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MCA Technical Working Group

Guideline for Withdrawal, Suspension, Revocation or Cancellation of Marketing Authorisation of Medicines

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Comments should be provided by using the template (MCA-F-021/03) for Submission of Comments and sent to info@mca.gm.

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Guideline for Withdrawal, Suspension, Revocation or Cancellation of Marketing Authorisation of Medicines

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Acknowledgements

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Executive summary

The development of this guideline is based on the outcomes and consensus of the meetings convened in January/February 2020 by GHPP-PharmTrain Project team of the Federal Institute for Drugs and Medical Devices (BfArM, Germany) with participants from the national medicines regulatory authorities (NMRA) of Liberia (LMHRA, Liberia Medicines and Health Products Regulatory Authority), Sierra Leone (PBSL, Pharmacy Board of Sierra Leone), and The Gambia (MCA, Medicines Control Agency).

The document has been discussed and adapted in exchange between LMHRA, PBSL, The Gambia MCA, Ghana (FDA, Food and Drugs Authority) and the GHPP-PharmTrain project team from September 2021 to September 2022. Version 1 of the Guideline on Withdrawal, Suspension, Revocation or Cancellation of Marketing Authorization for the National Medicines Regulatory Authorities of Ghana, Liberia, Sierra Leone, and The Gambia was finalised on 02 December 2022 for preparation of the NMRA's own guidelines.

This document should be read in conjunction with the relevant sections of MCA *Guideline for Marketing Authorisation (Registration) of Medicines* and other applicable guidance.

1 Introduction (background)

1.1. This guideline describes the conditions under which a marketing authorisation (MA) can be withdrawn, suspended, revoked or cancelled. When medicines (medicinal products) are suspected of being potentially harmful to users due to their defective quality, safety or efficacy, or administrative issues or malpractice of the manufacturer, importer, distributor or marketing authorisation holder (MAH) of the medicine (medicinal product) their marketing authorisation may be subjected to a withdrawal, suspension, revocation or cancellation process.

1.2. This in the worst case can trigger the recall of the product (find details on the recall process in MCA specific Guideline).

1.3. All related information must be reported to the MCA. MAHs are required, in all circumstances, to notify the MCA immediately of unanticipated adverse effects that could possibly be associated with an authorised product and that might call for restrictive regulatory action. This document provides guidance to ensure that the respective operations are effectively and efficiently carried out by all actors involved.

1.4. The MCA is responsible to assess are the nature of complaints/product defect and decide whether a regulatory consequence is warranted, which can be a suspension, revocation or cancellation of the MA.

Objective

1.5. This guideline provides guidance and clarification on what conditions a marketing authorisation can be withdrawn, suspended, revoked or cancelled and what measures need to be taken in any of these processes.

1.6. All final decisions on the status of the marketing authorisation of medicines and, if indicated, any subsequent action related to it will be taken by MCA.

2 Legal basis

2.1. This guideline is coherent with national/regional frameworks and policies. The usage of this guideline by the NMRA and the MAH is supported/embedded in the legal provision Medicines and Related Products Act, 2014 and Medicines and Related Products Regulations, 2020.

2.2. MAHs are encouraged to familiarise themselves with this document and the above law.

3 Scope

3.1. The guideline provides guidance regarding the withdrawal, suspension, revocation and cancellation of a marketing authorisation of medicines (medicinal products). The term "medicines (medicinal products)" in the context of this guideline includes finished pharmaceutical products (FPPs), herbal medicinal products, biologicals (biotherapeutics), and vaccines.

4 Various post-marketing authorisation scenarios resulting in withdrawal, suspension, revocation or cancellation of MA

4.1. ***Withdrawal*** - The permanent discontinuation of the marketing authorisation by the marketing authorisation holder (MAH). Reasons for withdrawal could be manifold, including administrative or commercial. The MAH shall declare the reason for withdrawal, particularly if his/her action concerns the quality, safety and/or efficacy of the medicinal product.

4.2. ***Suspension*** - Action taken by the NMRA, if a ground for refusal as defined in the legal provision developed or if one of the conditions imposed pursuant to maintaining the marketing authorisation has not been met and the flaw has not been corrected within a reasonable period of time that is to be specified by the NMRA.

4.3. ***Revocation*** - Action taken by the NMRA, if a marketing authorisation was granted unlawfully from the outset, e.g., due to deception or the like.

