

# ANTI-MALARIA MEDICINES POLICY

## GHANA HEALTH SERVICE

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Ministry of Health



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## PREFACE

This revised edition of the Anti-Malarial Medicine Policy is based on current evidence on malaria treatment and lessons learnt in the implementation of the 2014 policy.

The revision emerges from consultative meetings with all relevant stakeholders involved in malaria case management in the country. This document is written in very simple and precise language to make for easy reading and understanding.

I implore all stakeholders and health professionals to ensure that the guidelines contained in this document are complied with both Private and Public sector contribution in order to ensure effective treatment of malaria and reduce the malaria burden in the country.

It is my hope that the new Anti-Malarial Medicine Policy will form the basis for the standardization of malaria care throughout the country as it supports the new paradigm of creating wealth through health.



*Kwaku Agyeman-Manu*

**HON. MINISTER OF HEALTH**

## ACKNOWLEDGEMENT

The development of the Anti-malarial Medicine Policy has been successfully completed as a result of the hard work of the committee of experts who put the document together. We acknowledge especially the contributions of the following people who constituted the members of the policy experts review committee.

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**LIST OF ABBREVIATIONS**

ACT	Artemisinin-based Combination Therapy
AL	Artemether-lumefantrine
AS-AQ	Artesunate-Amodiaquine
DALYs	Disability Adjusted Life Years
DHAP	Dihydroartemisinin-Piperaquine
DOT	Directly Observed Therapy
EML	Essential Medicine List
EPI	Expanded Program on Immunisation
FDA	Food and Drugs Authority
GHSC	Global Health Supply Chain
GNDP	Ghana National Drugs Programme
GDP	Gross Domestic Product
GSA	Ghana Standards Authority
GMP	Ghana Manufacturing Practice
GHS	Ghana Health Service
G6PD	Glucose-6-phosphate dehydrogenase
HIV	Human Immunodeficiency Virus
IM	Intramuscular
ITNs	Insecticide-Treated bed Nets
IV	Intravenous
IPTp	Intermittent Preventive Treatment in Pregnancy
KBTH	Korle-bu Teaching Hospital

MIS	Malaria Indicator Survey
NHIML	National Health Insurance Medicines List
NMCP	National Malaria Control Programme
NMIMR	Noguchi Memorial Institute for Medical Research
OTC	Over-the-Counter
PCR	Polymerase chain reaction
<i>PF</i>	<i>Plasmodium falciparum</i>
<i>PO</i>	<i>Plasmodium ovale</i>
<i>PV</i>	<i>Plasmodium vivax</i>
PSM	Procurement and Supply Management
RDD	Research and Development Division
SBCC	Social Behavioural Change Communication
SMC	Seasonal Malaria Chemoprevention
SMD	School of Medicine and Dentistry
SPMDP	Society of Private Medical and Dental Practitioners
STG	Standard Treatment Guidelines
SP-AQ	Sulphadoxine-pyrimethamine and Amodiaquine
T3	Test, Treat and Track
UG	University of Ghana
UHAS	University of Health and Allied Sciences
WHO	World Health Organisation

**TABLE OF CONTENTS**

PREFACE	ii
ACKNOWLEDGEMENT	iii
LIST OF ABBREVIATIONS	v
LIST OF FIGURES	x
<b>1.0 INTRODUCTION</b>	1
<b>1.1 BACKGROUND</b>	4
<b>1.2 RATIONALE FOR REVISING MEDICINE POLICY</b>	6
<b>2.0 POLICY OBJECTIVE</b>	7
<b>2.1 MANAGEMENT OF UNCOMPLICATED MALARIA</b>	7
<b>2.1.1 DRUG OF CHOICE FOR UNCOMPLICATED MALARIA TREATMENT</b>	7
<b>2.2 MANAGEMENT OF UNCOMPLICATED MALARIA IN PREGNANCY</b>	8
<b>2.2.1 FIRST TRIMESTER</b>	8
<b>2.2.2 SECOND AND THIRD TRIMESTERS</b>	9
<b>2.3 COMMUNITY MANAGEMENT OF UNCOMPLICATED MALARIA</b>	9
<b>2.3.1 PRE-REFERRAL TREATMENT OF MALARIA IN COMMUNITIES</b>	10
<b>2.4 TREATMENT FAILURE</b>	10
<b>2.4.1 TREATMENT FAILURE OF UNCOMPLICATED MALARIA</b>	10
<b>2.4.2 TREATMENT FAILURE OF UNCOMPLICATED MALARIA IN PREGNANT WOMEN</b>	11

