BoMRA Experience with Medicines Renewals as of April 2023

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Objectives

1. BoMRA renewals strategy
2. Required documentation
3. Variations during Renewal submission
4. Renewal Timelines
5. Changes to the medicine register
6. Progress (Work done)
7. Challenges
8. Questions, Answers and Suggestions

BoMRA medicine renewals strategy

2020: Initial pieces of communication sent out to all stakeholders

April 2020: First communication sent to all stakeholders; applicants were requested to submit applications for renewal of registration for all ARV product applications registered before 31/04/2015.

October 2020: A reminder letter to all stakeholders; was sent out reference MRA 1/8/5 Vol II (51), applicants were reminded to submit applications for renewal of registration for all ARV product applications registered before 31/04/2015.

BoMRA medicine renewals strategy …

Strategy and timeline for submission of renewals: from 2020-2025

Q1 2020/2021	Q3 2022/2023	Q1 2023/2024	Q1 2024/ 2025
Piloted and opened for ARVs only. Initially communicated in April 2020. Reminder send in October 2020	MAH with products registered in period **1998-2009** required to submit renewal applications Communication dated 17/08/2022 Ref letter: MRA 1/9/2 Vol I (134) Approx. 1091 products	Call for submission of renewals for products registered from **2010 to 2014** Communication dated 17/08/2022 Ref letter: MRA 1/9/2 Vol I (134) 941 products	MAHs with products registered from **2015 to 2017** required to submit renewals. Communication dated 17/08/2022 Ref letter: MRA 1/9/2 Vol I (134) 520 products

BoMRA medicine renewals strategy …

Strategy and timeline for submission of renewals:

Q1 2020/2021	Q3 2022/2023	Q1 2023/2024	Q1 2024/ 2025
Piloted and opened for ARVs only. Anti tubercular and antimalarial medicines also expected . Initially communicated in April 2020. Reminder send in October 2020	Submit renewals applications for products registered from **1998-2009**.	Submit renewals applications for products registered from **2010 to 2014**	Submit renewals applications for products registered from **2015 to 2017**

This information on when to submit renewal products is expected to inform applicant's inhouse plans with regards to finances and documentation to ensure that all products in these noted periods are submitted for renewal at the right time.

Required documentation and fees

1. A completed, signed, dated application form with **BOT number** indicated.
2. A **full CTD dossier** with modules 1, 2, 3, 4 and 5 where applicable. The same will serve as a baseline dossier to ensure that going forward the Authority has the current-up to date dossiers for all products in the required CTD format. It is acknowledged that some products on the register are old, and the Authority does not have adequate information on these products. An opportunity to update this information and create baseline dossiers is seen.
3. Quality Information Summary **(QIS):** A fully completed, QIS in word format.

Renewal Fees: BWP 5 000

Variations & Renewal applications

1. Variations should not be submitted with the renewal application; they should be submitted separately via the BoMRA paid services.
2. Applicants are encouraged to not propose new changes in renewal applications e.g., applicant submit a renewal application and at the same time requests to increase the FPP batch size e.g, from 400 000 tablets to 800 000 tablets. Such variations should be submitted separately via BoMRA paid services.
3. A list of changes/ applications for variations submitted to BoMRA can also be included in your renewal application for the Authorities noting.

Renewal Timelines

BoMRA processing time (first communication)	6 Months
Applicant response time in case of LOQ	1 Months
Overall time to finalization of a renewal	12 Months

Changes to the Medicine Register as a result of renewal applications approvals

The bluebook/ register is currently undergoing changes, one of the changes which is to include date of expiry of initial registration which is usually valid for 5 years after.

The new, updated register is going to show the date of initial registration and expiry date of registration.

Some of the changes of course pertain inclusion of pack sizes for products which did not have these indicated.

Progress made thus far with submitted renewals

2020-2021	2022	2023
Received	Received	Received
83	27	55

- Multiple applicants have presented proposals for 221 products requesting for an extension period to submit initial renewal applications.
- Extension to respond to renewal queries
- Some requests have been accepted some have not been accepted the basis being the time extension requ ested

Current status: Going forward, what are applicants expected to do?

1. Currently we have sent out LOQs for some of the assessed renewals and we expect, and hope applicants respond on time to ensure timely approval of the renewals.
2. Call for submission of renewals for products registered from **2010 to 2014** is active.
3. If you haven't submitted renewal applications for: ARVs, Anti TBs, Anti Malarials, or products registered in period **1998-2009** you are required to do so these are considered overdue. Alternatively, a formal request for extension period to submit initial renewal applications should be submitted to BoMRA.
4. Going forward, BOMRA expect submission of applications as MA reached 5 years

Challenges

1. Low influx of renewal applications only **165** renewal applications received so far.
2. Incomplete documentation (renewals form not submitted or not completed)
3. QIS document not fully completed
4. QIS document not in word format
5. Annual Product Quality Reviews (APQR) not submitted
6. Human resources shortage

