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Renewals Update
06 May 2024

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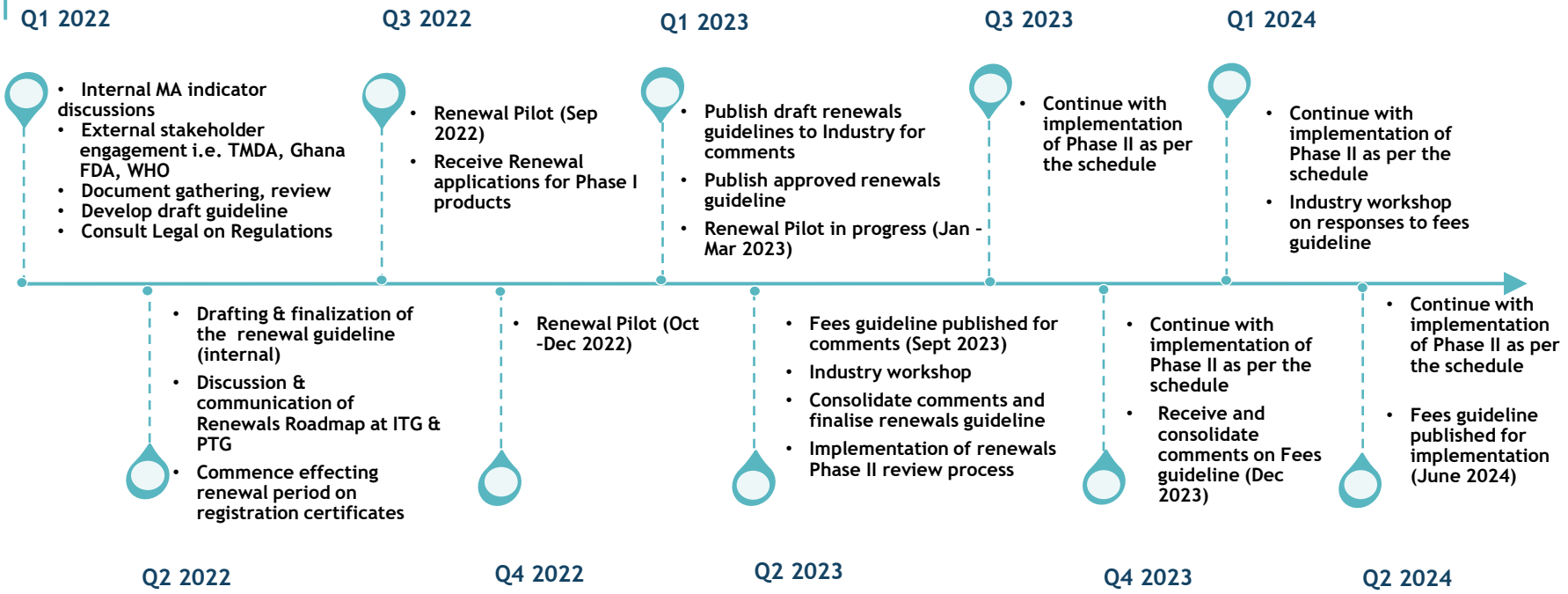
RENEWALS ROADMAP



*** Timelines reflect calendar year**

Renewals pilot (PHASE I)

The aim of the renewal pilot:

- To establish a robust and effective renewal process for SAHPRA.

The objectives of the renewal pilot was:

- To provide a model for future renewal processes, with clear guidelines and best practices that can be applied to other medicines as well
- To streamline the renewal templates and Standard Operating Procedures
- To identify gaps and risks in the renewal process

Pilot Implementation:

Renewals Pilot was published on the SAHPRA website in September 2022

The Pilot applications were received in September 2022 to October 2022

Pilot finalization:

Last renewal certificate was issued in August 2023

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Renewals pilot (PHASE I)

Pilot status update

- The renewal applications received for the pilot consisted of four Antivirals and one Immunological product. Which is five master (eight lines)
- One application was withdrawn
- Four renewal application certificates issued
- The overall time to complete this pilot project was 12 months

Shortcomings

- Evaluators that participated in the renewal pilot had experience only in the quality part of dossiers hence only evaluated the quality part of the renewal application leaving the clinical and inspectorate parts of the dossier to be evaluated by the internal evaluation teams.
- Resources from the internal evaluation teams were constrained and were unable to do the reviews timeously. This led to a delay in the pilot process.
- Product information was not up to date and a safety variation had to be submitted before the renewal could be finalised.

