REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

REGULATORY NOTICE

QUERY RESPONSE TIMELINES AND REVIEW CYCLES FOR NEW AND RENEWAL MARKETING AUTHORISATION APPLICATIONS

The Pharmacy and Poisons Board ("the Board") is mandated under the Pharmacy and Poisons Act, CAP 244 Laws of Kenya to protect and promote public health by ensuring access to quality, safe, and efficacious Health Products and Technologies ("HPTs").

To support timely, predictable, and efficient processing of applications for Marketing Authorization of HPTs, the Board hereby reminds all Marketing Authorization Holders (MAHs) and Local Technical Representatives (LTRs) of the timelines for responding to regulatory queries for both New and Renewal Applications**.**

Response periods and review cycles

1. MAHs and LTRs must strictly comply with the query response timelines and maximum allowable review cycles set out below for both New Applications and Renewal Applications.
2. The response periods and review cycles below are drawn from Part VII, sections 5.2, 5.5 and 5.6 of the Compendium of Guidelines on Medicines Evaluation and Registration in Kenya and section 4.0 of the Guidelines on Renewal of Marketing Authorization for Medicines and Vaccines.

Stage	**New applications**	**Renewal applications**
Screening of applications		
Screening: 1st Query Response	Respond within 28 calendar days of receiving the query	Respond within 28 calendar days of receiving the query
Screening: 2nd Query Response	Respond within 14 calendar days of receiving the query	Respond within 14 calendar days of receiving the query
Screening limit	Up to 3 screening cycles	Up to 3 screening cycles
Evaluation of applications		
Evaluation: 1st Query Response	Respond within 180 calendar days of receiving the query	Respond within 60 calendar days of receiving the query
Evaluation: Subsequent Query Responses	Respond within 120 calendar days of receiving the query	Respond within 20 calendar days of receiving the query
Evaluation limit	Up to 4 evaluation cycles	Up to 3 evaluation cycles

3. Upon issuance of a query, the Board's evaluation clock stops immediately and resumes only upon receipt and validation of a complete response package.
4. Where an applicant fails to submit a response within the prescribed timelines, or fails to satisfactorily address substantive queries within the permitted evaluation cycles, the Board shall proceed on the basis that the applicant no longer intends to pursue the application.
5. The application shall then be deemed lapsed, shall be closed and archived accordingly.
6. An applicant wishing to proceed after closure of an application shall be required to submit a fresh application, subject to all applicable requirements and fees.
7. MAHs and LTRs are further reminded to submit complete renewal applications at least three months before the expiry of the current marketing authorisation, in accordance with the renewal guideline and Rule 9 of the Pharmacy and Poisons (Registration of Health Products and Technologies) Rules, 2022.

Implementation and enquiries

8. Applicants are responsible for submitting complete, accurate and up-to-date applications that meet the applicable guidelines at the time of submission. A complete submission reduces avoidable queries and preserves the available review cycles for matters that require substantive assessment.
9. Where a query cannot reasonably be resolved within the prescribed period, the applicant must respond before the deadline through the designated product registration channel. The response should provide the available information, identify what remains outstanding, explain the delay, and propose a clear plan and submission date.
10. A proposed plan does not extend the deadline. Any exception applies only if the Board accepts it in writing, subject to the date and conditions communicated.
11. Applicants whose query response deadlines had lapsed by the date of this notice shall be required to submit their responses within 14 calendar days of this notice. Thereafter, the Board will apply clauses 4, 5 and 6 of this notice to applications for which no response has been received.
12. Applicants should monitor the product registration portal at https://products.pharmacyboardkenya.org/ and consult the current guidelines.

The Board remains committed to protecting and safeguarding public health, and will continue to provide the necessary technical guidance to support sustained regulatory compliance.

Dr. Ahmed I. Mohamed
CHIEF EXECUTIVE OFFICER
25th September 2026