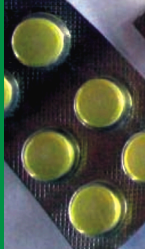

ANTI-MALARIA
DRUG POLICY FOR GHANA

REPUBLIC OF GHANA

ANTI-MALARIA
DRUG POLICY FOR GHANA

Ministry of Health

1st Revised Version 2007
2nd Revised Version 2009

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LIST OF ABBREVIATIONS

ACT	Artemisinin based combination therapy
AMDP	Anti-Malaria Drug Policy
ANCs	Antenatal Clinics
BCC	Behaviour Change Communication
CBA	Community-Based Agent
CBHWs	Community-Based Health Workers
CHIM	Centre for Health Information Management
DFID	Department for International Development
DHMT	District Health Management Team
DOT	Directly Observed Therapy
EPI	Expanded Programme on Immunisation
FDB	Food and Drugs Board
G6PD	Glucose-6 phosphate dehydrogenase
GHS	Ghana Health Service
GoG	Government of Ghana
HBC	Home Based Care
HIS	Health Information System
HPU	Health Promotion Unit
HRU	Health Research Unit
IEC	Information, Education and Communication
IMCI	Integrated Management of Childhood Illnesses
IPT	Intermittent Presumptive Treatment
ITMs	Insecticide Treated Materials
ITNs	Insecticide Treated Nets
JICA	Japan International Coorporation Agency
KABP	Knowledge, Attitude, Belief and Practice
M&E	Monitoring and Evaluation

MoH	Ministry of Health
NMCP	National Malaria Control Programme
NGOs	Non-governmental Organizations
NID	National Immunization Day
OPD	Out-Patients Department
RCH	Reproductive and Child Health
RBM	Roll Back Malaria
RHMTs	Regional Health Management Teams
SP	Sulphadoxine-Pyrimethamine
TBAs	Traditional Birth Attendants
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
WHO	World Health Organization

PREFACE

This revised edition of the Anti-Malaria Drug Policy is based on current evidence on malaria treatment and lessons learnt in the implementation of the previous policy.

The revision is borne out of consultative meetings of all relevant stakeholders involved in malaria case management in the country. This document is written in very simple and precise language to make it easy for everyone to read and understand.

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

It is my hope that, the New Malaria Treatment Policy will form the basis for the standardization of the management of all types of malaria throughout the country as it supports the new paradigm of creating wealth through health.

Hon. Dr. George Sipa-Adjah YANKEY
Minister of Health

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INTRODUCTION

Since 1998, Ghana has committed itself to the Roll Back Malaria (RBM) Initiative of the World Health Organisation (WHO), which builds on the Global Malaria Strategy with a focus on Africa and a goal to halve the world's malaria burden by 2010. Consequently, the country drew up a 'Medium Term Strategic Plan for Malaria Control in Ghana' (1998-2002), which sought to improve the coverage of malaria control activities by adopting an inter-sectoral approach involving and promoting partnership with the private sector and the community. It has also committed itself to the Abuja Declaration on Roll Back Malaria in Africa, which similarly seeks to achieve specific targets on malaria prevention and control.

In spite of these initiatives, Malaria remains hyper endemic in Ghana and is the single most important cause of mortality and morbidity especially among children under five years, pregnant women and the poor. Apart from the health consequences, malaria puts a heavy burden on productivity and hence economic development. In Ghana, 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. Therefore, the GPRS II identifies malaria control as one of the key health sector interventions.

In Ghana, as well as globally, malaria control programmes are threatened by the development of drug resistance to mono therapies necessitating revisions of treatment policies. In this regard, in 2002 Ghana initiated the process of using ACTs following WHO recommendations for all countries experiencing resistance to mono-therapies in the treatment of falciparum malaria. Based on evidence of efficacy, compliance, side effects, cost effectiveness, impact on local industry and key demographic variables such as the appropriateness for treating malaria in children under five years and in pregnancy, Artesunate-Amodiaquine was selected as the first line drug for the treatment of uncomplicated malaria.

