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Zambia Medicines Regulatory Authority

GUIDELINES FOR MARKETING AUTHORISATION OF A MEDICINE FOR HUMAN USE

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Version 1



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i) ABBREVIATIONS

CTD:	Common Technical Document
PQ:	Prequalification
RRAs:	Recognized Regulatory Authorities
SRAs:	Stringent Regulatory Authorities
WHO:	World Health Organisation
WLAs	WHO Listed Authorities
ZAMRA:	Zambia Medicines Regulatory Authority

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ii) DEFINITIONS

The definitions provided below apply to the words and phrases used in these guidelines and they are provided to facilitate their interpretation. Other terminologies can be found in the Medicines and Allied Substances act No.3 of 2013 glossary term.

Abridged review: A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a reference authority or trusted institution to inform the local decision. The abridged review is based on assessment reports, and Good Manufacturing practices (GMP) inspection reports from reference authorities, plus specific parts of the Common Technical Document (CTD).

Recognized Regulatory Authorities (RRA): term used to refer to the list of regulatory authorities whose assessment ZAMRA recognizes.

Regulatory time: Is a predetermined schedule and deadline established by the Authority for the submission, review, and approval processes of various regulated products or activities.

Stringent Regulatory Authority (SRA): A regulatory Authority which is a member of the International Conference on

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Harmonisation (ICH) or an ICH observer, or is associated with an ICH member through a legally-binding mutual recognition agreement. This term is being replaced by WLA.

WHO Listed Authority (WLA): A regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) AND a performance evaluation (PE) process.

1. INTRODUCTION

The full registration process requires the application of equal resources and attention to details to all products which may result in delays during the registration or listing process. The abridged procedures provide guidance for the implementation of a risk-based approach to product dossier assessment and details of documentation required to facilitate assessment, registration and/or listing. This will ensure effective utilization of resources available to the Authority without compromising the quality, safety and efficacy or performance of the products.

Therefore, the Authority recognizes the scientific evaluation of products by Stringent Regulatory Authority (SRAs), Recognized Regulatory Authority (RRA), and those Prequalified by World

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Health Organization which apply similarly stringent standards for quality, safety and efficacy or performance of the products.

This guideline is to be read with the respective marketing authorization guidelines.

2. SCOPE

These guidelines apply to innovator and generic medicines for human use and allied substances that have authorisation from SRAs or WHO Listed Authorities (WLAs) and those prequalified by WHO.

3. PURPOSE

The purpose of abridged procedures guidelines is to avoid duplication of effort and accelerate the process of assessment and registration of medicines and allied substances that qualify, using risk-based approach without compromising the quality, safety and efficacy or performance of the products.

4. GENERAL REQUIREMENTS

4.1 An abridged application for a medicine or an allied substance shall be submitted by an applicant or local responsible person to the Authority in line with the Guidance for the preparation and submission of dossiers in Common Technical Document (CTD) format available on the ZAMRA website.

4.2 The application shall be addressed to:

The Director General

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Zambia Medicines Regulatory Authority
Plot No. 2350/M,
Off Kenneth Kaunda International Airport Road
P.O. Box 31890
Zambia.

- 4.3 A separate application and payment of applicable fees shall be required for each application.

5. ABRIDGED REGISTRATION PROCEDURES

5.1 WHO Collaborative Registration Procedure

The procedure shall apply to an application for a WHO prequalified product.

- 5.2 In order to submit a prequalified product for registration in Zambia, the applicant shall sign and email a **consent form (Annex 1)** and **Annex 2, Part A** to prequalreg@who.int. This will serve to grant WHO permission to share its evaluation information with the Authority.

These appendices and the General Requirements above shall be submitted to the Authority in addition to the following:

- a) Approved variations letters and query responses to the prequalified product should be incorporated in the application submitted for registration to the Authority. Pending variations with WHO should not be included in the application submitted in order for the application to qualify for sameness.

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- b) Any differences between the prequalified dossier or data and the submission to the Authority should be stated as requested by Annex 2, Part A.

5.2.1 The Authority shall evaluate the product submitted as abridged application within 90 days of regulatory time. Regulatory time starts after a valid application for the registration according to the procedure has been received, applications fees have been paid and access to the confidential information has been granted (whichever is the later) and continues until the date of decision on registration. The regulatory time does not include the time granted to the applicant to complete missing parts of documentation, provide additional data or respond on queries raised by the Authority.