2.5	MALARIA TREATMENT WITH HERBAL MEDICINE	11
2.6	MALARIA VACCINES	12
3.0	PRE-REFERRAL TREATMENT OF SEVERE MALARIA IN COMMUNITIES	13
3.1	MANAGEMENT OF SEVERE MALARIA	13
3.2	MANAGEMENT OF SEVERE MALARIA IN PREGNANCY	14
4.0	INTERMITTENT PREVENTIVE TREATMENT OF MALARIA DURING PREGNANCY	15
4.1	DRUG OF CHOICE FOR INTERMITTENT PREVENTIVE TREATMENT IN PREGNANCY (IPTP)	15
4.1.1	CONDITIONS FOR USE OF SULPHADOXINE-PYRIMETHAMINE (SP)	15
4.2	ALTERNATIVE ANTI-MALARIALS TO (SP) FOR PREVENTING MALARIA IN PREGNANCY	16
5.0	SEASONAL MALARIA CHEMOPREVENTION	17
5.1	DRUG OF CHOICE FOR SEASONAL MALARIA CHEMOPREVENTION	17
5.2	TARGET AREA FOR SEASONAL MALARIA CHEMOPREVENTION	17
6.0	IMPLEMENTATION FRAMEWORK	19
6.1	CLASSIFYING ANTI-MALARIAL COMBINATION THERAPIES	19
6.2	SUPPLY OF ANTI-MALARIALS	20
6.3	OPERATIONAL CONSIDERATIONS	21
6.3.1	IMPLEMENTATION STRATEGY	21
6.3.2	PROCUREMENT	21



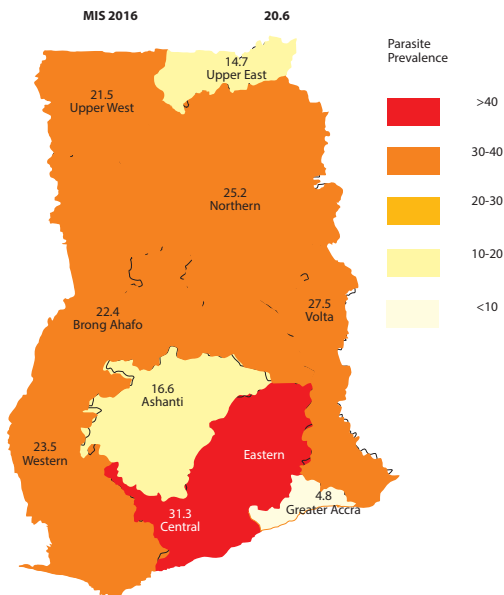
<b>6.3.3</b>	REVISION OF THE STGS, EML AND NHIML	22
<b>6.3.4</b>	SOCIAL BEHAVIOURAL CHANGE COMMUNICATION (SBCC)	22
<b>7.0</b>	CAPACITY BUILDING	23
<b>7.1</b>	SERVICE PROVIDERS	23
<b>7.2</b>	TRAINING	23
<b>7.3</b>	PUBLIC EDUCATION	24
<b>8.0</b>	MONITORING AND EVALUATION	25
<b>8.1</b>	PRESCRIBING AND DISPENSING	25
<b>8.2</b>	PATIENT ACCEPTANCE AND COMPLIANCE	25
<b>8.3</b>	QUALITY AND EFFICACY OF PRODUCTS	25
<b>8.4</b>	SAFETY MONITORING	26
<b>8.5</b>	AVAILABILITY AND ACCESSIBILITY	26
<b>9.0</b>	REGULATION	27
<b>9.1</b>	REGISTRATION OF PRODUCTS	27
<b>9.2</b>	DRUG DE-REGULATION	27
<b>9.2.1</b>	ARTEMISININ-BASED DERIVATIVES AND AMODIAQUINE AS MONOTHERAPIES	27
<b>9.2.2</b>	QUININE AS MONOTHERAPY IN FIRST TRIMESTER OF PREGNANCY	28
<b>9.2.3</b>	USE OF OTHER ANTIMALARIALS	28
<b>10.0</b>	PUBLIC – PRIVATE PARTNERSHIPS	29
	<b>REFERENCES</b>	30

