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Republic of Botswana

MINISTRY OF HEALTH
PRIVATE BAG 0038
GABORONE

DCS-DRU 4/2 Vol VI (68)

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To: All Applicants & Manufacturers

RE: DRU to switch from MH2048 to CTD

The above refers.

The Botswana Drugs Regulatory Unit (DRU) has invited submissions of medicines applications in piloted Common Technical Document (CTD) format since August 2014. Between August 2014 and March 2015, the DRU receives applications in either MH2048 format or piloted CTD format. Your comments on the piloted Botswana CTD guidelines are highly welcomed.

As of April 2015, the submissions will be strictly on CTD format as per the Botswana CTD guidelines that are available in the Botswana Ministry of Health website www.moh.gov.bw, Services, Regulatory Services, Drug Regulation Services read more, Botswana CTD Guidelines.

Should you need further clarification, please contact Mrs Kago at nkago@gov.bw or Dr Modutlwa at nmodutlwa@gov.bw.

Yours Faithfully

A handwritten signature in blue ink, appearing to read 'N. C. Modutlwa'.

Dr Nkaelang Modutlwa
For Chief Pharmacist