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CIRCULAR 3/2017

TO: ALL APPLICANTS WITH LISTED PRODUCTS

**CC: PHARMACEUTICAL MANUFACTURER'S ASSOCIATION (PMA)
PHARMACEUTICAL WHOLESALERS ASSOCIATION**

RE: REGISTRATION OF ALL LISTED PRODUCTS

The Medicines Control Authority of Zimbabwe (MCAZ) is in the process of reviewing legislation and plans to do away with terms that have been deemed to be problematic to its stakeholders. Such terms include "specified medicines". However, the term cannot be eliminated from the legislation without first changing the status of the medicines from "listed or specified" to "registered", through the process of registration. As a result, all listed products will now be registered.

We are confident of the safety and efficacy of these products as they have been on our market for decades. Letters of intent to register the products have been sent to applicants and objections to the proposal can be made in response to these letters. The implication of registering these medicines is that there will be need to revise the labelling to include the new registration number. Once the conditions of registration are agreed to and a registration number is issued, applicants with listed products will be given a sufficient period of time to comply with all labelling requirements. Retention fees for these products will continue to be payable annually as has been the practice.

Any queries, clarifications, contributions and feedback should be submitted to the Director-General, MCAZ, 106 Baines Avenue, Box 10559, Harare Telephone +263-4-736 981-5; e-mail: mcaz@mcaz.co.zw and copied to the Evaluations and Registration Division Head, Dr W. Wekwete wwekwete@mcaz.co.zw and adminEVR@mcaz.co.zw.

Yours Faithfully
MEDICINES CONTROL AUTHORITY OF ZIMBABWE


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G. N. MAHLANGU (MS)
DIRECTOR-GENERAL