MCAZ Medicines Control Authority of Zimbabwe

Processing Applications for Registration of Medicines_2025

29 NOVEMBER 2024

GRACE MATIMBA: CHIEF REGULATORY OFFICER: EVALUATIONS

Outline

1. Circular 26 of 2023
2. Updates
3. Processing applications 2025

Circular 26 of 2023

Solution

- High level Screening

-**Pass:** Proceed to evaluate

-**Fail:** NMT 120 respond

- Limit Review Cycles ≤ 2
- Regulatory Decision in NMT 9 months
- Previous Median Time to Registration <u>24 months</u>

Circular 26 of 2023

Anticipated Benefits

- Increase in efficiency in processing applications for registration
- Improvements in submissions: MCAZ/ICH Requirements
- Significant reduction in timelines for registration
- Efficient Talent Management
- Better Risk-Based Assessments on Quality submissions
- Abolishment of the tendency to hold queue by applicants with grossly deficient dossiers

Phase	Submission	Screening	1st Assessment Cycle	Submission of 1st Response	2nd Assessment Cycle	Final Regulatory Decision	Post-Decision
Regulatory requirements	MCAZ CTD Dossier Samples fees	Screening check list	Evaluation report Query letter	MCAZ CTD Dossier	Evaluation report	Evaluation report	Registration Certificate or Letter

Deadline extension request

With immediate effect, the Authority will not entertain any time-extension requests to respond to queries. Any such requests will be rejected and the application will be refused registration. The Authority will strictly monitor and track the following timelines following the Committee decisions:

Authority's Decision	Applicant's Timeline
Intent to refuse to register	60 calendar days
Intent to register	30 calendar days

Anticipated impact of the above measures

We trust that these measures will improve the efficiency of our processes by providing for the following:

1. Reduction in the accumulation of WIP, thereby increasing efficiency.
2. Compelling Applicants to work on updating their dossiers in accordance with the MCAZ and ICH guidelines prior to submitting their applications.
3. Significant reduction in timelines due to the reduced number of review cycles as well as the removal of deadline extensions.
4. More efficient use of assessors' time – assessors are an expensive and scarce resource, and any increase in their efficiency results in an overall increase in the efficiency of the whole system.
5. Assessors spend more time addressing matters of regulatory science, which impact on quality, safety and efficacy of medicines, as opposed to focusing on deficiencies in the product dossier.
6. An increase in the quality of submissions, which enables the Authority to better apply risk-based assessment techniques, which further improve the speed with which applications are processed.
7. Abolition of the tendency by some applicants to submit incomplete applications in a bid to hold positions in the "queue" of pending applications, and only committing to working on the applications once they receive query letters from the Authority. Under the new process, submitting incomplete applications will not only be costly, but will also proffer no benefits due to the quarantine process, which effectively abolishes the queue.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

R. T. Rukwata (Mr.)
DIRECTOR-GENERAL

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Updates: **Screening**

Statistics as of 31 October 2024:

- 90% of 2024 applications screened
- 57% met the 10 working days timeline
- 64% of backlog applications screened
- Cumulative pass rate: 44%
- Screening failure rate decreased from 84% to 6%

20% of failed applications had responses submitted
82% of passed applications had responses submitted

Updates: Evaluation and finalisation

- **Efficiency Improvements:**
  - Meeting 9-month timeline for finalisation
  - 35% more applications evaluated compared to 2023
  - 53% more applications registered compared to 2023

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Processing of Applications in 2025

- Continuation of Circular 26 of 2023
-Revised Timelines Effective January 2025

Process	Responsible party	2024 timeline	2025 timeline
Screening	MCAZ	10 working days	20 working days
Response submission after proceed to evaluate decision by the Authority	Applicant	30 calendar days	45 calendar days
Response submission after intent to refuse after screening	Applicant	120 calendar days	120 calendar days
Response submission after Intent to register after evaluation	Applicant	30 calendar days	45 calendar days
Response submission after Intent to refuse after evaluation	Applicant	60 calendar days	60 calendar days
Finalisation of applications after submission of a satisfactory response to screening	MCAZ	270 calendar days (MCAZ time)	270 calendar days (MCAZ time)

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Monitoring and tracking:2025

- Increased automation: Submission of dossiers online
- Strict Monitoring of Timelines
- Maintenance of 2 review cycles
- No Time-Extension Requests Entertained
- Screening of backlog files to be completed in December 2025
- Continuation of use of reliance
- Rejection of Applications Failing to Meet Timelines

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2025: WHO GBT ML4 Status

World Health Organization's (WHO) Global Benchmarking Tool (GBT) maturity level 4

- Publishing Public Assessment Reports (PARs)
- Increased automation
- Clear timelines for processes
- Adherence to timelines


thank
you