# Update of the new product registrations and variations status at BOMRA

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# Background

- BoMRA has the mandate to regulate medicines [human & veterinary], medical devices and cosmetics
- BoMRA started operations in 2019, taking over from Ministries of Health and Agriculture.
- Human medicines were undergoing registration process, but not so for veterinary, cosmetics and medical devices
- Complementary medicines were exempted from registration
- Backlogs of medicines, complementary meds and variations were inherited

# Approach to regulation of products

- Approach to regulation of the expanded scope
  - A phased approach was adopted for new products starting with backlogs
  - BoMRA opened to receive new applications for registration of medicines and complementary medicines in February 2020
  - Framework for veterinary medicines was developed including guidelines, tools, forms and start date for receiving veterinary medicines applications was set for November 2020
  - Framework for regulation of medical devices is being developed, starting with listing process which is ongoing
  - Framework for cosmetics is also being developed. We have started with listing of cosmeceutical, based on what is already on the market

# Specific questions from SAPRAA-CAMS

By what date do CAMS registration applications need to be submitted? No clarity online on timelines and requirements w.r.t currently marketed products vs. new products.

Complementary medicines have always had the requirement to be registered before sale in Botswana. The link to guidelines:

1. https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals/file/53-guideline-for-application-for-registration-of-complementary-medicines-iss-2

2. https://www.bomra.co.bw/index.php/bomra-downloads/forms/category/38-new-form

The timeline to registration is a maximum of 24 months for normal applications and 8 months for expedited applications

# Applicable fees

a) In the case of a complementary medicine imported into Botswana as a finished product for—

| | (BOTSWANA PULA) |
|---|---|
| Screening fee | 500 |
| Re-Screening fee | 500 |
| Complementary medicine | 5 000 |
| A line extension of complementary medicine | 1 000 |
| Renewal of registration | 4 000 |
| Annual fee | 4 00 |
| Variations | 500 |

b) In the case of a complementary medicine imported into Botswana for packaging, relabelling or repackaging before being sold as—

| | |
|---|---|
| Complementary medicine | 1 750 |

c) Full manufacturing in Botswana

| | |
|---|---|
| Complementary medicine | 1 000 |

d) In the case of expedited review of —

| | |
|---|---|
| Complementary medicine | 10 000 |

# CAMS cont.

CAMS – What would be considered an acceptable reason for not having Climate Zone IV stability studies (term 30±2 °C RH 65±5 %)? I.e., this is not a required climate study zone for SA or FDA and usually this stability data does not exist.

- Stability studies are a mandatory requirement for complementary medicines due to the high temperature conditions in Botswana

  - Acceptable Climatic Zones as per WHO for Botswana are either Zone IVb or Zone III.
  - SADC adopted the zone IV to accommodate the extreme conditions in some member states

# Cosmetics

- Cosmetics – Where can we find the Cosmetics Standards referred to in latest communications?

- Please find below the online store for the Botswana Bureau of Standards. You may purchase the standard from there.
- https://bobs.isolutions.iso.org/bobs

# Veterinary:

Medical device listing for veterinary- what are applicants supposed to submit if they do not have labels for those devices (the listed devices are more applicators used for easier administration of product to the animal)

- Labels for the devices are only submitted by the Manufacturer / Authorized Representative (Sole Agent).
- Other applicants (Local Representative/Importer/Distributor/Agent/Facility) do not have to submit labels for the medical devices but are required to fill the Manufacturer details in Annexure 1 for BoMRA to contact the Manufacturer for those.

# Veterinary

Shampoos- will we have to register them, more especially the cosmetic ones (i.e., the one which are not registered even with Act 36). If we have to register, what is the process?

- These products generally do not require registration if:
- - they do not contain antiseptics, antimicrobials, antibiotics, or other active constituents.
- - they do not make any health, production, or performance claim.

# Veterinary

- Products listed on the BoMRA link, when are we expected to submit dossier, or will they be automatically recognised as registered?
- The listing process being implemented for VMPs is a temporary measure based on prior existence of a product on the Botswana Market upon DVS approval.
- The temporary approval will be valid for 5years from date of publishing the BV List.
- During these 5 years, Companies would be expected to submit dossiers for full Market Authorisation / registration based on successful evaluation of the quality, safety, and efficacy of the product.

# Veterinary

- Local representative- what are the requirements regarding having a local representative in Botswana?
- The principal or Manufacturer or Foreign applicant is required to write to the Authority nominating an entity or an individual as a local representative to facilitate communication between the Authority and themselves

- Will RSA labels be allowed for regional harmonization?
- Requirements for product information is harmonized in the SADC region.

- What are the timelines for dossier registration in Botswana for veterinary applicants?
- The Authority had not yet finalized the timelines.

# Human medicines

- What is the deadline for the registration of B-listed medicines?

- Not set yet

- With reference to correspondence dated 25 Jan 2021, Ref.: MRA 1/8/5 Vol I (130) – does BOMRA respond to the proposed schedules for applications for registration of B-listed medicines submitted by applicants, or can this be assumed as accepted?
- If your proposal has not been responded to, then it should be taken as automatic approval. Where there is an objection, the Authority would have communicated to the respective or concerned parties.

# Human medicines

- For B-listed medicines, would BOMRA grant exemption from Modules 4 and 5?
- Module 4 and 5 may be waived on case by case basis.
- What are the approval timelines for new registrations?
- The time from submission to registration of new applications is as follows:
- Normal process: 36 months.
- Expedited / Fast tracked products: 12 months.
- Products partly manufactured locally: 24 months.
- Products fully manufactured locally: 18 months.

# Human medicines

- With regard to Product Renewals in Botswana, is it possible to propose to BoMRA to provide Industry with at least a 12-month notification timeline to prepare for the respective Therapeutic Area Renewal submissions?
- It is an acceptable approach, to allow proper preparations from both parties.
- Applicants are requested to submit their proposals for when they can submit. BoMRA will review the proposals when made and come to an agreement with industry

BOMRA

MEDICINES REGULATORY AUTHORITY

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