## LIST OF FIGURES

FIGURE 1: MALARIA PARASITE PREVALENCE AMONG CHILDREN UNDER FIVE YEARS IN GHANA (MIS 2016)	1
FIGURE 2: SITE-SPECIFIC PCR-CORRECTED CURE RATE FOR AS-AQ AND AL (2015 - 2017)	5

## 1.0 INTRODUCTION

Malaria is a major cause of illness and death in Ghana, particularly among children and pregnant women. In 2018, malaria accounted for 34.5% of all out-patient illnesses and 21.8% of all admissions<sup>1</sup>. The average malaria parasite prevalence among children aged 6-59 months in the 2016 Malaria Indicator Survey (MIS) was 20.6% with regional variations from as low as 4.8% in the Greater Accra Region to as high as 31.3% in the Central Region (Fig. 1)



*Figure 1: Malaria Parasite prevalence among children under five years in Ghana (MIS 2016)<sup>2</sup>*

Malaria infection during pregnancy causes maternal anaemia and placental parasitaemia both of which are responsible for miscarriages and low birth weight babies among pregnant women. Pregnant women account for about 4% of OPD malaria cases in the country.

Malaria is a major cause of under-development and inflicts serious socio-economic burden on the entire citizenry. In 2014, businesses lost about US\$6.58 million to malaria in Ghana, 90 % of which were direct costs<sup>3</sup>. Malaria is estimated to cause the loss of about 10.6% Disability Adjusted Life Years (DALYs) costing an equivalent of up to 6% of GDP annually in economic burden<sup>4</sup>.

The Ministry of Health in its Mid-Term Strategic Plan, considers malaria a priority disease which has to be tackled in order to achieve the Sustainable Development Goal 3.3.

Case Management has been and continues to be one of the main strategic interventions for the control of malaria in the country.

The Ghana Health Service (GHS)/National Malaria Control Programme (NMCP) since 2009 has been promoting World Health Organisation's (WHO) recommendation of universal parasitological diagnosis of malaria. This brings a shift from presumptive clinical diagnosis to the test, treat and track (T3) policy.

The effectiveness of this intervention is highly dependent on antimalarials, which should be safe, effective, available, affordable and acceptable to the entire population. To achieve this objective, an up-to-date evidence-based Anti-Malarial Medicine Policy for the country is needed.

The policy will contribute to:

- Preventing progression of uncomplicated malaria to severe disease and death
- Shortening clinical episodes of malaria and reducing the occurrence of malaria-associated complications such as anaemia in populations residing in areas of high malaria transmission
- Reducing consequences of placental malaria infection and maternal malaria-associated anaemia through intermittent preventive treatment during pregnancy.
- Delaying the development and spread of resistance to antimalarials.

This Anti-Malarial Medicine Policy is therefore a fundamental and dynamic document that needs to be regularly reviewed to reflect changes in global trends and the country context.