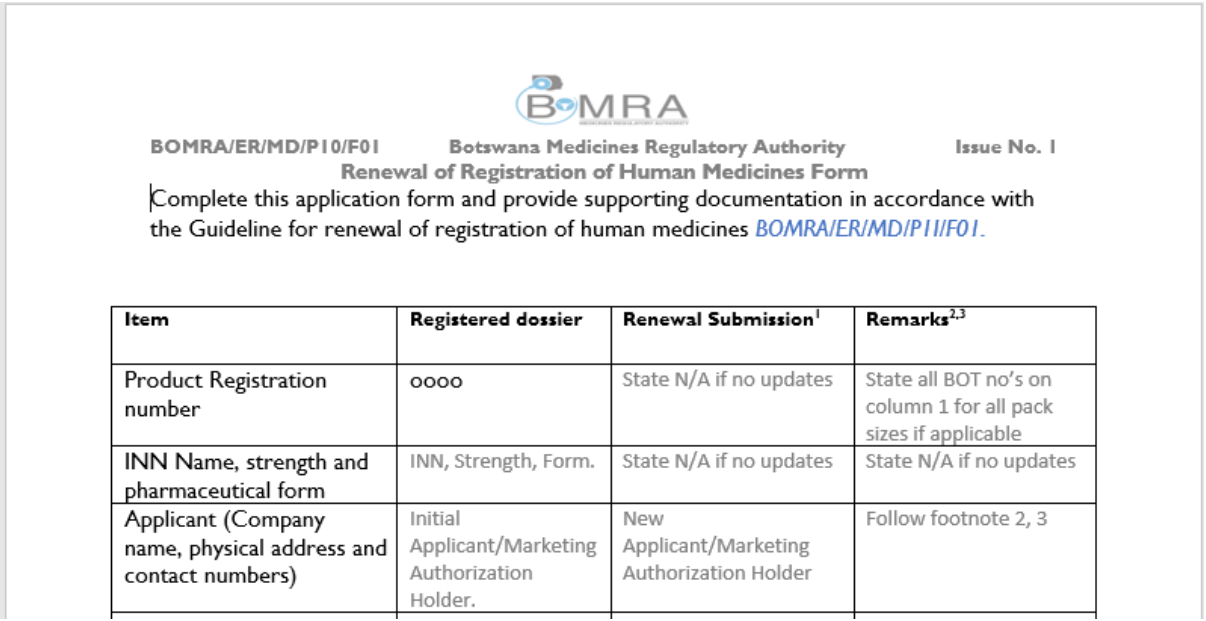
Challenges and Solutions

Low influx of renewal applications only 165 renewal applications received so far.

1. What could be a cause for low influx of renewal applications?
2. We also want to seek input from Applicants with regards to this issue, i.e., where are they facing challenges and what do they suggest should be done?
3. How do they think the Authority can facilitate them to ensure products are submitted for renewal.
4. We welcome your feedback and would like to hear from you.

Challenges and Solutions…

Incomplete documentation (renewals form not submitted or not fully completed)



BOMRA/ER/MD/P10/F01 Botswana Medicines Regulatory Authority Issue No. 1

Renewal of Registration of Human Medicines Form

Complete this application form and provide supporting documentation in accordance with the Guideline for renewal of registration of human medicines *BOMRA/ER/MD/P11/F01*.

Item	Registered dossier	Renewal Submission[1]	Remarks[2,3]
Product Registration number	oooo	State N/A if no updates	State all BOT no's on column 1 for all pack sizes if applicable
INN Name, strength and pharmaceutical form	INN, Strength, Form.	State N/A if no updates	State N/A if no updates
Applicant (Company name, physical address and contact numbers)	Initial Applicant/Marketing Authorization Holder.	New Applicant/Marketing Authorization Holder	Follow footnote 2, 3

This document is critical and required. It should be duly completed and should show the currently approved dossier status and what is in the renewal dossier, this helps to see if there have been major changes to critical aspects e.g., shelf life or FPP batch sizes etc.

Challenges and Solutions

Annual Product Quality Reviews (APQR) not submitted

- An annual product quality review document is required to ensure and demonstrate control on the starting materials, API and finished product as received, used and manufactured at the proposed FPP manufacturing site.
- Consistency of the manufacturing processes are also demonstrated by this document.

Requirement:

Option 1: The report should be for at least 10 consecutive batches manufactured over a period of 12 months for the Botswana market.

Option 2: Or where 10 batches were not manufactured in the last 12 months, NLT 25 consecutive batches manufactured in the past 36 months.

Option 3: If these batches are not available as marketed/manufactured for the Botswana market, the applicant can submit products manufactured from the same FPP site but meant for other markets. The idea of the APQR is to demonstrate control in as far as starting materials, APIs, and the final product is concerned. Also highlighting trends, so it would give BoMRA important information on whether the process is under control at the proposed site even though some of the batches are not meant for out market.

Challenges and Solutions…

QIS document not fully completed or not in required word format

- Should be completed and should be in word format.
- This document is a condensed summary of the critical quality information of the API, FPP sections and should be completed in its entirety.
- We are using this document inhouse for assessment, its critical, renewal assessment won't start without these 3 critical documents (QIS in word format, APQR, Completed Renewal). Always ensure these documents are attached.

Challenges and Solutions

Human resources shortage

The Authority is exploring multiple inhouse strategies to ensure timely assessment of renewals. Some of the strategies which are being considered include, outsourcing to external assessors/ experts, focused retreats etc.

BOMRA
MEDICINES REGULATORY AUTHORITY

Promoting access to safe medicines

THANK YOU !

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Q & A and Suggestions ?!?