However, the implementation process was faced with challenges such as adverse drug reactions, lack of other treatment options and safety concerns. It has therefore become necessary to review the drug policy and address all identified concerns.

A team commissioned by the Minister of Health was tasked to review existing policy guidelines and select additional ACT drugs and dosage forms to cater for those who for one reason or another, cannot tolerate Artesunate-Amodiaquine. Two additional ACTs namely; Artemether-Lumefantrine and Dihydroartemisinin/Piperaquine were selected. Nevertheless, Artesunate-Amodiaquine still remains the preferred ACT for the treatment of uncomplicated malaria.

This document is thus a revision of the 2004 anti-malarial policy and provides policy measures and an implementation framework for the treatment of malaria.

BACKGROUND/SITUATIONAL ANALYSIS

Malaria is a major cause of illness and death in Ghana, particularly among children and pregnant women in Ghana. In 2006, malaria accounted for 38.6% of all outpatient illnesses and 36.9% of all admissions. Malaria prevalence per thousand population was 171 and 2,835 malaria-attributable deaths (all ages) representing 19% of all deaths were recorded. Infection rates are high in children peaking at more than 80% in those aged 5 - 9 years and falling to low levels in adults. Malaria infection during pregnancy causes maternal anaemia and placental parasitemia both of which are responsible for miscarriages and low birth weight babies among pregnant women. As many as 13.7% of all admissions of pregnant women in 2006, was as a result of malaria whilst 9.0% of them died from the disease.

Case Management has been and continues to be one of the main strategies for the control of malaria in the country. Treatment is generally presumptive and cases of fever are first treated as malaria with the recommended anti-malaria drug. However, the effectiveness of this intervention is highly dependent on anti-malarials, which should not only be safe and effective, but also available, affordable and

acceptable to the population at risk. The rational use of an effective anti-malarial not only reduces the risk of severe disease and death and shortens the duration of the illness, but also contributes to slowing down the development of the parasite's resistance.

In Ghana as well as worldwide, the emergence and rapid spread of *P. falciparum* resistance to commonly used anti-malarials such as chloroquine poses a serious challenge to the benefits of early diagnosis and prompt treatment as a priority within the current strategy for malaria control efforts.

In November 2000, an informal Consultation on the use of anti-malaria drugs was convened by W.H.O. in Geneva. The meeting reviewed and updated recommendations on the use of anti-malaria drugs for chemoprophylaxis and treatment, based on the information available. The potential value of malaria therapy using combinations of drugs was identified as a strategic and viable option in improving efficacy and delaying development and selection of resistant parasites.

In this regard, the National Malaria Control Programme in collaboration with the Noguchi Memorial Institute for Medical Research studied the efficacy of chloroquine country wide in 2002 and found that treatment failure following chloroquine was in the range between 6% and 25% and parasite clearance rates were low and in some

cases below 50% (fig 2 & 3). These results prompted the search for alternative treatment for uncomplicated malaria. A comparative study conducted subsequent to the chloroquine efficacy tests showed that the efficacy of Artemether - Lumefantrine and Artesunate +Amodiaquine were similar (fig 3).

A task force was also formed to review the situation and the available data on malaria including the malaria morbidity and mortality trends, quality of anti-malaria drugs on the market, socio-economic aspects of malaria, cost effectiveness of proposed new treatment and the problem of malaria in pregnancy. After several deliberations, the task force recommended the use of Artesunate - Amodiaquine combination for the treatment of uncomplicated malaria.

Thus in 2004, Ghana changed its anti-malaria drug policy selecting Artesunate-Amodiaquine combination as the first line drug for the management of uncomplicated malaria. The introduction was set for 1st January, 2005 but roll out was later in that year. Systems were put in place to monitor the efficacy, quality, adverse drug reaction as well as G6PD status of pregnant women (with respect to the adoption of Sulphadoxine - Pyrimethamine for Intermittent Preventive Treatment {IPT}).