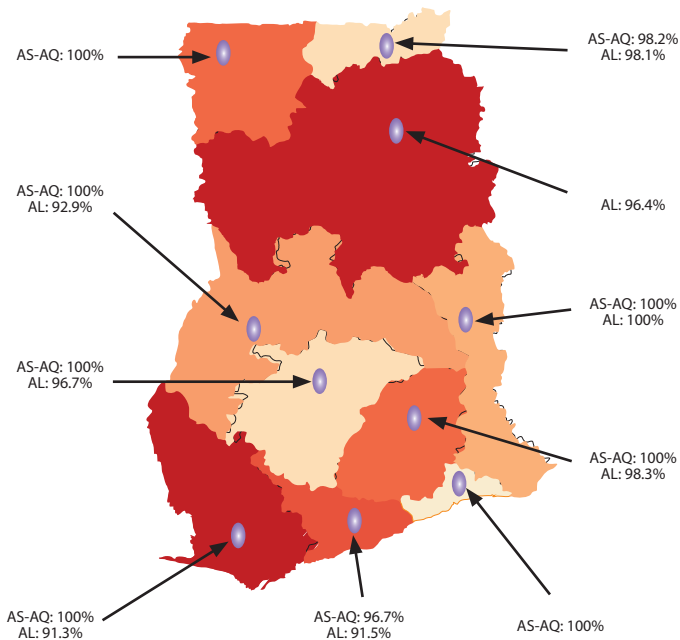
## 1.1 Background

Following WHO recommendation on the use of combination therapy for malaria treatment in 2000, Ghana, based on its drug efficacy findings, adopted Artemisinin-based Combination Therapy (ACT), specifically Artesunate-Amodiaquine (AS-AQ), as first line treatment for malaria in 2004. The policy has been revised subsequently and the latest revision was in 2014.

Artesunate Amodiaquine (AS-AQ) combination was maintained as medicine of choice for treating uncomplicated malaria whilst Artemether-Lumefantrine (AL) and Dihydroartemisinin Piperaquine (DHAP) were alternative ACTs for patients who were unable to tolerate AS-AQ. ACTs have remained efficacious since their introduction in Ghana. Data obtained from sentinel sites during the 2013-2014 surveillance period showed PCR corrected cure rates of 100% for AS-AQ and 97.6% for AL<sup>5</sup>. Recent data from the 2015-2017 surveillance period showed PCR corrected cure rates of 99.2 % for AS-AQ and 96% for AL, with regional variations as shown in Figure 2.<sup>6</sup>

Parenteral Artesunate replaced Quinine as the medicine of choice for initiating the management of severe malaria followed by full course of ACTs when the patient is able to take oral preparations.

Sulphadoxine-Pyrimethamine and Amodiaquine combination (SP-AQ) was introduced as medicine of choice for Seasonal Malaria Chemoprevention (SMC) in the Northern savannah zone. The revised policy has been in use since 2014.



**Figure 2: Site-specific PCR-corrected cure rates for AS-AQ and AL (2015 - 2017)**

National averages:

AS-AQ : 99.2%

AL : 96.0%

## **1.2 Rationale for Revising Medicine Policy**

The Ministry of Health constituted the Anti-Malarial Medicine Policy Expert Review Committee on 4th February 2019 to review the existing drug policy. This was necessitated by:

1. Beneficial evidence of multiple first line therapy against parasite resistance
2. Revised WHO guidelines for case management
3. Changing parasite prevalence rates across the country
4. Current information on prevalence of Plasmodium species
5. Anecdotal evidence on prescriber preference in the use of ACT (i.e. drug pressure)



## 2.0 POLICY OBJECTIVE

To provide prompt, safe, effective and appropriate anti-malaria treatment to the entire population.

### 2.1 Management of Uncomplicated Malaria

Studies conducted on drug efficacies and safety have not shown marked difference between Artesunate-Amodiaquine (AS-AQ) and Artemether-Lumefantrine (AL)<sup>5-7</sup>. Although national data on the efficacy of DHAP is limited, global data suggests comparable cure rates with AS-AQ and AL<sup>8</sup>.

The three ACTs therefore remain the medicines of choice for managing uncomplicated malaria in Ghana as described in section 2.1.1.

#### 2.1.1 Drug of Choice for Uncomplicated Malaria Treatment

##### **The First Line Antimalarial:**

Based on the comparable efficacies of the three ACTs and the benefit of multiple first line therapy in delaying the emergence and spread of drug resistance<sup>9,10</sup>, Ghana is adopting a multiple first line approach in the treatment of uncomplicated malaria.

