Renewal of Registration for Therapeutic Human Medicines - FAQs

The Department of Product Evaluation and Registration (DPER) is responsible for processing of applications submitted for renewal of registrations for Human Medicines.

General questions:

What steps should I follow to submit an application/ dossier for renewal of a medicine?
A: You are required to submit a service request form either via email to: **humanmeds.renewal@BOMRA.co.bw** or submission at BoMRA offices. To download the service request form on BoMRA website **www.bomra.co.bw**, go to Downloads>Forms>Service request form. You shall be issued with a proforma invoice / sales order which you will use to process/make a payment for the intended service. After payment, submit the proof of payment, and the application to BoMRA. For more details visit the following guidelines:

a. Guideline on submission of applications and BoMRA timelines
b. Guideline for submission of requests for paid services

These can be accessed on the BoMRA website **www.bomra.co.bw.** You can access them by following the following steps: under Downloads > Guidelines/Manuals > registration

How do I submit a renewal application for a registered medicine?
A: You would need to submit an updated dossier/application to BoMRA. and payment of the relevant fee. Note that the Screening process will not apply.

For applications where the full dossier is available, applicants are encouraged to submit Modules 1 to 5, however, submission of Modules 1 and 3 would be acceptable for products registered before the implementation of the CTD format.

Can the applicant submit variations together with the renewal application?
A: Variations and renewals may not be submitted at the same time. Therefore, these should be submitted separately for approval.

We strongly encourage applicants to submit evidence of approval of any variations by other Authorities so that we can expedite assessment of the variations.

What is the BoMRA approach with regards to renewal of registration process and what are the associated timelines?
A: BoMRA is implementing a phased approach to the renewal process based on the classification of the product.

The registration of any product class that has not been announced for renewal will remain valid. The following renewal strategy will be implemented:

2020/21 - antiretroviral products
2021/22 - antiretrovirals + antituberculosis products
2022/23 - antiretrovirals + antituberculosis + antimalarial products

The timeline for approvals is six months (BoMRA time) from time of application submission provided all the variations affecting the application have been approved.

What is the timeline for assessment of a renewal application?
A: Applications will be assessed within 6 months from the date of submission.

Would provision of WHO Public Assessment Reports (WHOPARs) or European Public Assessment Reports (EPARs) speed approval/facilitate review by BoMRA?
A: WHO Public Assessment Reports or European Public Assessment Reports are publicly available, and we normally leverage on them during assessment.
Applicants are encouraged to make use of the WHO collaborative registration pathway or to request unredacted reports from SRAs, where applicable for faster turnaround times.

Does BoMRA have the deadline for submission of renewals as mentioned on the above strategy?
A: The submission deadline for applications for renewals of antiretroviral medicines has not been set but when communicated, it will not be earlier than 30 June 2021.

Note that for the remaining categories, the proposed dates shall apply accordingly.

What is the implication if the applicant does not submit the renewal dossier on time?
A: Since BoMRA is implementing a phased approach, the registration of any product class that has not been announced for renewal will remain valid. Failure to submit a renewal application or a request for a reasonable extension, will result in the products being de-registered.

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