The introduction of Artesunate - Amodiaquine combination was however not without problems. One of the major problems that the programme faced was the management of negative press reports of adverse events which nearly derailed the programme. Continuous monitoring of the efficacy in the age group with the largest proportion of malaria problem - children under 5 years - pointed to the possibility of differences in drug responses between adults and children. Nonetheless, the efficacy of Artesunate - Amodiaquine has remained high and currently is over 90% after 28 days of treatment. (Fig 1). Recent results from ten sentinel sites monitoring the efficacy of Artesunate-Amodiaquine combination, show adequate clinical response of 97%.

Regarding the use of Sulphadoxine-Pyrimethamine for IPT, results from three sentinel sites monitoring the G6PD prevalence in pregnant women, shows full G6PD prevalence rate of 2.9% and partial G6PD prevalence rate of 17.7%.

1.0 POLICY FOR DRUG USE IN MALARIA

1.1 POLICY OBJECTIVE

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

2.0 UNCOMPLICATED MALARIA

2.1 MANAGEMENT OF UNCOMPLICATED MALARIA

2.1.1. Artesunate-Amodiaquine Combination

Artesunate-Amodiaquine Combination shall be the combination drug of choice for the treatment of uncomplicated malaria.

2.1.2 Alternative first line therapies

The alternative Artemisinin combination therapies recommended for the treatment of uncomplicated malaria shall be the recommended strengths and dosage forms of:

(a) Artemether - Lumefantrine
(b) Dihydroartemisinin Piperaquine

These additional ACTs shall be used for patients who cannot tolerate the Artesunate -Amodiaquine combination.

2.2. MANAGEMENT OF UNCOMPLICATED MALARIA IN PREGNANCY

2.2.1 First Trimester

Oral Quinine or a combination of oral quinine and clindamycin shall be used.

2.2.2 Second and Third Trimesters

Oral Quinine or the combination of Artesunate-Amodiaquine or Artemether -Lumefantrine shall be used.

Pregnant women with co-morbidities of HIV and sickle cell anaemia shall be treated as above for malaria.

2.3 HOME MANAGEMENT OF UNCOMPLICATED MALARIA

Artesunate-Amodiaquine shall be the combination drug of choice for treating uncomplicated malaria in the community or near-home setting for children below five (5) years of age.

The Ministry of Health and other stakeholders involved in home management of malaria in the context of the High Impact Rapid Delivery Approach and Community

Integrated Management of Childhood Illness shall ensure that community based agents involved in home management of malaria are adequately supported, supervised and provided with essential skills in behaviour change communication.

2.4 TREATMENT FAILURE

2.4.1 Treatment Failure of Uncomplicated Malaria

Quinine shall remain the drug of choice for the management of malaria in the event of treatment failure.

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 with-held in cases where they are considered to be life-saving and other anti-malarials are deemed to be unsuitable.

2.4.2.2 Second and Third Trimesters:

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

option other than what was first used shall be given where treatment failure is established.

3.0 COMPLICATED (SEVERE) MALARIA

Complicated/Severe Malaria is caused by Plasmodium falciparum and confirmed by the presence of the asexual parasite forms in the blood.

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

3.1 Pre-referral treatment of malaria in Homes and Communities

All children who do not respond to treatment with Artesunate-Amodiaquine within 24 hours shall be referred immediately to the nearest health facility after tepid sponging. Such children shall be given an initial dose of an artemisinin-based suppository prior to referral to the nearest health facility.

3.2 Management of Complicated (Severe) Malaria

Quinine or I.M. Artemether shall be the drugs of choice for treating complicated malaria.

The necessary support therapy shall be provided as and when appropriate.

3.3 Management of Complicated (Severe) Malaria in Pregnancy

3.3.1 All Trimesters

The treatment of pregnant women with severe malaria shall be with parenteral Quinine (I.V. or I.M. in all trimesters) until the patient can take oral preparations

3.3.2 Second and Third Trimesters

Intramuscular Artemether injection is recommended for the second and third trimesters.

Pregnant women with co-morbidities of HIV and sickle cell anaemia shall be treated as above.