The first line ACTs are therefore as follows;

- i. Artesunate-Amodiaquine (AS-AQ)
- ii. Artemether-Lumefantrine (AL)

The choice of the first line ACT shall be based on patient's tolerance and acceptance.

### **The Second Line Antimalarial:**

The second line ACT for the treatment of uncomplicated malaria (all parasites-*Pf, Pm, Po*) shall be the recommended strength and dosage forms of:

- iii. Dihydroartemisinin-Piperaquine (DHAP)

Adherence to testing before treatment using the appropriate dosing is essential to ensure prompt and effective treatment. In cases of confirmed *P. ovale* infection, Primaquine should be added to the ACT for the purpose of preventing relapse. The G6PD status of the patient should be used to guide use of primaquine.

## **2.2 Management of Uncomplicated Malaria In Pregnancy**

### **2.2.1 First Trimester**

A combination of oral quinine plus clindamycin shall be the drug of choice for the management of malaria in

the first trimester of pregnancy. Currently, ACTs are not recommended for use in the first trimester. However, their use should not be withheld in cases where they are considered to be lifesaving.

### **2.2.2 Second and Third Trimesters**

Artesunate-Amodiaquine or Artemether-Lumefantrine shall be used for the management of malaria in the second and third trimesters of pregnancy. A combination of Quinine and Clindamycin can be used as alternatives if ACTs are not available. Pregnant women with co-morbidities (incidence) of HIV and sickle cell anaemia shall be treated as above for malaria.

## **2.3 Community Management of Uncomplicated Malaria**

ACTs shall be the medicine of choice for treating uncomplicated malaria in the community.

All patients who deteriorate or do not improve within 24 hours of treatment of uncomplicated malaria shall be referred immediately to the next level health facility.

### **2.3.1 Pre-Referral Treatment of Malaria in Communities**

All children who do not respond to treatment for uncomplicated malaria with Artesunate- Amodiaquine or Artemether-Lumefantrine within 24 hours shall be referred immediately to the next level health facility. Children under 6 years shall be given an initial dose of an artemisinin- based suppository prior to referral to the next level health facility. Fever should be controlled with tepid sponging and Paracetamol.

## **2.4 Treatment Failure**

### **2.4.1 Treatment Failure of Uncomplicated Malaria**

For the management of treatment failures, the following options are recommended:

- a. An alternative first line ACT (Artesunate-Amodiaquine or Artemether-Lumefantrine) which has not been administered as first line of treatment. If this fails, the second line ACT (DHAP) shall be used for treatment.
- b. If for any reason ACT cannot be administered, then a combination of Quinine and Clindamycin could be used. Treatment Failure should be distinguished from Inadequate Treatment.

Inadequate treatment can be defined as failure to complete the initial course of treatment for whatever reason (e.g. vomiting, non-compliance, etc.). In case of inadequate treatment a full course of the initial drug used should be repeated.

## **2.4.2 Treatment Failure of Uncomplicated Malaria in Pregnant Women**

### **2.4.2.1 First Trimester**

ACTs are not recommended for use in the first trimester; however their use shall not be withheld in cases where they are considered to be life-saving and other antimalarials are deemed to be unsuitable.

### **2.4.2.2 Second and Third Trimesters**

A combination of Quinine and Clindamycin or Artesunate-Amodiaquine or Artemether–Lumefantrine combination therapies shall be given depending on which medicine was used first.

## **2.5 Malaria Treatment With Herbal Medicine**

Malaria treatment with herbal medicines shall be by the recommended antimalarial herbal medicines approved by the Food and Drugs Authority (FDA).

## **2.6 Malaria Vaccines**

Malaria vaccines that are found to be safe and efficacious shall be incorporated into the National immunisation schedules e.g. Expanded Programme for Immunisation (EPI) for use to prevent malaria.

### **3.0 PRE-REFERRAL TREATMENT OF SEVERE MALARIA IN COMMUNITIES**

All patients presenting with severe malaria should be referred immediately to the next level health facility. Children under 6 years shall be given an initial dose of an artemisinin-based suppository prior to referral to the next level health facility. Fever should be controlled with tepid sponging and Paracetamol.

