STONEBRIDGE REGULATORY CONSULTING
medicines | medical devices | cosmetics

BOTSWANA

HUMAN MEDICINES REGISTRATION STAKEHOLDER ENGAGEMENT

MEETING NOTES

Venue: Cresta Lodge, Gaborone

Date: 19th October 2020

Time: 1400hrs-1600hrs

1. **Opening remarks by BoMRA:**

   Dr. N Modutlwa, Director of Product Evaluation and Registration, welcomed the industry's key stakeholders and introduced the authority's value proposition.

2. **Clarification of the BoMRA registration process and timelines**

   2.1 Screening timeline: 2 months.

   2.2 Standard registration process timeline: 36 months.

   2.3 Expedited/Fast-tracked registration process timeline: 12 months.

   2.4 Products partly manufactured locally registration process timeline: 24 months.

   2.5 Products entirely manufactured locally registration process timeline: 18 months.

3. **Variation timelines**

   3.1 Notifications: 2 months

   3.2 Minor Variations: 3 months

   3.3 Major Variations: 5 months

4. **Decision to Reject**

   4.1 Applicants are given a maximum of 3 months to respond to queries.

   4.2 A regulatory decision to reject/close an application will be made, if:

   4.2.1 Deadlines to respond to queries sent are not met.

   4.2.2 Any highlighted quality, safety, or efficacy deficiencies are not satisfactorily met at the end of the 3rd review. (Applicants are given up to 2 attempts to respond to Botswana Medicines Regulatory Authority (BoMRA) queries).

5. CTD Dossier Structure

5.1 Module 1: Administrative Information {motivation/cover letter, application form, screening checklist, Labelling information, current Good Manufacturing Practice (cGMP) certificates, Manufacturing and Market Authorisation (MA), proof of payment etc.}

5.2 Module 2: Technical Summaries: QOS, QIS, Non-Clinical Overview and summaries, Clinical Overview and summaries/ (BTIF).

5.3 Module 3: Quality

5.4 Module 4: Non-Clinical Data

5.5 Module 5: Clinical Data

6. Labelling of a CD for Submission

6.1 The following information should be reflected on the CD top surface in indelible ink:

6.1.1 The applicant's name

6.1.2 The proprietary name of the product

6.1.3 Available modules, e.g. Module 1-5 where applicable

6.1.4 The evaluation pathway is chosen, e.g. ZaZiBoNa or WHO CRP where applicable

6.1.5 Indicate whether the CD contains information for:

6.1.5.1 Screening

6.1.5.2 New submission

6.1.5.3 Response to (new application queries or variation queries)

6.1.5.4 Restricted part of DMF

6.1.5.5 Variation

6.1.5.6 Renewal etc.

7. Guideline to compiling a dossier

7.1 The dossier should always be in CTD format. Organization and granularity should be as per the BoMRA guide available at:

https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals/file/34-guideline-on-submission-of-applications-and-bomra-timelines

7.2 The content of the product dossier should be compiled as recommended in the Botswana Registration Quality guide and other efficacy and safety guidelines available from the BoMRA website.

8. Document formatting

8.1 The information shall be readable and usable on standard Microsoft Office software.

8.2 One CD is recommended per product. If this is not possible, multiple CDs may be used. Individual modules should not be split over numerous CDs.

8.3 The dossier **should not** be submitted as a single PDF document; this presents many challenges to assessors during screening or assessment.

8.3.1 Challenges include failure to locate critical information which may lead to rejection of the product etc.

8.4 For documents submitted in PDF format, text searchable formats should be used and appropriately indexed. For instance, in the submission of responses, the PDF format should be bookmarked for the various responses to the queries.

8.5 The folders **should not** be packed into a zip-file, rar-file or any other file format that has been compressed.

9. Critical information required in the cover letter:

9.1 The evaluation pathway the applicant is interested in pursuing.

9.1.1 ZaZiBoNa

9.1.2 WHO CRP

9.1.3 Normal review pathway.

9.2 Applicants are also encouraged to list ZaZiBoNa members and the Stringent Regulatory Authority (SRA) where the product has been approved. The registration certificates from ZaZiBoNa or SRA countries should be attached as proof of registration in the respective country.

10. Human Medicine Screening General overview:

10.1 Screening fee - BWP 1,160.00 per product

10.2 Single/multiple applications - Please refer to section 1.5.2 Same/Separate applications page 20 of 95 of the BoMRA registration quality guide for clarity on whether your product/s are considered as one or multiple applications. Example: Filgrastim 300mcg/5ml Prefilled Syringe and Filgrastim 300mcg/5ml Prefilled Pen-set will require separate applications.

10.3 Screening process

10.3.1 After your application is screened for the first time, it will either pass, or a list of queries to address will be sent to you.

10.3.2 If a list of queries (LOQs) is sent, you are required to address the queries within the deadline by updating the relevant sections of the dossier. Then submit a full updated dossier for screening. Please do not send separate responses to queries. No additional payment is required when responding to queries.

10.3.3 If, after responding to queries, the applicant has not addressed the issues, or the applicant fails to respond within the stated time, the application will fail screening. If you wish to pursue registration, a new application, with the fees should be submitted, and a new screening number will be issued.

10.4 Screening commonly appearing deficiencies

10.4.1 *Batch Manufacturing Records*

10.4.1.1 The executed production document should be provided for the: