MCAZ Medicines Control Authority of Zimbabwe

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REF: B/279/35/12/2024

CIRCULAR 12 of 2024

Date: 10/05/2024

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES: RE-REGISTRATION FEES

This Circular is a follow-up to the following previous communication from the Authority:

Communication	Reference	Date
Circular 3 of 2022	Clarification of conditions for registration requirements and subsequent expansion of registration certificate, section 15 format annexure	17/02/2022
Circular 14 of 2022	Implementation plan for re-registration of human allopathic medicines	16/09/2022
Circular 11 of 2023	Follow-up plan for re-registration of human allopathic medicines	30/05/2023
Circular 19 of 2023	Implementation plan for re-registration of human allopathic medicines: Proposed fees	21/07/2023
Circular 21 of 2023	Implementation plan for re-registration of human allopathic medicines: Extension of fees waiver	15/09/2023
Circular 4 of 2024	Implementation Plan For Re-Registration of Human Allopathic Medicines: Extension of Re-Registration Fee Waiver	04/02/2024

Reference is made to **Circular 4 of 2024** where we indicated that, with effect from **1st May 2024**, the Authority will levy fees for new applications for re-registration and those incomplete re-registration applications already received as stipulated in item 7(a)(x) of the MCAZ Fees Schedule. The Authority will levy fees on all application for human allopathic re-registrations with effect from 1st May 2024 to December 2025 as follows:

Ref. Fee Schedule	Application	Fees (USD)
7 (a) (x)	In case of a medicines imported into Zimbabwe as a finished product	$1000
7 (b) (vi)	In case of a medicines which is imported into Zimbabwe and which is re-labelled or repackaged before being sold as a finished product	$ 750
7 (c) (v)	In any other case	$ 200

The Authority **may** levy fees for re-registration (marketing authorisations renewals) close to the expiry of date 31st December 2027 to submit renewals application as follows:

Ref. Fee Schedule	Date of Submission	Fees (USD)
7 (a) (iii)	January to December 2026	$ 2500
7 (d) (ii)	January to December 2027	$ 4000

From January to December 2027, the Authority will be levying the fee for expedited review of applications (Reference item 7(d)(ii) of the MCAZ Fee Schedule) because at this point, this will be the only way that such applications can be processed before the end of December 2027.

The proposed fees are designed to discourage influx of re-registration applications close to the end of 5-year period specified in Circular 11 of 2023. **The Authority strongly encourages applicants to take advantage of the lower fees for re-registration to comply with re-registration requirements.**

Yours faithfully,
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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

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REF: B/279/35/3/2022

CIRCULAR 3 of 2022

Date: 17/02/2022

To: ALL CURRENT AND PROSPECTIVE, LOCAL AND EXTERNAL, APPLICANTS, MANUFACTURERS AND PRINCIPALS FOR REGISTRATION OF MEDICINES

RE: CLARIFICATION OF CONDITIONS FOR MEDICINES REGISTRATION REQUIREMENTS AND SUBSEQUENT EXPANSION OF REGISTRATION CERTIFICATE, SECTION 15 FORMAT ANNEXURE.

This circular serves to inform all applicants, manufacturers, and principals, that the Medicines Control Authority of Zimbabwe clarified the conditions for medicines registration and subsequently expanded section 15 of the registration certificate, i.e. "Conditions for registration imposed by the Authority", as an annexure that is meant to capture more information on the medicines registration conditions requirements. The annexure shall include information on:

General conditions of registration

Subject to:

1. Compliance with labelling requirements.
2. Mandatory Reporting of Individual Case Safety Reports(ICSRs) that includes (ADRs, AEs, SAEs, & AEFIs) and/or product defects;
3. Applicant, manufacturer and/or market authorization holder (MAH) is required to have a functional Pharmacovigilance system in place for their medical products;
4. Applicant, manufacturer and/or MAH is required to designate a responsible person for Pharmacovigilance (QPPV) to be in charge of the pharmacovigilance system for the MAH;
5. Compliance with any request by the Authority to conduct post-authorisation safety and efficacy studies whenever the need may arise;
6. Renewal of market authorisation every five (5) years on condition of demonstration of quality, safety and efficacy.

Product specific conditions of registration

- API manufacturer(s).
- Approved batch size(s).
- Written commitment(s) by the FPP manufacturer.
- Approved label.
- Risk management plan.

NB: Please note that the MCAZ registration conditions stated above are also part of the legal provisions for existence of a national vigilance systems based on requirements for sections 33(2) (iii), 33(3) and 29 (1) (b) of the Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03], MCAZ National Pharmacovigilance handbook 2016 Edition, MCAZ circular 1/2000 dated 21st March 2000, MCAZ Pharmacovigilance Guideline for Pharmaceutical

Industry MCAZ/PVCT/GL-02, Guideline for Pharmacovigilance of COVID-19 Vaccines MCAZ/PVCT/GL-03 and Zimbabwe National Adverse Events Following Immunization (AEFIs) Guideline 2017.The use of the new format for the registration certificate will clarify all the registration conditions requirements plus product-specific information to ensure compliance, and vigilance post-registration processes. The clarification of the registration conditions and subsequent new registration certificate format, with the annexure, will be implemented with immediate effect from the date of publication of the circular that is 15th February 2022.

These changes were necessitated by further clarification of medicines registration conditions requirements in line with MASCA Chapter 15:03 including additional compliance with critical international good regulatory best practices to ensure that effective, quality, and safe medicines are available to the public. We thank you for your usual co-operation in regulatory compliance and promoting patient safety.

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. Rukwata (Mr.)
ACTING DIRECTOR-GENERAL

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REF: B/279/35/14/2022

CIRCULAR 14 of 2022

Date: 16 September 2022

To: All applicants

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES

This circular serves to inform applicants, manufacturers and principals the implementation plan for re-registrations (marketing authorization renewals). The requirement for re-registrations was communicated in the MCAZ circular 3 of 2022 (point 6) dated 17 February 2022. With effect from 1 January 2023, product registrations for human allopathic medicines will have a validity period of five (5) years. Applications for re-registration would therefore need to be submitted every five (5) years in order to maintain the products on the MCAZ register.

The process of re-registration will be applicable to all human allopathic medicines registered by MCAZ. The process will be carried out as follows:

1. Products registered from the 1st of January 2023

With effect from 1st January 2023, all new registrations will have a validity period of 5 years from the date of registration. The validity period will be indicated on the registration certificate. An application for re-registration of the product should be submitted before the validity period of the product expires and can be submitted 3 months before the re-registration date.

2. Products registered prior to the 1st of January 2023

Registration of all products registered before 1st January 2023 will expire on the 31st of December 2027. Applications for re-registration of these products can be submitted from the 1st of January 2023 to the 31st of September 2027. A validity period of 5 years from the date of re-registration will be indicated on the registration certificate.

In both cases, applications for re-registration of the product should be submitted before registration expires. In the case where the applicant does not submit an application for re-registration 3 months after expiry, product registration will be cancelled.

The following should be considered when making an application for re-registration:

1. The submission should be made in CTD format
2. The re-registration process should be in-line with the MCAZ guideline on product re-registrations.
3. Post approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post variations should be made separately.

Please note that the re-registration process does not replace the process of annual retentions. No processing fees will be charged for re-registrations. Requests for exemptions to any of the requirements should be submitted before the re-registration dates and will be considered on a case-by-case basis.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. RUKWATA (Mr)
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REF: B/279/35/11/2023

CIRCULAR NO. 11 of 2023

Date: 30 May 2023

To: All applicants

RE: FOLLOW-UP PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES

This Circular is a follow up to Circular 14 of 22 published on the 16th of September 2022 which communicated the introduction of re-registration of products and the implementation plan for re-registration of products by the Medicines Control Authority of Zimbabwe (MCAZ).

1. Applicants should note the following:
   i. For products which were registered prior to 2023 which had no re-registration period specified, the 5-year re-registration period indicated in the previous circulars remains valid.
   ii. It is worth noting that MCAZ **may** consider levying an application fee on re-registrations from 16th September 2023 (Q4) of 2023, at the anniversary of circular 14 of 2022, and further that fee may be **SUBSTANTIALLY** reviewed upwards biannually to provide for more resources to deal with anticipated influx of applications as we get to the end of the 5-year period. Applicants who submit applications before the third quarter of 2023 will not have this fee levied on their re-registration applications.
   iii. Re-registrations for products which have been re-registered or renewed in other countries in the Southern African Development Community (SADC) region within the last 24 months will be abridged based on acceptance in the respective SADC countries, however a fee may be applicable as indicated above. This fee may however be lower than for scenario 1(ii) above.

2. The following should be considered when making an application for re-registration:
   i. The submission should be made in CTD format.
   ii. The re-registration process should be in-line with the draft MCAZ guideline on re-registrations which can be found on the MCAZ website.
   iii. Post-approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post-approval variations should be made separately.

Please note that the re-registration process does not replace the process of annual retentions. Requests for exemptions to any of the requirements should be submitted before the re-registration dates and will be considered on a case-by-case basis.

The Authority strongly encourages applicants to take advantage of the waiver of fees which expires on the 15th of September 2023. The Authority further encourages earlier submissions as this will allow us more time to deal with any requests for exemptions.