#### **3.1 Management of Severe Malaria**

Severe Malaria is a life-threatening infection caused by *Plasmodium falciparum* that needs immediate and urgent treatment.

Management of severe malaria requires parenteral treatment to provide adequate blood-serum concentrations as quickly as possible initially; subsequently reverting to oral treatment as soon as the patient's condition permits.

Following the recommendation by WHO, parenteral Artesunate shall be used as the medicine of choice for managing severe malaria, to be followed by a full course of ACT when the patient is able to take in oral preparations<sup>11</sup>.

In the event of injection Artesunate not being readily available, IM Artemether should be used as an alternative to save lives. The necessary support therapy shall be provided as and when appropriate.

### **3.2 Management of Severe Malaria in Pregnancy**

#### First, Second and Third Trimesters

Following new evidence and WHO recommendation, treat pregnant women in all trimesters and lactating women with severe malaria with IV or IM Artesunate followed by a full course of ACTs except first trimester where a combination of Quinine plus Clindamycin should be given. Pregnant women with co-morbidities of HIV and sickle cell anaemia shall be treated same as above.



## **4.0 INTERMITTENT PREVENTIVE TREATMENT OF MALARIA DURING PREGNANCY**

Currently, apart from ITNs the most preferred intervention to prevent malaria in pregnancy is Intermittent Preventive Treatment (IPT) using SP. This shall be administered at predefined intervals starting of at 16 weeks of gestation

IPTp is preferably provided as part of a comprehensive antenatal package with other medicines like haematinics and anti-helminthics. The medicine shall be administered under the supervision of a qualified health worker – “Directly Observed Therapy (DOT)”.

### **4.1 Drug of Choice for Intermittent Preventive Treatment In Pregnancy (IPTp)**

Sulphadoxine-Pyrimethamine (Sulphadoxine 500mg + Pyrimethamine 25mg) shall be reserved for Intermittent Preventive Treatment (IPTp) given as DOT.

#### **4.1.1 Conditions for use of Sulphadoxine-Pyrimethamine (SP)**

All pregnant women shall undergo screening before the commencement of IPTp in order to exclude those who are either G6PD deficient or allergic to sulphonamides.

All pregnant women shall be encouraged to sleep under Insecticide Treated Nets (ITNs).

Folic acid at a daily dose equal or above 5mg should not be given concomitantly with SP as this counteracts its efficacy as an antimalarial. Low dose Folic acid (0.4mg) should be given daily when administration of SP begins.

#### **4.2 Alternatives to (SP) For Preventing Malaria In Pregnancy**

1. Currently there are no recommended alternatives to (SP) for IPTp. It must therefore, be emphasized that, for women who cannot take (SP), they need to consistently use Long Lasting Insecticidal Nets (LLINs) and other protective measures. They must also be educated to report early to the nearest health facility when they have symptoms suggestive of malaria.
2. Pregnant women with HIV shall receive monthly doses of Sulphadoxine-Pyrimethamine, except when they are receiving Co-trimoxazole

## **5.0 SEASONAL MALARIA CHEMOPREVENTION**

Seasonal Malaria Chemoprevention (SMC) is defined as the intermittent administration of full treatment courses using the recommended antimalarial medicine during peak malaria transmission season to prevent malaria illness with the objective of maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malaria risk.

A complete treatment course of antimalarial is given to children aged between 3 and 59 months at monthly intervals, at the beginning of the transmission season, to a maximum of four doses during the malaria transmission season.

### **5.1 Drug of Choice for Seasonal Malaria Chemoprevention**

The recommended antimalarial for this intervention is Sulphadoxine-Pyrimethamine plus Amodiaquine (SP-AQ).

### **5.2 Target Area for Seasonal Malaria Chemoprevention**

Target area for implementation is the Sahel sub-region, where:

Malaria transmission is highly seasonal and the majority of clinical malaria cases occur during a short period of about 4 months. In Ghana, SMC will be implemented in the Northern Savannah.

