



106 Baines Avenue
Tel: +263 242 736 981-7
708 255 / 792 165 / 0772 145 191/2/3
Email: mcaz@mcaz.co.zw
Website: www.mcaz.co.zw

P.O. Box 10559
Harare
Zimbabwe

REF: B/279/35/26/2024

CIRCULAR 26 of 2024

Date: 12/12/2024

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: PROCESSING OF APPLICATIONS FOR REGISTRATION OF MEDICINES

The Authority makes reference to Circular 26 of 2023, dated 24th November 2023 which outlined the new framework on processing applications for registration of medicines. This new framework was implemented starting 1st January 2024 and resulted in registration of 54% more medicines in 2024 compared to those registered in 2023. The measures communicated through Circular 26 of 2023 prioritised high level screening of applications within 10 working days and limited review cycles to a maximum of two (2). The Authority has, after continuous consultation with its stakeholders during the implementation of Circular 26 of 2023, further revised the framework aimed at improving efficiency and effectiveness as follows:

Automation of submission of applications for Registration of Medicines in 2025

In line with the MCAZ strategic plan 2022 to 2026 to fully automate all regulatory processes, the Authority will roll out a pilot on-line submission and payment portal for applications for registration of human, veterinary and complementary medicines with effect from January 2025. The Authority will allow both manual and online submission of applications for registration options to co-function during the rest of 2025.

Processing of Applications for Registration of Medicines in 2025

Based on the positive shift in timelines and productivity, the Authority has further revised key regulatory performance indicators (RPIs) for marketing authorisation of medicines with effect from 1st January 2025 towards ensuring efficiency and effectiveness in medicines registration as follows:

Table with 4 columns: Process, Responsible party, 2024 timeline, 2025 timeline. It details regulatory performance indicators for screening, including communication after high level screening, submission of response after a decision to proceed, and submission of response after failing screening.

Process	Responsible party	2024 timeline	2025 timeline
Regulatory Performance Indicator: First Review Cycle or Second Review Cycle			
Communication after evaluation	MCAZ	-	60 working days
Submission of response after a decision to intent to register by the Authority post evaluation	Applicant	30 calendar days	45 calendar days
Submission of response after a decision to intent to refuse to register by the Authority post evaluation	Applicant	60 calendar days	60 calendar days

Process	Responsible party	2024 timeline	2025 timeline
Regulatory Performance Indicator: Regulatory Decision			
Communication after assessments of response to second evaluation	MCAZ	-	60 working days
Overall Timeline for the Medicines Registration Process	MCAZ	600-900 calendar days	270 calendar days (MCAZ time)

Deadline extension requests

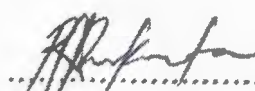
The Authority will not entertain any timeline-extension requests to respond to queries. Any such requests will be rejected, and the application will be refused registration.

Backlog files (Applications received prior January 2024)

It is anticipated that by the 31st January 2025, all backlog files pending screening will have been screened. After submission of a satisfactory response to screening, the timelines communicated above table will apply.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



R. T. RUKWATA (MR.)
DIRECTOR-GENERAL