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Date: 25/03/2022

To: **Holders of Wholesale Dealers Permits and Manufacturing Licences**

RE: INSPECTION OF PREMISES PRIOR TO RENEWAL OF LICENCES AND PERMITS

This circular serves to advise you that the Medicines Control Authority of Zimbabwe had a formal benchmarking assessment for the World Health Organisation (WHO) Global Benchmarking Tool (GBT), in 2021. In this assessment, the WHO assesses National Regulatory Authorities (NRA) according to functions and the assessment is ranked from Maturity Level 1 to Level 4.

When a National Regulatory Authority achieves Maturity Level 3, they are deemed as a stable and well-functioning Regulatory Authority. For the Authority to attain this level, one of the requirements is that the Authority should have a risk-based approach to the renewal of licences and permits, especially for wholesale dealers and manufacturers. In addition, it is recommended that there should be a statement of compliance or an inspection report of a site prior to the renewal of a licence or permit.

Therefore, the Authority advises that all applications for renewal of wholesale dealers' permits and manufacturers' licences for 2022, should be submitted on time and the issuance of these licences and permits will be subject to a routine inspection.

Please note that according to the Medicines and Allied Substances Control (General) Regulations, S.I. 150 of 1991, Section 15 (3), as long as a complete application for renewal, including the requisite application fee has been submitted to the Authority on time, the previously issued premises licences and permits shall remain valid.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

Richard T. Rukwata (Mr)

ACTING DIRECTOR-GENERAL