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Renewals pilot (PHASE I)

Learnings

- For applications that have a renewal query that warrants variation, the applicant shall submit the variation to relevant post-registration unit and share the proof of submission with HPA for the renewal to be finalised.
- Increase resource pool of evaluators who could review all the required sections in the renewals submissions.
- Capacitate the renewal workstream to have dedicated Internal Evaluators/ MROs

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Current Status – Phase I

	PHASE 1 Q2	PHASE 1 Q3	Phase 1 Q4
STATUS			
Total Master applications	**20**	**17**	**22**
Admin Screening completed Total	**20**	**17**	**20**
In evaluation – primary review	2	11	12
To be allocated for Peer Review	-	2	-
Approved		-	-
Evaluation query (round 1)	6	-	-
Peer Response review complete – in QC	4	-	-
Peer review complete - In QC	1	3	-
Response Review Peer	6	-	-
Response Review Primary	-	1	-
Response to be allocated	1	-	-
To be allocated (Technical screening)	-	-	1

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Renewal Framework – Steps Completed

Step	Activity	Description	Target Date/ Status
1	External Engagements	Consultations with WHO, TMDA, ZAMRA and BOMRA	Completed
2	Guidelines from various regulatory authorities	– Guidelines from TMDA, BOMRA, ZAMRA, NAFDAC, FDA GHANA, – the MENA region regulatory authorities' requirements, and – EMA requirements.	Completed
3	SAHPRA Guideline (Draft)	– Reviewed internally – SAHPRA Legal Committee consulted	Completed
4	Renewals Roadmap Schedule	Reviewed internally	Completed
5	Guideline development	– Background on WHO GBT process discussed, – Draft guideline also discussed to give context to communication that will be published on website for comments	Completed
6	Guideline Communication	Draft guideline and communication to Industry	Completed

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Renewal Framework – Steps Completed (Cont.)

Step	Activity	Description	Target date/ Status
7	Guideline	Comments	Completed
8	Final version of Guideline	Industry Roadmap schedule	Completed
9	Workshop	Workshop the guideline and template with 4 selected Phase I participants	Completed
10	Open for renewal applications	Receive Renewal applications for Phase I products	Completed
11	First reviews	Complete Phase I first reviews	Completed
12	SOP establishment	Update the SOP and/or guideline if necessary	Completed

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Renewal Framework – Steps to be completed with anticipated completion dates

Step	Activity	Description	Target Date/ Status
13	Assessments/ Evaluations	Initiate Phase II assessments for the first applications according to schedule	Implemented Aug 2023
14	Gazette	To be Gazetted	June 2024
15	Recruitment & Training	Structure has been developed and there are resources supporting the process. Recruitment and training of permanent resources to be completed by June 2024.	June 2024

Renewals Document management

- Renewals documents are uploaded on website accordingly

  - **Industry communication**
    - HPA01-2022_2 v6 Renewals Framework Communication_Updated_COMM
    - HPA08-2022_23 v5_Renewals Frequently Asked Questions (FAQs)_COMM Issue

  - **Guideline**
    - SAHPGL-HPA-04-v4 Renewal of Registration of Human and Veterinary Medicines

  - **Validation template**
    - GLF-HPA-04A_v3-Renewals-Validation-Template-for-eCTD_Aug23_v3

  - **Fees** – To be Gazetted

  Note: Update on renewals communication and guideline will be published before the 30th June 2024
  Extension of dormant product submission period from December 2024 to Dec 2025

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The do’s and don’ts

Don’ts	Do’s
Ignore the road map schedule and then ask for extension requests	Look at your road map schedule and plan ahead
Send validation templates in pdf only	Send validation templates in word
Send an email enquiry without first reading the Renewals guideline, Renewals framework communication and FAQ	Read the Renewals guideline, Renewals framework communication and FAQ
Use outdated templates	Use the latest templates supplied on the SAHPRA website
Submit a renewal application if there are pending variations in esubmission	Request an extension request if there are pending variations in submission
Tick the sections in the validation template if the documents are not available	Confirm that the documents are available when ticking the validation template
Submit poor quality baseline dossiers not meeting the requirements	Submit a dossier with currently approved information

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Thanks for your Attention

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