Sulphadoxine-Pyrimethamine (SP)-Amodiaquine (AQ) shall not be given to

- A child with an acute febrile illness or severely ill children unable to take oral medication
- An HIV positive child receiving co-trimoxazole prophylaxis
- A child who has received a dose of either SP or AQ during the past month
- A child who is allergic to either SP or AQ

## 6.0 IMPLEMENTATION FRAMEWORK

Government has the task of ensuring access to medicines and product safety to forestall implementation challenges. It is critical that all antimalarials deployed are of good quality, safe and efficacious. To this end, the pharmaceutical inspection programmes of the national drug regulatory authority have been intensified and national drug quality control laboratories further equipped and resourced.

Improved patient acceptance of Artemisinin-based Combination Therapies (ACTs) shall be promoted by appropriate agencies of the Ministry of Health to ensure compliance. This will entail extensive public education on the new management of malaria using multiple approaches through print, mass media and social behavioural change communication strategies. The FDA shall ensure the quality and safety of recommended antimalarials to increase public confidence in the implementation of this policy.

### 6.1 Classifying Anti-Malarial Combination Therapies

The recommended ACTs shall remain as Over-the-Counter (OTC) medicines permissible to be dispensed at all levels to ensure ready availability to the general public.

## 6.2 Supply of Anti-Malarials

The Government of Ghana shall support the local pharmaceutical manufacturing industry to build capacity to meet internationally accepted requirements of Good Manufacturing Practices in the production of ACTs and other antimalarials. This will facilitate sustainability of this policy especially the provision of facilities for conducting bioavailability and bioequivalence studies among others so as to enhance the manufacture and supply of the ACTs and other antimalarials to both the public and the private sectors.

The FDA shall monitor the quality, efficacy and safety as well as any reported Adverse Drug Reactions (ADRs) resulting from the use of all antimalarials in accordance with the provisions of the Public Health Act 851, 2012.

Sulphadoxine-Pyrimethamine reserved solely for use in Intermittent Preventive Treatment of malaria in pregnancy is produced locally and therefore readily available. The FDA shall continue to monitor the quality of these products whether locally produced or imported as well as the Adverse Drug Reactions (ADRs) associated with their use.

Primaquine shall be reserved solely for use in confirmed *P. ovale* malaria cases in addition to the recommended ACTs.

Access to medicines under this policy: To ensure smooth implementation of this policy, the Ministry of Health and its agencies shall ensure access and availability of the recommended antimalarials under this policy in all facilities.

### **6.3 Operational Considerations**

For effective implementation of this policy, the strategies with regard to procurement, revision of guidelines and SBCC shall be as follows:

#### **6.3.1 Implementation strategy**

This revised policy shall be implemented through an immediate nationwide rollout. This shall entail the rollout of the revised policy in the entire country at the same time.

#### **6.3.2 Procurement**

Existing mechanisms will be maintained to ensure minimal price disparities between products from the public and private sectors.

### **6.3.3 Revision of the STGs, EML and NHIML**

Sections of the Standard Treatment Guidelines (STGs), Essential Medicines List (EML), National Health Insurance Medicines List (NHIML), and other guidelines for health workers, curricula or documents recommending treatment for malaria shall be revised in line with this policy.

### **6.3.4 Social Behavioural Change Communication (SBCC)**

The revision of STGs, EML and NHIML shall be harmonised with the development of the Social Behavioural Change Communication (SBCC) to ensure that the same messages are communicated to health care workers and members of the public.



## **7.0 CAPACITY BUILDING**

The Ministry of Health shall ensure appropriate activities are conducted to facilitate the smooth implementation of the policy.

### **7.1 Service Providers**

Health professionals, policy makers, manufacturers, other service providers, relevant training institutions (including medical schools, nurses' training colleges and pharmacy schools etc.), health managers in the public and private sectors, as well as the general public, shall be well informed about the revised policy.

### **7.2 Training**

Training needs shall be assessed and training manuals developed and updated to ensure every target group is catered for. The health industry shall be re-oriented to become responsive to local needs and not compromise on quality and value for money. A comprehensive training programme shall be conducted for all relevant healthcare providers prior to the rollout of public education programmes.