5.2.2 The **consent form (Annex 1)** and **Annex 2, Part A** to be used in this procedure, are available on the WHO prequalification website.

5.3 WHO SRA Collaborative Registration Procedure

The applicant may participate in this procedure if they:

5.3.1 Hold a marketing authorisation issued by an SRA for a product intended for submission.

5.3.2 Agree with WHO on:

- a) the selection of the product for which the procedure is to be organized, and on the SRA that will be invited to

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share its full assessment and inspection reports for the product,

- b) applying for registration and proposed date(s) of submission(s) in Zambia,
 - c) the procedure that will be applied to the specific product(s) and that WHO will have access to the data shared with the Authority by signing annex 3 and submitting it to WHO.
- 5.3.3 Agree with the relevant SRA on sharing full updated assessment report and inspection report with the Authority through WHO,
- 5.3.4 Grant the relevant SRA permission to share information concerning the product(s) with the Authority and WHO by completing appendix 4B and requests SRA permission to share the SRA's assessment and inspection reports with the Authority and WHO by completing annex 4A,
- 5.3.5 Submit an application for registration of the product(s), with the same set of technical data, electronically and/or in hard copy, to the Authority, in line with the procedure and respecting specific national requirements (Annexes 5, 6, 7 and 8). In the case of deviations from the SRA-approved product, these must be specified by the applicant.

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- 5.3.6 Provide a "bridging report" that contains additional discussion of data relevant to Zambia, if the SRA assessment report does not cover these elements sufficiently. This applies in the case of innovator medicines.

The Authority shall evaluate the product submitted as abridged application within 90 days of regulatory time.

The authority has adopted the WHO SRA procedure, documents and appendices. Applicant should endeavor to use the most recent updated documents available on WHO website for the SRA procedure.

5.4 Verification Procedure for Medicine and Allied Substances (non-WHO or SRA Collaborative Registration Procedures)

The verification evaluation route applies to a product that has been evaluated and approved by a Recognized Regulatory Authority when use of the WHO SRA procedure is not possible.

- 5.4.1 The following documents shall be submitted under this evaluation route in addition to the documents under General Requirements:

- a) Duly completed sameness declaration form (Annex 1) and attach it to the dossier.

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- b) The completed assessment report and other relevant supporting documents from the chosen Recognized Regulatory Authority shall be submitted. The assessment reports from the RRA shall be unredacted or unedited, and should include details of imposed licensing conditions, final product labelling, chemistry and clinical reviews, and other information in relation to the product's approval. Reports obtained from the public domain such as public assessment reports are deemed unacceptable.
- c) A duly completed verification review template (Annex 2) attached to the dossier.

5.4.2 Applications submitted to the Authority through this route without the unredacted/ unedited reports from the RRA will not qualify for the verification evaluation route. The applicant shall be required to withdraw and resubmit the application via other routes if the applicant intends to pursue the application.

5.4.3 Additional eligibility criteria for the verification procedure includes:

- a) The application must be submitted to the Authority within two years from the date of approval by the chosen RRA;
- b) Declaration letter issued by the applicant must be provided stating that all aspects of the product's quality

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are identical to that currently approved by the chosen RRA at the time of submission.

6. MANAGEMENT OF POST-APPROVAL ABRIDGED.

- 6.1** For Medicines and Allied substances approved using the WHO collaborative procedure and WHO-SRA procedure, the Authority shall require prior approval of the amendment by WHO or the SRA and the applicant will have the responsibility of providing the amendment approval letter(s) from WHO or SRA and payment of relevant amendment fees depending on the classification of the amendment as provided in the guidelines for amendments to a marketing authorisation. The WHO, SRA, the applicant and the Authority shall keep themselves informed throughout the post-registration phase regarding relevant variations made to the product, withdrawal, suspension, delisting from the WHO List of Prequalified Medicinal Products or national deregistration.
- 6.2** For the verification procedure post approval changes shall follow the main amendment guidelines issued by the authority.
- 6.3** Renewal of the marketing authorisation shall follow the renewal guidelines issued by the Authority.