4.4. ***Cancellation*** - Action taken by the NMRA for the invalidation of a marketing authorisation that was lawful at the time of its granting and for which the reason for invalidation occurred subsequently (e.g. due to additional [post-marketing] information about the medicinal product).

5 Classification of scenarios

Marketing authorisation of an authorised product may be withdrawn, suspended, revoked or cancelled in various circumstances that can be allocated into three classes:

Circumstances related to

- Administrative issues;
- Malpractice of the manufacturer, importer, distributor or MAH of the medicinal product;
- Issues related to quality, safety or efficacy of the medicinal product.

5.1 Administrative issues

5.1.1 Suspension of marketing authorisation

5.2.1.1. Marketing authorisation may be suspended where a conditional marketing authorisation has been issued and the MAH could not meet the condition on time.

5.2.1.1. For imported products, if marketing authorisation is suspended or withdrawn in the country of origin, the MAH is obliged to report this to MCA, by stating the reasons. The MAH should indicate whether the quality, safety or efficacy of the product or Good Manufacturing Practices (GMP) certification of the sites of manufacture are affected.

5.1.2 Cancellation of marketing authorisation

a. If applicable: Where the product is not available on the market after one year of marketing authorisation

b. Where the MAH failed to apply for renewal within time (if applicable).

c. Where there is change in the treatment policy for public health programmes.

d. The circumstances under which the medicinal product was authorised/registered no longer exist

5.2 Malpractice of the manufacturer, importer, distributor or certificate holder of the medicinal product

5.2.1 Revocation of marketing authorisation

5.2.1.1. Marketing authorisation may be revoked under the following circumstances

a. The premises, in which the medicine or part thereof is manufactured, packaged or stored by or on behalf of the holder of the Marketing Authorisation Certificate is unsuitable for the manufacture, packaging or storage of the medicines.

b. Unauthorised variation (e.g. mislabelling, change of applicant, manufacturer, labelling, product information or other registered particulars).

c. Importation without permission and/or through unapproved route.

d. Distribution of products to unauthorised facilities/premises, where applicable.

e. the product is found to have been promoted (by MAH, distributor, any other stakeholder) in an inappropriate or unethical manner.

5.3 Defective quality, safety or efficacy

5.3.1 Suspension of marketing authorisation

5.3.1.1. The NMRA may suspend the marketing authorisation where a complaint is received from the MAH, the public or through NMRA's post market activities, and where the under listed issues are reported, investigated and found to be credible:

a. Product defect (e.g. quality defect) affecting public health.

b. The quantitative or qualitative composition is not as specified in the marketing authorisation.

c. Lack of compliance to cGMP.

d. Accumulation of reported unanticipated adverse effects/ reactions.

e. The product is not in compliance with the conditions of marketing authorisation

f. It is strongly suspected that the product is unsafe in the normal conditions of use.

5.3.1.2. In the event where a product is suspended in any country because of safety, quality, or efficacy issues, the MAH shall notify the NMRA within one month of the suspension, failure to do so may lead to cancellation of the MA.

5.3.2 Cancellation of marketing authorisation

5.3.2.1. The MCA may cancel the marketing authorisation where a complaint is received from the public or through its post market activities, and where the under listed issues are reported, investigated and found to be credible:

a. Product defect (e.g. quality defect) affecting public health.

b. The quantitative or qualitative composition is not as specified in the marketing authorisation.

c. Lack of compliance to cGMP.

d. Accumulation of reported unanticipated adverse effects/ reactions.

e. New published research findings stating irreversible quality, safety or efficacy concerns.

f. The standard of quality, safety and efficacy as prescribed in the documentation for marketing authorisation is not being complied with.

g. The product is not in compliance with the conditions of marketing authorisation.

h. The product has proven to be ineffective for the approved indication(s).

i. It is proven that the product is unsafe in the normal conditions of use.

j. If during the lifecycle of the generic product it is confirmed that the risk-benefit balance of the reference medicine is not favourable and the marketing authorisation of that reference medicine is cancelled, the same action would be required also towards the generic medicine of that reference medicine.

5.3.2.2. In the event where a product is cancelled in any country because of safety, quality or efficacy issues, the MAH shall notify the NMRA within one month of the cancellation, failure to do so will lead to cancellation of the MA.

