



Medicines Control Authority of Zimbabwe

PROCESS UPDATES

**HYBRID COMPLEMENTARY
MEDICINES STAKEHOLDER
ENGAGEMENT**



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Introduction

- **Workflow**
- **Deadlines**
- **Decision making**



NEXT PAGE





WORKFLOW



STEP ONE

- If the applicant is not sure about the registrability of their product, they should send an email to adminivr@mcaz.co.zw
- The email should include the labeling and packaging material with:
 - ❖ Clearly visible names and quantities of the active ingredients
 - ❖ The route of administration stated

WORKFLOW



STEP TWO

- The applicant is required to:
 - ❖ Complete the statutory application form, i.e., CM1 form ([CM1 form template \(1\).pdf](#))
 - ❖ Complete the dossier as per the Complementary Medicines Document Submission Guideline.
 - Supporting documentation should be compiled
 - Dossier should be structured
 - ❖ Liaise with the MCAZ inspectorate to arrange for the inspection of the manufacturing site.



STEP THREE

- The applicant should request a quotation form (EVRF 32), complete it, and send it to adminivr@mcaz.co.zw
- The division staff will complete the form and include the appropriate fees for the service required.
- **Fee structure**

DESCRIPTION	FEES
Imported products	USD600
Imported products that are locally repackaged and relabelled	USD300
Locally manufactured products	USD200
Expedited products	USD900

NB: Please do not pay the application fees before being issued with a signed and dated quotation confirmation

WORKFLOW



STEP FOUR

➤ Submission of the application:

- ❖ Proof of payment
- ❖ A fully completed, signed and dated application form, i.e., CM1 form
- ❖ A dossier of supporting documents in the format and presentation acceptable according to the Complementary Medicines Document Submission Guideline.
- ❖ At least two samples of the product

WORKFLOW



STEP FIVE

- **Screening process**
 - ❖ **The dossier is checked for accuracy and correctness**
 - ❖ **Two outcomes**
 - **Intent to refuse after screening**
 - **Proceed to evaluate**
 - ❖ **A query letter is then sent to the applicant**

WORKFLOW



STEP SIX

- **Evaluation Process**
- **Two cycles**
 - ❖ **Initial evaluation review outcomes**
 - **Intent to refuse to approve**
 - **Intent to approve**
 - ❖ **A query letter is then sent to the applicant**
 - ❖ **Second evaluation review process outcomes**
 - **Approval of the product**
 - **Refusal of the product**



TIMELINES

Screening



SCREENING

Proceed to evaluate

Intent to refuse

20

**DAYS
MCAZ TIME**

45

**CALENDAR
DAYS**

120

**CALENDAR
DAYS**





TIMELINES

Evaluation



Intent to approve

45

CALENDAR DAYS



Intent to refuse

60

CALENDAR DAYS



TIMELINES

Final regulatory decision



FINAL REGULATORY DECISION

9 months

MCAZ time



DECISION MAKING



SCREENING



Proceed to evaluate

- The submission meets the minimum requirements stated in the Complementary Medicines Document Submission Guideline.

Intent to refuse after screening

- Failure to submit documentation that proves that the product is of high quality and it is safe for human use
- More than 5 administrative issues



DECISION MAKING

EVALUATION



Intent to approve



Less than 5 outstanding administrative issues

Intent to refuse after evaluation



Failure to resolve issues pertaining to the quality and safety of the product



More than 5 administrative issues



DECISION MAKING

FINAL REGULATORY DECISION



Approval certificate



No outstanding queries

Refusal letter



Failure to resolve issues pertaining to the quality and safety of the product



Failure to resolve administrative issues after 2 cycles



Failure to meet the deadline for the Intent to refuse query letter (both at screening and evaluation)



**THANK
YOU!!**