7. Annexures

Annex 1: Sameness Declaration for Verification Evaluation Procedure

To be Completed by the Applicant:

Application for {Proposed product name}	{Name of Recognized Regulatory Authority}
Registration date	
Date(s) of approval of post-registration variation(s) if applicable	

I, {Full name}, {Job title} at {Company's full legal name}, hereby confirm the following for application for registration of {name of product} submitted to the Zambia Medicines Regulatory Authority (ZAMRA) on {Date of application submission}:

- The information and documentation provided in support of this submission for registration is true and correct.
- The product submitted for registration with ZAMRA is the same as the product registered with the above specified RRA.
- The technical information in the dossier submitted to ZAMRA for registration is the same as the technical information approved by the above specified RRA, taking into account all amendments that the above specified RRA has approved since registration.
- The "same" product is characterized by:
 - a) The same product dossier content;
For WHO PQ vaccines submitted to the WHO in Product Summary File (PSF) format, this content needs to be transferred to CTD format

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- b) The same manufacturing chain, processes and control of materials and finished product, and in the case of vaccines also by the same batch release scheme;
- c) The same active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) specifications
- d) The same essential elements of product information for pharmaceutical products, and in the case of vaccines, by the same product information, packaging presentation and labelling.

Information which need not be the same:

- a) Module 1, region-specific administrative requirements
- b) Minor differences which are not considered essential may include differences in administrative information, brand name, format and level of detail of product information as per regional requirements, labelling of internal and external packaging and language of product information.

I hereby confirm that if documents have been submitted by [Insert full company legal name here] which were received by the above specified RRA, these documents are completed and unredacted.

Full name of Responsible Pharmacist / Person Authorised to communicate with the Authority:

Company:

Email address:

Telephone Number:

Signature:

Date:

Place:

Annex 2: Verification Review Template



VERIFICATION REVIEW TEMPLATE
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THIS DOCUMENT SHOULD BE COMPLETED BY THE APPLICANT TO ENSURE INCLUSION OF ALL NECESSARY INFORMATION

This verified review template will be used for assessment in cases where the applicant's product has been registered with a Recognized Regulatory Authority. The following shall be noted:

- Ensure that this template is submitted as word document and not as PDF.
- If full/unredacted assessment reports cannot be obtained by the applicant from the Recognized Regulatory Authority please use other registration routes.
- **Complete all sections.** The columns for RRA and ZAMRA submission shall be completed with text taken directly from the relevant section in the respective reports, as well as the reference to the location in the dossier.
- **References to the location in the dossier will not be accepted without the actual text accompanying them.**
- Ensure sufficient detail is included in this template to make an accurate comparison between the RRA and ZAMRA submission.
- Do not copy and paste between the columns for RRA and ZAMRA submission. These shall all be completed as per the exact information in the original reports.

1. Administrative data

Non-proprietary Name of the Finished Pharmaceutical Product (FPP)	
Proprietary name of the Finished Pharmaceutical Product (FPP)	
International non-proprietary name(s) of the Active Pharmaceutical Ingredient(s) (API(s)), including form (salt, hydrate, polymorph)	
Strength(s)	
Date of Submission <for official use only>	
Date of Evaluation <for official use only>	
Number of Binders	
Product Registration receipt number <for official use only>	
Application Number <for official use only>	
ATC code	
Dosage form	
Route of administration	
Proposed indication(s)	
Applicant name and address	
Contact information	
Conclusion of the evaluation <for official use only>	

2. Similarity of Data Set: PRODUCT QUALITY

Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Name and complete address of the applicant	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)], biological drug products(s) (DP(s)), including the final product release if different from the manufacturer.	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
ACTIVE PHARMACEUTICAL INGREDIENT (API) (NAME, MANUFACTURER)			
Name of API	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
General properties that may affect the performance of the finished product (e.g. polymorphism, solubility in physiological media)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	

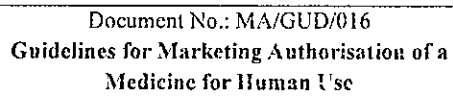
Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Name and address(es) of the manufacturer(s) of the API(s)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
DMF/APIMF number	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Control of the API (including, the specification reference number, version and date. The copy of the specification may be included as attachment to the report)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Container closure system	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Stability summary and conclusions (including storage statement and re-test period)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
FINISHED PHARMACEUTICAL PRODUCT (FPP)			
Description	{Extract from relevant report section}	{Extract from relevant dossier section}	



Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
	Location in report:	Location in dossier:	
Manufacturer (Name, address and responsibility)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Narrative description of the manufacturing process [No need to compare the whole manufacturing process. can just look at the blank master production document reference number, version and date, together with information on the site.]	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Control of FPP/DP State the specification reference number, version and date, copy of the specification must be attached as attachment to the report.	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Container closure system	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	

