



ZAMBIA MEDICINES REGULATORY AUTHORITY

06th MARCH, 2023

NOTICE TO ALL IMPORTERS OF REAGENTS FOR IN - VITRO DIAGNOSTICS MEDICAL DEVICES (IVDs) IN ZAMBIA

The Zambia Medicines Regulatory Authority is established under the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control the manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances. The main objective of the Authority is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

The Authority wishes to inform its esteemed clients that import reagents for use with In Vitro Diagnostics Medical Devices (IVD) that in order to ensure the smooth flow of the import permit application process with regards to the aforementioned products, importers are advised to include the following supporting documents at application;

1. IVD Reagents imported for supply to the public health sector;
 - a) Purchase order from the Ministry of Health;
 - b) A proforma invoice;
 - c) Batch Certificates of Analysis (3) for the product;
 - d) Details (Name & address(es)) of the manufacturer and manufacturing site of the product;
 - e) Proof of registration of the product in the country of origin (regulatory approval) and
 - f) Documentary proof of compliance to ISO 13485 by the manufacturing site.

2. IVD Reagents imported for supply to the private health sector
 - a) A proforma invoice
 - b) Batch Certificates of Analysis (3) for the product;
 - c) Details (Name & address(es)) of the manufacturer and manufacturing site of the product;
 - d) Proof of registration of the product in the country of origin (regulatory approval) and
 - e) Documentary proof of compliance to ISO 13485 by the manufacturing site.

Importers are further advised to apply for import permits at least 14 days prior to the desired importation date to provide adequate time for processing for the import permit application.

For further information or clarification on the above kindly contact the Authority at pharmacy@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.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Makomani Siyanga (Mr)
Acting Director – General