This will become progressively more difficult as we get to the deadline. The Authority will be sending out regular statistics on these issues. From September 2022 to date, the Authority has only processed one (1) application. This means that generally **ALL** applicants except for one have not headed to the Authority's call for voluntary submissions and all the concessions that they come with**. It is extremely important to reiterate that the closer we get to the deadline, the more expensive and difficult this process is going to become.**

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. RUKWATA (Mr)
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REF: B/279/35/19/2023

CIRCULAR 19 of 2023

Date: 21/07/2023

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES: PROPOSED FEES

This circular is a follow-up to circular 11 of 2023, dated 30th May 2023 and updated circular 14 of 2022 dated 16th September 2022 and serves to inform applicants, manufacturers and principals that MCAZ **may** charge fees for re-registrations (marketing authorisation renewals) of medicines with effect from 18th September 2023. The proposed re-registration fee is separate from registration fees and will be as follows:

Date of submission for Application for Renewal	Fee per Application
September 2023 – March 2024	USD 500
April 2024 – September 2024	USD 1000
September 2024 – March 2025	USD 1500
April 2025 – September 2025	USD 2000
September 2025 – December 2027	USD 2500

The proposed fees are meant to provide resources to deal with the anticipated influx of applications as we approach the end of the 5-year period specified in circular 11 of 2023.
The following are the requirements for re-registrations:

1. The submission should be in CTD format.
2. The re-registration application should be in-line with the MCAZ guideline on products re-registrations, accessible from the MCAZ website, www.mcaz.co.zw
3. Re-registration fees as stipulated in the schedule above.
4. Post approval variations to the products dossier will not be accepted at the time of re-registration. Applications for the post approval variations should be made separately.

The Authority has received **ONLY 13** applications for re-registrations since the call for voluntary submissions for re-registration was communicated in circular 3 of 2022, dated 14th September 2022. This waiver of fees expires on the 15th of September 2023 and applicants are strongly encouraged to take advantage of this period to submit re-registration applications.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. Rukwata (Mr.)
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REF: B/279/35/21/2023

CIRCULAR 21 of 2023

Date: 15/09/2023

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES: EXTENSION OF FEES WAIVER

This circular is a follow-up to circular 19 and 11 of 2023, dated 20th July and 30th May 2023 respectively, on implementation of re-registrations (marketing authorisation renewals). Taking into consideration the concerns from stakeholders, the Medicines Control Authority of Zimbabwe has extended the waiver to levy fees for applications of re-registration to the 31st December 2023.

To date, the Authority has received **over 150** applications for re-registrations since the call for voluntary submissions was communicated in circular 3 of 2022, dated 14th September 2022. The Authority strongly encourages its applicants, principals and manufacturers to take advantage of this additional time to submit re-registration applications.

The following are the requirements for re-registrations:

1. The submission should be in CTD format
2. The re-registration should be in-line with the MCAZ guideline on products re-registrations, accessible from the MCAZ website, mcaz.co.zw
3. Post approval variations to the product dossiers will not be accepted at the time of re-registration. Applications for the post approval variations should be made separately

The Authority **may** levy fees communicated in circular 19 of 2023, dated 20th July 2023 with effect from 1st January 2024.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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

25 1997-2022 YEARS OF PROTECTING PUBLIC AND ANIMAL HEALTH

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REF: B/279/35/4/2024

CIRCULAR 4 of 2024

Date: 04/02/2024

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

RE: IMPLEMENTATION PLAN FOR RE-REGISTRATION OF HUMAN ALLOPATHIC MEDICINES - EXTENSION OF RE-REGISTRATION FEE WAIVER

This circular is a follow-up to circular 21, 19 and 11 of 2023, dated 15th September, 15th July and 30th May 2023 respectively, on the implementation of re-registrations (marketing authorization renewals). The Authority has, after consultation with key stakeholders, further extended the waiver to levy fees for applications for re-registrations to the 30th of April 2024.

To date, the Authority has received over six hundred **(600)** applications for re-registration since the call for voluntary submissions was issued in Circular 3 of 2022, dated September 14, 2022. However, it has been noted that some applications for re-registrations are grossly deficient and fall short of the requirements stipulated in the MCAZ Guideline on product re-registrations. Such applications will be rejected after the assessment process, however the concerned products will continue having marketing authorisation rights until the 31st December 2027. The Authority strongly encourages its applicants, principals and manufacturers to take advantage of this additional time to submit **complete** re-registration applications to avoid disappointments.

With effect from 1st May 2024, the Authority will levy fees for new applications for re-registration and those **incomplete** re-registration applications already received as stipulated in item 7(a)(x) of the MCAZ Fees Schedule. Those applicants, principals and manufacturers who know that they have submitted incomplete applications are advised to take advantage of the extended waiver of fees and regularize before the 1st May 2024 deadline.

The following are the requirements for re-registrations:

1. The submission should be in CTD format
2. The re-registration should be in-line with the MCAZ Guidelines on products re-registrations, accessible from the MCAZ website, https://www.mcaz.co.zw/human-medicines-guidelines
3. Post approval variations to the product dossiers will not be accepted at the time of re-registration. Applications for post approval variations should be made separately.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R.T. Rukwata (Mr)
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