MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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10th December 2020

To
All Marketing Authorization Holders (MAHs)

Through
The Local Technical Representatives

RE: APPLICATION FOR REGISTRATION AND RETENTION OF MEDICAL DEVICES & IVDS

Reference is made to the above subject matter.

The Board wishes to inform you that from the date of issue of this circular that the Medical devices & IVDs Classes A and B, that have upto date been undergoing listing process, shall forthwith be subjected to evaluation and registration process.

Considering the above, it is imperative that the marketing authorization holders (MAHs) who have listing letters for any medical device class apply for registration through the Board's PRIMS system by 31st March 2021.

Please note that the registration applications, for currently listed medical devices & IVDs, shall be subjected to screening process for the purpose of retention and eventual import and trade in the year 2021. All products that currently hold a listing letter i.e. for the current year 2020, shall be granted retention certificate for the year 2021 upon successful screening. The retention certificate shall be valid upto 31st December 2021 or terminate upon negative outcome of product evaluation and registration process. Conversely, all products that have a listing letter and not meeting the application for registration deadline and successful screening shall not be issued with retention certificate until upon issuance of marketing authorization following positive outcome of the full evaluation process.

The purpose of this circular therefore is to request the Marketing Authorization Holders to apply for registration of all currently listed medical devices & IVDs within the prescribed timeline of 31st of March 2020.

Dr. Ronald M. Inyangala
Director, Product Evaluation & Registration
For: CHIEF EXECUTIVE OFFICER