



POST MARKETING SURVEILLANCE PLAN FOR ARTEMISININ-BASED COMBINATION THERAPIES (ACTS) AND ARTESUNATE USED IN THE MANAGEMENT OF MALARIA IN RWANDA

1. Introduction

According to the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA, its organization and functioning especially in Article 8 paragraph 9, Rwanda FDA is mandated to conduct pharmacovigilance and post marketing surveillance for safety and quality of products regulated under this Law; It is in this regards Rwanda FDA has established the post marketing surveillance plan for Artemisinin based combination therapies and Artesunate which are medicines used in management of malaria in Rwanda this plan states the objectives, methodology, the list of products and the criteria for selection of the products/molecules that are to undergo quality tests in the laboratory and the estimated budget. Furthermore, the selection of sites where the sampling will be done is detailed as well as the guide on sampling. Tools that should be used during the implementation of the plan are part of the document as annexes.

1.1 Background

To achieve the Rwanda's Extended Malaria Strategic Plan 2013–2020 in its strategy 3 “Strengthen quality assurance and control of all malaria consumables and commodities”, the President's Malaria Initiative (PMI) is supporting the National Malaria control program and Rwanda Food Drug Authority (Rwanda FDA) to conduct the quality control of antimalarial medicines sampled across the different supply chain levels. The aim of the activity is to assess whether antimalarial medicines keep or not the quality after being stored and distributed throughout supply chain

levels. Rwanda FDA will conduct this activity with collaboration of Rwanda Biomedical Center and Global Health Supply Chain-Procurement Supply Management

2.0 Objectives:

The main objective of the activity is to assess whether antimalarial medicines keep or not the quality after being stored and distributed throughout different level of supply chain

2.1 Specific objectives

- a) To collect samples of antimalarial medicines at different levels of the supply chain in Rwanda
- b) To bring the collected samples to the central level
- c) To send the samples to WHO accredited laboratory for testing quality against the recommended pharmacopoeias (USP, BP, Ph. Int.) specifications

3.0 Methodology

The collection sample will be done to different districts based to geographical and endemic zones. The selected sites in each province are Nyagatare, Kirehe, Burera, Ruhango, Gisagara, Rusizi, Gasabo and RMS Ltd



Fig 1: Selected districts for sampling (Nyagatare, Kirehe, Gasabo, Ruhango, Gisagara, Burera, Rusizi, Rubavu).

3.0 Duration

The sampling activity shall be conducted within one week and the collected samples shall be sent to the recognized laboratory for quality control testing.

4.0 Sampling

The sample to be collected should have at least passed a minimum of one month at selected site to assess if the storage condition of drugs have not affected the quality of anti-malarial products. While sampling the sample collector will fill a sample collection form which include preliminary information of the sample, storage condition at the site and visual description

4.1 Sample size

The minimum sample size required per batch is estimated at 100 tablet of ACTs and 110 vials of Artesunate injection.

The total number of samples for ACTs shall be 93 samples:64 from eight districts (8 samples per district x 8 districts) 4 from RMS,16 samples from 4 endemic districts (Rusizi, Nyagatare, Gasabo, Gisagara) in the community and 9 samples of artesunate injection to be collected at District Pharmacies and Health facilities around the DP

4.2 Storage and transportation of the samples

The collected samples shall be stored and transported in the manufacturers' recommended storage condition for the ACTs and artesunate injection.

4.3 Replacement of sample collected

Mal&OPDD shall replace the sample collected to avoid stock out in the site where medicines shall be collected from.

5.0 Selection of laboratory for quality control

GHSC-PSM shall select an international WHO approved laboratory to perform necessary analysis of antimalarial medicines. Once selected GHSC-PSM shall communicate to Rwanda FDA and RBC the selected laboratory for approval before initiating the sample collection.

5.1 Quality control to be performed by the selected laboratory

The quality control to be performed should be in line with International Pharmacopoeia (Ph.Int.) latest Edition (9th Edition,2019). The test to be performed for antimalarial medicines must comply at least to the following requirements:

For ACTs tablets:

- Comply with the monograph for tablets (Uniformity of mass, Disintegration/Dissolution)
- Identity test
- Relate substances(Impurity)
- Assay

For Artesunate injection

- Comply with the monograph for parenteral preparation (Clarity and color of solution, Particulate matters, PH, Water content, Sterillity, Filling quantity variation)
- Bacterial endotoxins
- Related substances

- Assay

6.0 Expected result

- a) Results on Antimalarial medicines quality control that will help Rwanda FDA to know the status of the quality of antimalarial medicines on Rwanda Market
- b) The quality control result will orient MOPDD in taking appropriate decision on storage condition to be maintained or improved at the central medical store(MPPD) and peripheral levels(DP)
- c) To share the result with Malaria program stakeholders: USAID/GHSC-PSM, GF, MPPD, District Pharmacies, Hospitals and Health centers
- d) To generate evidence based data for decision making to inform regulatory action against identified non-conforming products.
- e) Remove non compliant anti malarial products on the market
- f) Initiate action to address the source cause of non compliant products
- g) To prevent non compliant anti malarial drugs products from entering in Rwanda supply chain
- h) Identify gaps in quality assurance system

7.0 BUDGET

All budget related to this Post Marketing Surveillance sampling plan for Artemisinin-based Combination Therapies (ACTs) and Artesunate used in the management of malaria in Rwanda shall be covered by GHSC-PSM

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