ZAMBIA MEDICINES REGULATORY AUTHORITY

NOTICE TO ALL MARKETING AUTHORISATION HOLDERS (MAH), LOCAL RESPONSIBLE PERSONS (LRP) AND AUTHORISED LOCAL DISTRIBUTORS OF IN-VITRO DIAGNOSTICS MEDICAL DEVICES (IVDs) IN ZAMBIA

The Zambia Medicines Regulatory Authority (ZAMRA) wishes to inform its esteemed clients that it has joined the World Health Organisation (WHO) prequalification Collaborative Procedures for Accelerated registration of IVDs (CRP) and Emergency Use Listing procedures – Facilitated procedure (EUL – FP) for both emergency and routine authorization of medical devices and IVDs of WHO prequalified and Listed In Vitro Diagnostics.

Below is vital information on the WHO prequalification Collaborative Procedures for Accelerated Registration of IVDs (CRP).

Areas of the WHO CRP reliance

1. Dossier assessment of Prequalified IVD Medical Devices
2. Performance evaluation of Prequalified IVD Medical Devices
3. GMP inspection of manufacturing sites of Prequalified IVD Medical Devices
4. Approval of changes of Prequalified IVD Medical Devices

What is the WHO Collaborative Registration Procedure (CRP)?

The WHO Collaborative Registration Procedure (CRP)Is a voluntary procedure whereby an applicant agrees to share with ZAMRA the assessment reports developed during WHO – prequalification. It is a collaboration between ZAMRA and WHO in an effort to reduce duplication of work and to ensure timely accessibility of products.

Who can apply?

An applicant for an IVD Medical Device which has been pre-qualified by the WHO.

Why apply for WHO–CRP?

The WHO–CRP shortens the registration process by:

1. Utilizing available resources and reducing duplication of efforts
2. Conducting desk review of the manufacturing facility in lieu of a physical quality audit of the site
3. Having a reduced regulatory timeline of within ninety (90) days from the date of submission.

How to apply?

1. Applicants should voluntarily express interest in applying the procedure for accelerated registration of their prequalified products by completing the WHO expression of interest form (Appendix 3);
2. Applicants should authorize WHO to share its assessment and inspection outcomes for the specific product(s), with ZAMRA by further completing the WHO consent form (Appendix 2);
3. An applicant must submit the same dossier to ZAMRA as the one approved by WHO for prequalification, along with ZAMRA application form for registration and Appendix 3 form; and
4. Requirements for ZAMRA online submission and fees for registration of In-Vitro Diagnostic Medical Devices remain the same.

For further information on the WHO Collaborative Registration Procedure (CRP) on In – Vitro Medical Diagnostics at https://extranet.who.int/pqweb/vitro-diagnostics/collaborative-procedure-accelerated-registration and you can kindly contact the Authority at pharmacy@zamra.co.zm and allieds@zamra.co.zm or visit us in person at our Head Office located at Plot No. 2350/M Off Kenneth Kaunda International Airport Road, ZAF-KK Bypass Route between HITACHI and Delta Auto, Lusaka.

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