REQUIREMENTS FOR REGISTRATION OF MEDICINES IN BOTSWANA

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INTRODUCTION

- The law requires that all medicines must be registered based on safety, efficacy and quality
- Guidelines to help applicant submit right and complete information in the prescribed way and reduce processing(waiting) time
- Applications must be in format MH 2048
- All submissions must be in English. In case of documents that are not in English, a notarized copy of translated version must be submitted as well

BOARD MEETINGS

- The Drugs Regulatory Unit evaluates applications for registration. The recommendations are submitted to the Board for the final resolution;
- Under normal circumstances the Board meetings are at intervals of approximately six to eight weeks
- Applicants are notified in writing about Board resolutions regarding their applications

REGISTRATION GUIDELINE

- Registration guidelines and supporting guidelines are available on the ministry of health website. www.moh.gov.bw. Go to services, then clinical services

Procedure for Submission of applications

1. Submit the electronic version for screening. Also bring purchase order for registration samples for import authorization.
2. after screening DRU will communicate with the applicant for submission of the hard copies and samples.
3. Incomplete submissions will not be accepted

GUIDELINE CTD

Documents required

- One (1) hard copy of the registration application (dossiers) shall be submitted
- One (1) soft copy of the dossier. This should include summary of dossier in word format.
- Registration samples as required in the guidelines

GUIDELINE CTD…

- Proof of payment. Pay cash at Ministry of Health 3rd floor B Block office B8 or B6
- Evaluation process of some products may be fast-tracked due to a public health need or some other reason as the DAB may identify
- DRU accepts CTD format

LABELLING

- There are still products in the market that do not have the Botswana registration number and schedule in the label and package insert.
- This is a registration requirement as it is clearly stated in the registration letter.
- The manufacturing facility should also be on the label

FORM MH 2048- OUR FORMAT

- Page 1: applicant details, product details, manufacturing facility, declaration
- Page 2: composition + pharmaceutical development
- Page 3: Package Insert, Patient Information leaflet, Summary of Product characteristics (S*m*PC)

FORM MH 2048- OUR FORMAT CONT.

- Page 4: container /closure specs
- Page 5:Pharmaceutical documentations including raw material info, final product info, manufacturing process, stability data
- Page 6: Pharmacological and clinical documentation
- Page 7: WHO type certificates, registration certificates, packaging, labels, promotional & advertising materials if applicable

EXPEDITED REVIEW/FAST TRACK PROCESS

- The Drugs Advisory Board recognizes the competence of Stringent Regulatory Authorities [SRA](as defined by WHO)
- In addition to the SRA as listed by WHO, WHO prequalified medicines and USFDA Tentatively approved products are included in this requirement.
- The applications must comply with all other guidelines and requirements relating to medicines in Botswana.

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EXPEDITED REVIEW/FAST TRACK PROCESS CTD…

- Medicines registered in SRA will be fast-tracked and evaluated within four (4) months of submission
- The applications must be all the requirements as outlined in the guidelines.
- The applicant should always notify the DRU of any variations that have been approved by the SRA.
- Failure to notify will lead to e.g. suspension, cancellation etc of products registration.
- Other applications will be evaluated within 9-12 months

VARIATIONS

- The DRU application form “Application for Variation to a Marketing Authorization” should always be used.
- The application form is self explanatory.
- **Procedure for Minor variations**
- The applicant should ensure that the specific conditions for the minor variation are met, and that the application form is accompanied by:
- A copy of the relevant page(s) of the “Guideline on dossier requirements for minor variations”.
- All required documentation as specified in the Guideline.
- Where relevant, the **revised product information**.

PROCEDURE FOR MAJOR VARIATION

- **Procedure for Major variation**
- The applicant should ensure that the specific conditions for the major variation are met and that the application form is accompanied by:
- Supporting data relating to the variation applied for;
- Update/Addendum to quality summaries, non-clinical overviews and/or clinical overviews. When non-clinical/clinical study reports are submitted, their relevant

  Summaries should be included.
- All required documentation as specified in the Guideline.
- Where relevant, **the revised product information**

B LISTED PRODUCTS

. B-listed products are not to be varied see correspondence dated 17 February 2014

- These are old products that have been in the market before the Drugs and Related Substance Act was enacted.
- Applicants intending to submit applications for variations are advised to submit complete dossiers according to the registration guidelines or renewal guidelines.

REGISTRATION SAMPLES

- Sealed samples, from at least two (2) batches, in the actual distribution container along with certificates of analysis shall be submitted.
- The required quantities of each sample are given in page 43 in the guideline.

- **Advertising and promotion.**
- All promotional and advertising materials should be approved by the Ministry before use

FUTURE DEVELOPMENTS

- Implementation of the new law
- Updating guidelines and requirements
- Updating the website (clients will also be apprised of changes and updates)

COMPLIMENTARY MEDICINES

- **Submission of applications**
- The applicant shall submit one hard copy of the completed application including all required attachments.
- The Soft copy (Word Format on the CD) of the application must be typed in font New
- Times Roman, font size 12. Attachments should be scanned and included in the CD.
- The Completed application shall be submitted with a covering letter. To expedite unpacking of documents the covering letter should itemise the contents of the submission.

COMPLIMENTARY MEDICINES

- **Samples**

Sealed samples (at least one samples), in the actual distribution container shall be submitted.

DRU may request for more samples for testing.

- **Promotional material**

Copies of existing and proposed promotional material should be submitted.

- **All documents must be in English.**