### **7.3 Public Education**

Public education shall be directed at all target groups including health professionals, community-based service providers and the general public using the appropriate tools and media.

## **8.0 MONITORING AND EVALUATION**

A framework for monitoring this policy shall include the following:

### **8.1 Prescribing and Dispensing**

Prescribing and dispensing practices at all service delivery points shall be monitored to enhance rational use of the recommended antimalarials.

### **8.2 Patient Acceptance and Compliance**

The Ministry of Health and its agencies shall conduct regular surveys to assess patient acceptance of and compliance with the medicines under this policy.

### **8.3 Quality and Efficacy of Products**

Post-market surveillance and laboratory testing shall be conducted by the FDA to ensure that both imported products and locally manufactured products meet the relevant pharmacopoeia and manufacturing standards of quality and efficacy.

GMP audit inspections of manufacturing facilities both local and overseas shall be rigorously enforced by the FDA.

The FDA shall also be required to furnish the Ministry of Health with periodic updates of the quality of products on the market.

The NMCP shall monitor antimalarial drug efficacy through the country.

The quality and efficacy of malaria diagnostic devices and reagents shall also be monitored by FDA and GSA.

#### **8.4 Safety Monitoring**

The FDA, health agencies and research institutions shall develop and outline procedures for efficient Safety Monitoring countrywide.

#### **8.5 Availability and Accessibility**

Relevant indicators shall be developed to measure and monitor the availability and accessibility of the products under this policy to the general public.

## **9.0 REGULATION**

### **9.1 Registration of Products**

Only antimalarials recommended by the policy and duly registered by the FDA shall be authorised for supply and use by the general public. The registration includes evaluation of information on quality, efficacy and safety by the FDA. New fixed-dose combinations and new pre-packaged products must be registered even if the individual components of the combination are already registered.

### **9.2 Drug De-Regulation**

#### **9.2.1 Artemisinin-Based Derivatives and Amodiaquine as Monotherapies.**

The use of Artemisinin-based derivatives and Amodiaquine as monotherapies for the treatment of any type of malaria outside the provisions of the new antimalarial medicine policy shall remain discontinued in all health institutions. However, Artesunate and Artemeter injections will continue to be used as initial therapy for severe malaria. This should be followed by a full course of ACT treatment.

## **9.2.2 Quinine as Monotherapy in First Trimester of Pregnancy**

The use of quinine as monotherapy for the treatment of uncomplicated malaria in the first trimester of pregnancy shall be discontinued. Instead it shall be used in combination with Clindamycin.

## **9.2.3 Use of Other Antimalarials**

### **9.2.3.1 Use of Sulphadoxine-Pyrimethamine (SP)**

Sulphadoxine-Pyrimethamine (SP) shall be reserved only for use in the prevention of malaria during pregnancy as Directly Observed Therapy (DOT) and in combination with Amodiaquine for Seasonal Malaria Chemoprevention (SMC). The use of Sulphadoxine-Pyrimethamine (SP) as monotherapy for uncomplicated malaria shall remain discontinued.

### **9.2.3.2 Use of Primaquine**

Primaquine shall be reserved for use in addition to ACTs for treatment of confirmed *P. ovale* malaria to prevent relapse. G6PD test shall be a prerequisite for the prescription and/or administration of Primaquine.

## **10.0 PUBLIC – PRIVATE PARTNERSHIPS**

The current policy shall build on the earlier work of capacity building in the private sector and other providers of care. The emphasis would be to promote the adoption of standards and regulation of the industry in collaboration with the Ministry of Trade and Industry, the Ghana Standards Authority, Association of Ghana Industries, and other relevant regulatory agencies.

The Ministry of Health shall encourage collaboration with all stakeholders in the industry to understand the components, structure, conduct, performance and contribution to the national economy.

The local industry shall be supported to develop and market products and services for the health care market, establish and strengthen intra-sectoral policy dialogue, coordination, planning and accountability.

The Ministry shall provide a framework of relevant incentives and sanctions that enhance performance, promote accountability and continuously refine the role of Government in the delivery of health.

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