossier in line with Guidance on Submission of Documentation for Registration of a Multisource (Generic) Finished Pharmaceutical Product (FPP): Quality Part in the Common Technical Document (CTD) Format. The dossier must be updated in-line with all resolutions by the ZAZIBONA.
4. A declaration letter of sameness of the dossier submitted to PMRA and ZAZIBONA.
5. All queries raised by ZAZIBONA and their responses.
6. Samples as per the Sample Submission Guidelines.
7. A declaration of any changes made post ZAZIBONA registration recommendation. Please note that if major change as per the Pharmacy and Medicines Regulatory Authority variations guidelines is made post ZAZIBONA recommendation, the application will not be eligible to be registered thorough the ZAZIBONA pathway.
8. Evidence of payment of fast-track registration fees as per the Authority's fees schedule

Application form, Guidance on Submission of Documentation for Registration of a Multisource (Generic) Finished Pharmaceutical Product (FPP): Quality Part in the Common Technical Document (CTD) Format and fee schedule can be downloaded from www.pmra.mw

The submitted application will be screened for completeness.

If the dossier is complete, PMRA will review the application following its internal procedures for reviewing the application through the ZAZIBONA pathway. PMRA will at minimum verify sameness of the product submitted for registration and the product recommended for registration by ZAZIBONA to make its registration

decision. In addition to verifying sameness of the application, the PMRA will review country specific information in line with the country's guidelines.

Decision to either reject or register the product will be made within 90 days.