MCAZ Medicines Control Authority of Zimbabwe

POLICY TITLE: POST MARKET SURVEILLANCE FOR HUMAN AND VETERINARY REGISTERED AND UNREGISTERED MEDICAL PRODUCTS			
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1.0 INTRODUCTION

1.1 Purpose

The purpose of this policy is to strengthen the Authority`s system for effective Post Marketing Surveillance of medicines, and regulated products including medical devices to ensure that only quality and safe medicines and other regulated products are distributed throughout the country.

1.2 What is Post Market Surveillance?

Post Marketing Surveillance (PMS): is a regulatory function of National Medicines Regulatory Authorities involving the assessment of safety and quality of pharmaceutical products throughout their shelf life and at all levels of the supply chain. PMS is meant to continuously monitor the quality, safety and efficacy of pharmaceutical products on the market at all levels of the supply chain.

2.0 PMS for Registered Medical Products

2.1 The MCAZ will conduct routine inspections for local manufacturing sites and collect samples of registered local products for analysis during post market surveillance activities at different levels of the supply chain.

2.2 The MCAZ will conduct physical examination of all consignments for medical products that are imported into the country at the port of entry or before distribution to verify that they comply with the registration requirements.

2.2 It is impossible to test the quality of all registered products in the country hence the need to prioritize medical products based on the perceived risk to the consumer. High risk medical products will be sampled prior to distribution, the wholesalers will be allowed to distribute the products pending the outcome of the analysis. Should the products fail laboratory analysis, the so affected products will be subject to a recall.

2.3 The MCAZ shall make use of field detection tools during routine inspections of licensed and approved establishments to detect substandard and/ or falsified medical products. Products that fail screening shall be subjected to full analytical testing.

2.4 Products that are approved by MCAZ through reliance frameworks, e.g. Egyptian Drug Authority (EDA) approved products, South African Health Products Regulatory Authority (SAHPRA) approved products, "grandfather products", shall be subject to testing and analysis for every first batch per product that is imported into the country. Furthermore, this approach will apply to all products that are registered by the MCAZ without testing conducted.

2.5 Manufacturers, distributors, healthcare professionals, and consumers must promptly report any adverse events, product defects, or quality issues associated with registered medical products to the Medicines Control Authority of Zimbabwe (MCAZ).

2.6 Upon receiving reports of adverse events or quality concerns, the MCAZ will conduct thorough risk assessments to determine the severity and likelihood of harm associated with the product. Where necessary, the products will be subjected to testing. The MCAZ will disseminate relevant information regarding registered products, including safety alerts, recalls, and corrective actions, to healthcare professionals, consumers, and the public through accessible channels such as media releases and the MCAZ website.

2.7 Non-compliance with reporting requirements or failure to address safety concerns may result in regulatory actions, including product suspension or revocation of registration.

3.0 PMS for Unregistered Medical Products

3.1 The importation and distribution of unregistered medical products are strictly regulated. Only products approved by the MCAZ or recognized regulatory authorities with stringent oversight will be allowed for importation and distribution.

3.2 The MCAZ will conduct physical examination of all consignments for unregistered medical products that are imported into the country at the port of

entry or before distribution to verify that they comply with the conditions on the authorisation letter.

3.3 Since it is impossible to test the quality of all unregistered medical products imported into the country there is need to prioritize medical products based on the perceived risk to the consumer. High risk medical products will be sampled prior to distribution, the wholesalers will be allowed to distribute the products pending the outcome of the analysis. Should the products fail laboratory analysis, the so affected products will be subject to a recall.

3.4 The MCAZ will conduct surveillance activities targeting unregistered products available in the market, including unauthorized imports and suspected substandard and/ or falsified medical products. This includes market inspections, product sampling, and collaboration with law enforcement agencies.

3.5 The MCAZ will engage in public awareness campaigns to educate consumers about the risks associated with unregistered products and encourage them to purchase registered medicines from licensed and authorized sources only.

3.6 Consumers and healthcare professionals are encouraged to report any adverse events or suspected substandard and/ or falsified medical products related to unregistered medical products to the MCAZ for investigation.

3.7 Unregistered medical products found on licensed and approved premises shall be confiscated. The offenders will be penalised following the Authority's administrative processes.

4.0 PMS for Veterinary Medical Products

4.1 MCAZ receives a significant number of veterinary medical products that were approved under the South African Act 36 of 1947. These products are of unknown quality due to the dual regulation of veterinary medicines in South Africa. South Africa has two medicines regulators namely Department of Agriculture that implements Act 36 (biologicals, pesticides and other pharmaceuticals) and SAHPRA that implements Act 101 (pharmaceuticals). These products shall therefore be mapped and identified for post market surveillance activities.

4.2 The policy shall also include other products from other jurisdictions without strong regulatory systems.

4.3 The MCAZ shall make use of field detection tools during routine inspections of licensed and approved establishments to detect substandard and/ or falsified veterinary products. Products that fail screening shall be subjected to full analytical testing.

5.0 REFERENCES

5.1 WHO guidelines for sampling of pharmaceutical products and related materials. (TRS No. 929, 2005)

5.2 Guidance for implementing risk-based post –marketing quality surveillance in low- and middle-income countries, 2016.

5.3 Guideline for Post Market Surveillance, MCAZ/LED/GL-11

6.0 ATTACHMENTS

N/A

7.0 HISTORY

DOCUMENT HISTORY		
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