6 Processing withdrawal, suspension, revocation and cancellation of MA.

6.1 Withdrawal

6.1.1. The MAH will officially write to the NMRA the reason(s) for withdrawing the MA.

6.1.2. The MAH must notify the NMRA of any actions taken to withdraw the authorisation of a medicine (medicinal product) from the market, to request the withdrawal or to not request the renewal of a marketing authorisation together with the reasons for such action. He/she must in particular declare if his/her action concerns the quality, safety or efficacy of the medicinal product or if it is based on an administrative or commercial decision.

6.1.3. A template for voluntary withdrawal by the MAH is attached in the Annex 1.

6.1.4. After resolving the issue that led to the withdrawal, the MAH may apply for marketing authorisation again, if applicable, with a revised dossier and all problems concerning the medicinal product sorted.

6.1.5. The NMRA will respond upon this request and archive the product's / companies' history.

6.2 Suspension, revocation or cancellation

a. An issue that may lead to suspension, revocation or cancellation as per section 5 is detected by the NMRA, filed in or received from either the MAH or the public.

b. The report is processed and investigated by the NMRA.

c. Based upon case specific outcomes, once guilty, MAH is notified of the appropriate regulatory actions (suspension of MA).

Definitions

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm.**

The definitions provided below apply to the terms used in this guideline. They may have different meanings in other contexts and documents.

The interpretation of terms provided in the Act and Regulations apply, unless further defined in this guideline.

Applicant (for MA)
A person or entity who has applied for regulatory approval of a product or a change thereof. All applicants are to own the product. Representatives of product owners may not hold themselves as applicants unless they own the product.
In some jurisdictions this term is used in a wider sense (see "Marketing authorisation holder)".

Marketing Authorisation (MA)
Approval to market a medicine (medicinal product) in the NMRA's country. MA is issued by the NMRA with a legal document for the purpose of marketing or distribution of a product within the country after evaluation for safety, efficacy and quality in the marketing authorization assessment process.

Marketing Authorisation Holder (MAH)
A company or other legal entity that has the authorisation by a regulatory authority to market a medicine or related product and who is responsible for its quality, efficacy and safety and for compliance with conditions of authorisation (registration)

Medicine/Medicinal Product
Any substance or combination of substances prepared, sold or presented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it or restoring, correcting or modifying organic functions in human beings
The term medicines/medicinal products in the context of this guideline includes finished pharmaceutical products, biologicals (biotherapeutics), and vaccines for human and animal use. Not included are medical devices, in-vitro diagnostics and blood products, if not indicated otherwise.

Recall
The removal of specific batch/batches of a medicine (medicinal product) or related materials from the market for reasons relating to deficiencies in the quality, safety or efficacy.

References

- MCA Zimbabwe. Guidelines for the Notification of a Medicinal Product Problem/Defect and Recall Procedure. https://www.mcaz.co.zw/images/pdf/circular.pdf
- WHO. The BlueBook 2nd Edition. Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for Drug Regulatory Authorities. https://apps.who.int/iris/bitstream/handle/10665/65175/WHO_DMP_RGS_98.5.pdf;sequence=1
- FDA Ghana. Guideline for the Cancellation/Suspension of a Registered Drug. https://fdaghana.gov.gh/img/organisation/GUIDELINES%20FOR%20THE%20CANCELLATION%20%20%20SUSPENSION%20OF%20MARKETING%20AUTHORIZATION%20OF%20DRUGS.pdf
- European Medicines Agency (EMA), VOLUME 2A Procedures for marketing authorisation CHAPTER 1 MARKETING AUTHORISATION July 2019. https://health.ec.europa.eu/system/files/2019-07/vol2a_chap1_en_0.pdf
- WHO. Guiding principles for small national drug regulatory authorities. WHO Expert Committee on Specifications for Pharmaceutical Preparations: thirty-first report. Geneva: World Health Organization; 1990: Annex 6 (WHO Technical Report Series, No. 790)
- WHO. Guidelines for national authorities on quality assurance for biological products. WHO Expert Committee on Biological Standardization: forty-second report. Geneva. World Health Organization; 1992: Annex 2 (WHO Technical Report Series, No. 822) (http://www.who.int/biologicals/publications/trs/areas/biological_products/WHO_TRS_822_A2.pdf)
- EMA. European Medicines Agency post-authorisation procedural advice for users of the centralised procedure. 20 June 2022 EMEA-H-19984/03 Rev. 99
- EMA Website: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/notifying-change-marketing-status
- EMA Website: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-publication-information-withdrawals-applications-related-marketing-authorisation_en.pdf

Annex

Annex 1: Withdrawal letter template (MCA-T-115/01)