4.0 INTERMITTENT PREVENTIVE TREATMENT (IPT) OF MALARIA DURING PREGNANCY

4.1 Preamble

Currently, apart from ITNs the most preferred intervention to prevent malaria in pregnancy is the use Intermittent Preventive Treatment (IPT) and is based on the use of anti-malaria drugs given in treatment doses at predefined intervals after quickening (16 gestational weeks) to reduce malaria parasitaemia and poor pregnancy outcomes.

IPT is preferably provided as part of a comprehensive antenatal package with other products like haematinics and anthelmintics. The drug will also be administered under the supervision of a qualified health worker - "Directly Observed Therapy (DOT)". Every pregnant woman should also have access to insecticide treated nets (ITNs), which should be used throughout the pregnancy as an additional method of malaria prevention.

4.2 Drug Of Choice for Intermittent Preventive Treatment (IPT)

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

4.2.1 Conditions for use of Sulphadoxine-Pyrimethamine

All pregnant women shall undergo screening before the commencement of IPT in order to exclude those who are either G-6PD deficient or allergic to sulphonamides.

Pregnant women who cannot take the Sulphadoxine-Pyrimethamine in IPT shall be encouraged to sleep under Insecticide Treated Nets and to report early when they have symptoms suggestive of malaria.

4.3 Alternative Antimalarials to SP for Preventing Malaria in Pregnancy

4.3.1 Pregnant women, especially those who are non-immune, may be put on Proguanil beginning in the first trimester of pregnancy

5.0 MALARIA PROPHYLAXIS IN NON-IMMUNES

Non-immune persons include:

(a) Persons living in non-malarious countries for six months or more

(b) Immmuno-compromised subjects

No anti-malarial prophylactic regimen confers total protection against malaria, However, appropriate chemoprophylaxis reduces the risk of severe malaria.

Note:

- All persons travelling to Ghana from non-malarious countries should consult their general practitioners for the appropriate advice on malaria prophylaxis.

- Dosing schedules for children should be based on body weight.

- Anti-malarials should be started 2-14 days before arriving in Ghana, and continued for 1-4 weeks after departure, depending on the anti-malarial chosen.

The recommended doses of any of the following anti-malarials may be used for malaria prophylaxis in non-immune persons while visiting Ghana:

(a) Doxycycline
(b) Mefloquine
(c) Proguanil
(d) Atovaquone/Proguanil

6.0 STEPS INVOLVED IN THE CHANGE PROCESS / IMPLEMENTATION FRAMEWORK

6.1 Preamble

The local pharmaceutical manufacturing industry has been engaged throughout the policy development process to facilitate a smooth process with minimal cost to both industry and public health.

A lot of public and private sector investments in equipment and infrastructure have already gone into the production and distribution of Artesunate-Amodiaquine combination therapy. The introduction of the more expensive Artemisinin-based Combination Therapies (ACTs) has further cost implications. To reduce the increased cost burden of ACTs on the most vulnerable populations and ensure their availability and affordability to the population, the recommended ACTs have been incorporated into the National Health Insurance Medicines List .

Government also has the task of ensuring access to medicines and product safety to forestall the implementation challenges. It is critical that all anti-malarials 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 community-based Information, Education and Communication strategies. The FDB shall ensure the quality and safety of ACTs to increase public confidence in the implementation of this policy.

6.2 Transition Periods

The New Anti-Malaria Treatment Policy for Ghana which was first implemented in January, 2005 shall be re-launched.

In this regard, a transition period shall be allowed to rid the market of all monotherapies for the treatment of uncomplicated malaria whilst ensuring the availability and accessibility of the combination therapies under this policy.

During this period, the Food and Drugs Board shall disallow the importation of monotherapies for the treatment of uncomplicated malaria. Local manufacturers shall also be granted a reasonable period of time to exhaust their existing stocks of raw materials, following which the

manufacture of monotherapies for the treatment of uncomplicated malaria shall not be allowed.

6.3 Re-Classifying Anti-Malaria Combination Therapies

Artemisinin based combination therapies are classified as 'prescription only' drugs. This means that they have to be prescribed by a clinician and dispensed by a pharmacist.