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Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Stability summary and conclusions (incl.. the storage statement and shelf life)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Lot / batch release documents for biologicals	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			



Composition

RRA: {Name of RRA}

Component and quality standard	Function	Quant. per unit (mg)	%
Total			
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

ZAMRA submission

[illegible]

Total			
General comments from evaluator			
Comments from second assessor			

Commercial batch size and batch formula

RRA: {Name of RRA}

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard (and grade, if applicable)	Quantity per batch (kg/batch)
Total	
General comments from evaluator	
Comments from second assessor	

ZAMRA Submission:

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard (and grade, if applicable)	Quantity per batch (kg/batch)

Total	
<i>General comments from evaluator</i>	
<i>Comments from second assessor</i>	

3. Similarity of Data Set – CLINICAL (SAFETY AND EFFICACY) – *If applicable*

Pharmacokinetic / safety / efficacy related information used for SRA approval. Indicate:		
Type of study	"X" in appropriate box	Comparator product, where applicable
Bioequivalence / Comparative pharmacokinetics,		
Biowaiver based on Biopharmaceutics Classification System (BCS) biowaiver		
Additional strength biowaiver		
Clinical data		
Comparative pharmacodynamic and potential immunogenicity		
Other (please specify)		
<i>General comments from evaluator</i>		



Comments from second assessor

BIOEQUIVALENCE / BIOWAIVERS

Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Study number	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Study title	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Clinical facility or the Contract Research Organisation (CRO)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Bioanalytical laboratories	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Company performing pharmacokinetic / statistical analysis	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	

BIOEQUIVALENCE / BIOWAIVERS			
Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Overall trial design and plan: Description, study dates, sample size	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Test Product: Name, manufacturer, batch number, batch size, location of multi-point dissolution data in physiological media and release media, if different	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Reference product: Name, manufacturer, source, batch number, expiry date	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Results: Conclusion and review of summary of results (table)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

4. Labelling

The following minimum information appears on the label:

Particulars to appear on <the outer packaging> <and> <the immediate packaging>	Yes / No	Evaluator comments
1. Name of the product: {(invented) name strength pharmaceutical form} {active substance(s)}		
2. Statement of active substance(s)		
3. List of excipients {only critical/special excipients are listed here}		
4. Pharmaceutical form and contents		
5. Method and route(s) of administration /if no specific information: "read the package leaflet before use."		
6. Special warning that the medicinal product must be stored out of the sight and reach of children {normally: "keep out of the sight and reach of children."}		
7. Other special warning(s), if necessary		
8. Expiry date		
9. Storage conditions		
10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate		
11. Name and address of the supplier / applicant		
12. Provision for marketing authorization number}		
13. Batch number		
14. Proposed category of distribution		
15. Instructions on use		

General comments from evaluator	
Comments from second assessor	

Additional information as per Zambian requirements

Minimum particulars to appear on blisters or strips	Yes / No	Evaluator comments
1. Name of the product: {(Invented) name strength pharmaceutical form} {Active substance(s)}		
2. Name of the supplier / applicant		
3. Expiry date		
4. Batch number		
<i>General comments from evaluator</i>		
<i>Comments from second assessor</i>		

Additional information as per Zambian requirements

Minimum particulars to appear on small immediate packaging units	Yes / No	Evaluator comments
1. Name of the product: {(Invented) name strength pharmaceutical form} {Active substance(s); Route of administration}		
2. Method of administration		
3. Expiry date		
4. Batch number		
5. Contents by weight, by volume or by unit		
6. Storage condition		



7. Category of distribution		
<i>General comments from evaluator</i>		
<i>Comments from second assessor</i>		

5. APPLICANT COMMITMENTS TO RRA

Applicant to state any commitments to RRA that may require follow up.

Please do not just state a reference to a section of a report. Please insert a summary of text as per the example below:

1. [The Applicant undertook to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year)]
2. The Applicant undertook to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year)
3. The Applicant committed that three consecutive production batches would be prospectively validated and a validation report in accordance with the details of the validation protocol provided in the dossier— would be made available as soon as possible for evaluation by assessors or for verification by the inspection team.]

Literature References

1. Global Health Supplies: Paradigm Shifts in Market Authorization, Procurement and Supply Chains Approaches. 28 November - 01 December 2022, UN City, Copenhagen, Denmark: Diapositive 1 (who.int).
2. WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control) Accelerated Registration of FPPs Approved by SRAs | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)