MCAZ Medicines Control Authority of Zimbabwe

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To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: PROCESSING OF APPLICATIONS FOR REGISTRATION OF MEDICINES

The Authority has, after consultation with stakeholders, significantly revised the processes for handling applications for registration of medicines. Stakeholders have complained over the years about the timelines for registration of medicines, which are considered to be too long. Further complaints have been around the communication of progress on the assessment of applications. After conducting an exercise in the third quarter of 2023 to map the status of all pending applications, the following reasons were noted as contributing to the inefficiencies and persistent backlog of applications in the system:

(1) Submission by Applicants of grossly deficient applications for registration.
(2) A significant number of Applicants requesting for multiple deadline extensions for submission of responses after receiving evaluation outcome letters.
(3) Protracted evaluation and response cycles between the Authority and Applicants at various stages of the evaluation and registration process, resulting in an increase in the volume of work-in-progress (WIP) over time.
(4) An increase in WIP resulting in increasing costs and reduction of productivity for the Authority without an accompanying increase in resources, leading to an ever increasing backlog of applications.
(5) A general increase in the volume of applications for registration received by the Authority.
(6) Staff attrition resulting in a decrease in the number of experienced assessors.
(7) Inefficient monitoring and tracking of timelines by the Authority.

The following are measures that the Authority will implement, starting in January 2024, in order to eliminate the inefficiencies emanating from a confluence of the above factors:

Screening

With effect from 1st January 2024, the Authority will perform high level screening of all applications for registration. This screening will be performed by the Authority´s most experienced and most proficient assessors to ensure that applications that get accepted for evaluation are complete before they are cleared for the first assessment process.

Screening Timelines

For the screening process to be effective, the applicants must get rapid feedback from the Authority as soon as they submit their applications. The Authority is therefore committed to undertake screening for all applications within **ten (10) working days** of submission of an application. It is however noted that there are a number of pending applications in the backlog

that are yet to be assessed. To avoid further inefficiencies resulting from implementing multiple processes, these applications will also be screened prior to assessment, even though they have already been accepted and issued with Application numbers.

Applications failing screening

Applications that fail screening will be allocated with **Quarantine numbers**. A Quarantine number in essence means that the application is held in abeyance pending resolution by the Applicant of shortcomings noted during the screening process. **It is critical to note that there is no priority afforded to quarantined applications.**

Once an application is quarantined, the Authority will issue a letter to the applicant, intending to refuse to register the product, unless a complete application is submitted within 120 days. Failure by the Applicant to resubmit a complete application within the prescribed timelines will result in refusal to register the application and Applicants interested in pursuing such applications will be required to resubmit new applications accompanied by payment of the full application fee.

Upon resubmission of a complete dossier and payment of the statutory resubmission fees as stipulated in item 7(a)(ix), 7(b)(v) and 7(c)(iv) of the MCAZ Fee Schedule, applications will undergo a second round of screening. **Applications that fail the second round of screening will be refused registration without assessment**. It is also critical to note that in computation of the Authority's timelines, quarantined products will be tracked separately from complete applications.

Applications passing screening

Application numbers will **ONLY** be allocated to complete applications that pass screening at first attempt or those that pass screening following resubmission of a complete dossier and payment of statutory resubmission fees as discussed above. **Only complete applications that are issued with application numbers will be admitted for assessment**.

Review cycles

With immediate effect, stakeholders are advised that the Authority will conduct a maximum of two (2) review cycles per product before reaching a **final regulatory decision** (*registration or refusal to register*). Applicants are advised to take all issues raised in the assessment report seriously to avoid exceeding the maximum number of review cycles. At the end of the 1st review cycle, applicants will be further advised to withdrawal their applications **voluntarily** if they cannot address the queries raised by the Authority. The Authority will reach a final regulatory decision at the end of the 2nd cycle.

Registration process regulatory phases

With immediate effect, the Authority will use a tracker (clock start-clock stop system) to efficiently monitor and track each application as a separate project as indicated below:

Phase	Submission	Screening	1st Assessment Cycle	Submission of 1st Response	2nd Assessment Cycle	Final Regulatory Decision	Post-Decision
Activity	Applicant submits Dossier	High level screening by MCAZ assessors	1st Assessment session by MCAZ	Applicant submits Response	2nd Assessment session by MCAZ	Final Committee decision	Administrative and Regulatory activities

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

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R. T. Rukwata (Mr.)

DIRECTOR-GENERAL