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

6.4 Supply of Anti-malarials

6.4.1 The Ministry of Health shall support the local pharmaceutical manufacturing industry to build capacity to meet internationally accepted requirements of Good Manufacturing Practices in the production of ACTs. 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 to both the public and the private sectors.

6.4.2 The Ministry of Health and other relevant agencies shall ensure the availability of all recommended anti-malarials for the treatment of uncomplicated and severe malaria.

6.4.3 The FDB shall monitor the quality as well as any reported Adverse Drug Reactions(ADRs) resulting from the use of all anti-malarials in accordance with the provisions of the Ghana National Drug Policy.

6.4.4 Sulphadoxine-pyrimethamine reserved solely for use in Intermittent Preventive Treatment of malaria in pregnancy is produced locally and therefore readily available. The FDB 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.

6.4.5 Access to drugs under this policy

To ensure smooth implementation of this policy, the MOH and its agencies shall ensure access and availability of the recommended anti-malarials under this policy in all facilities.

6.4.6 Operational Considerations

6.4.6.1 Nationwide Implementation Programme

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

6.4.6.2 Procurement

Mechanisms will be put in place to ensure minimal price disparities between products from the public and private sectors.

6.4.6.3 Revision of the STGs, EDL and NHIDL

Sections of the Standard Treatment Guidelines (STGs), Essential Medicines List (EML), National Health Insurance Drug List (NHIDL), and other guidelines for health workers, curricula or documents recommending treatments for malaria shall be revised. The revision shall be harmonised with the development of the Behavioural Change Communication to ensure that the same messages are communicated to health care workers and members of the public.

7.0 CAPACITY BUILDING

7.1 Health professionals, policy makers, manufacturers, other service providers, relevant training institutions (including medical schools, nurses' training

colleges, pharmacy schools etc), health managers in the public and private sector as well as the general public shall be well informed about the new policy.

7.2 A comprehensive training programme shall be conducted for all relevant healthcare providers prior to the roll-out of public education programmes.

7.3 Training programmes shall be organized at all levels of the health care system to include licensed chemical sellers, medicine counter/pharmacy assistants, community leaders and workers to understand the policy.

7.4 Public Education

7.4.1 Training needs shall be assessed and training manual 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.

7.4.2 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.

The MOH shall ensure appropriate activities are conducted to facilitate the smooth implementation of this policy.

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 Anti-malarials.

8.2 Patient Compliance and Acceptance

The Ministry of Health (MOH) and its agencies shall conduct regular surveys to assess patient compliance and acceptance of the drugs under this new policy.

8.3 Quality and Efficacy of Products

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

The FDB shall also be required to furnish the MoH with periodic updates of the quality of products on the market. GMP audit inspections of manufacturing facilities both local and overseas shall be rigorously enforced by the FDB.

8.4 Safety Monitoring

The FDB, health agencies and research institutions shall develop and outline procedures for efficient Safety Monitoring country wide.

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 anti-malarials recommended by the policy and duly registered by the Food and Drugs Board shall be authorised for supply and use by the general public. This will involve going through a drug registration process that includes information on efficacy and safety. 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 treatment policy shall be discontinued in all health institutions.

9.2.2 Re-classification of Artemisinin Combination Therapies

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

9.2.3 Use of Sulphadoxine-Pyrimethamine

Sulphadoxine-Pyrimethamine shall be reserved only for use in the prevention of malaria during pregnancy under observation (IPT). The use of Sulphadoxine-Pyrimethamine as monotherapy for uncomplicated malaria shall be discontinued.

10. 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 Board, Association of Ghana Industries, and other relevant regulatory agencies.

The MOH 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.

The Ministry shall provide the platform for local pharmaceutical manufacturers to re-engineer their technologies and systems for the local production of ACTs. Government shall actively facilitate the process to ensure a

successful change particularly in view of the current additions. Innovative research within the local industry shall be promoted by Government to aim at the development of co-formulated ACTs for enhanced compliance.