GUIDELINE ON MARKETING AUTHORISATION RENEWAL

EFFECTIVE DATE: *To be included*

Medicines Control Authority of Zimbabwe

106 Baines Avenue

P O Box 10559

Harare

Email: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

Abbreviations

API	Active Pharmaceutical Ingredient
CTD	Common Technical Document
CRO	Clinical Research Organisation
FPP	Finished Pharmaceutical Product
MA	Marketing Authorisation
PIL	Patient Information Leaflet
QIS	Quality Information Summary
QOS	Quality Overall Summary
SmPC	Summary of Product Characteristics
MCAZ	Medicines Control Authority of Zimbabwe

1.0 APPLICATION

This guideline applies to holders of market authorisations hereinafter referred to as applicants.

2.0 PURPOSE

These guidelines are intended to assist applicants to prepare applications for renewal of marketing authorisations. The applicants are required to demonstrate conformity of the product to the current standards and norms, and consistency of product quality over the MA validity period.

3.0 BACKGROUND / INTRODUCTION

A registration, approval or market authorisation of a medicinal product is valid for a period of five years unless the product is cancelled or suspended. The registration should therefore be renewed before expiry of the validity period.

4.0 DEFINITIONS

In these guidelines, unless the context requires otherwise –

"Active substance" means a biologically or chemically active substance or compound that is used or intended to be used in the manufacture of a product as an active compound (ingredient);

"Applicant" means a person who submits an application for renewal of marketing authorisation; who may be a manufacturer, patent holder or a person responsible for placing the product on the market with Power of Attorney from, or in contract with, the manufacturer or patent holder;

"Authority" means the Medicines Control Authority of Zimbabwe;

"Marketing Authorisation" means the authorisation granted under Section 38 of the Medical Products and Allied Substances Control Bill, for the placement of a medicine or allied substance on the market. Synonymous to product registration;

5.0 GUIDELINES

5.1 GENERAL REQUIREMENTS

5.1.1 A marketing authorisation/registration will expire after 5 years. In the

case where the applicant does not submit the renewal application and the MA expires, the product will be deregistered.

5.1.2 An application for renewal of marketing authorization of a medicine may be made by:

i. The applicant
ii. A nominee of the applicant who must submit evidence of power of attorney

5.1.3 No update of Module 3 quality data should be made at renewal. The marketing authorisation holder has an obligation to keep this module updated on an on-going basis throughout the life of the product using variation applications.

5.1.4 The applicant shall submit an application to the Authority 6-9 months before expiry of the marketing authorization.

5.1.5 The application should be submitted to the following address:

The Director General
Medicines Control Authority of Zimbabwe
106 Baines Avenue
Harare
Zimbabwe

5.2 HOW TO SUBMIT AN APPLICATION FOR RENEWAL

5.2.1 The applicant shall submit an application to the Authority 6-9 months before expiry of the marketing authorization.

5.2.2 A separate application and payment of fees shall be required for each marketing authorisation (MA).

5.2.3 Data shall be presented on A4 and 80g/m^2 paper with readily readable letters of at least Times New Roman 12 font size. *Lever arch files are not acceptable*. Every page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

5.3 TECHNICAL REQUIREMENTS FOR RENEWAL OF MARKETING AUTHORISATION

5.3.1 The MAH shall submit a hard copy covering letter and an electronic copy of the application (in PDF or WinWord format, on CD-ROM or Flash Drive) which includes the following documents, specified:

i. A covering letter, which should contain a clear statement by the responsible person submitting the quality review, indicating that the information submitted is true and correct;
ii. A duly completed application form for renewal of MA
iii. Proof of payment of the prescribed fees. Applicants should consult the current fee schedule for the correct and appropriate fee. Unless the full MA renewal fee is received, the application will not be accepted;
iv. A completed Quality information Summary (QIS)
v. One (1) sample of smallest commercial pack of the product;
vi. Product information i.e. Summary of Product Characteristics (SmPC) and/or Patient Information Leaflet (PIL), in PDF and WinWord format. If a revised Summary of Product Characteristics (SmPC), labelling and/or Package Leaflet (PL) is proposed within the renewal application, the precise current and proposed wording should be specified on the form. Alternatively, such listing may be provided as a separate document attached to the application form under a tabular format (indicating the current and proposed texts). Any change(s) not listed, will not be considered as part of the renewal application.;
vii. Attestation notifying the Authority that no further amendments have occurred to information provided in the initial application, other than those already submitted to MCAZ as applications for amendments. A consolidated report of all amendments made to the product should be submitted, in PDF format (as per Annex 3); and
viii. A pharmacovigilance plan and a consolidated report on adverse drug reaction reports, as well as other safety updates, in PDF format. For medicinal products which have a Risk Management Plan (RMP), the applicant is requested to submit an update of the RMP within the renewal application in view of re-assessing the overall benefit-risk balance of the medicinal product concerned.
ix. For applications submitted before the CTD format was implemented, a copy of the complete dossier in CTD format should also be submitted.
x. For products approved on the basis of tentative shelf life of 24 months at the time of registration, updated stability data for the 36, 48, 60 months time points should provided or for the last timepoint where stability specifications were met before the product started failing. NB: Zimbabwe is a resource-limited LMIC and products with short shelf-life cause logistical nightmares and wastages for our healthcare system.

5.4 PROCESSING OF APPLICATIONS

5.4.1 The Authority may during assessment of applications request for additional samples, documents, information or clarifications. The application may be rejected, resulting in lapse of MA, if the applicant fails to satisfactorily address the issues within thirty (60) days from the date of request.

5.4.2 The Authority may reject an application for renewal if:

i. It is found that a product and/or specified manufacturing site no longer complies with the our recommended standards;
ii. Any fraud or omissions by the applicant, manufacturer(s) of a finished pharmaceutical product (FPP) or active pharmaceutical ingredient (API) or clinical research organisation (CROs) in the initial application, becomes evident; and
iii. The Authority considers that a batch (or batches) of the supplied approved product is (were) not in compliance with the approved specifications.
iv. The benefit-risk balance of the product has changed from positive to negative in the light of new scientific evidence from post-marketing experience, studies and publications
v. The MA is deemed to have failed to adhere to the conditions of approval of the product such as approved indications, labelling, production information for users

5.4.3 Where the Authority refuses to renew the marketing authorisation, it shall notify the MAH in writing of such a decision and the reason(s) thereof.

6.0 KEY RELEVANT DOCUMENTS

N/A

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	New document
N/A	N/A	