

Increasing Community Access of ACTs in Kenya by Changing the Regulatory Status from Prescription Only to Over-The-Counter: A Guidance Document

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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ACRONYMS AND ABBREVIATIONS

ACT	artemisinin-based combination therapy
ADRs	adverse drug reactions
AL	artemether/lumefantrine
AMFm	Affordable Medicines Facility for Malaria
CMD	Community Medicine Dispensers
DOMC	Division of Malaria Control
DPTWG	Drug Policy Technical Working Group
FDA	U.S. Food and Drug Administration
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GSL	General Sales List
GoK	Government of Kenya
HMM	home management of malaria
KEMSA	Kenya Medical Supplies Agency
KMA	Kenya Medical Association
MHRA	Medicines, Health and Regulatory Agency
MICC	Malaria Interagency Coordinating Committee
MoH	Ministry of Health
NAFDAC	National Agency for Food and Drug Administration and Control
NMCC	National Malaria Coordinating Committee
NMCP	National Malaria Control Program
OTC	over-the-counter
P	pharmacy only medicines
POM	prescription only medicine
PPB	Pharmacy and Poisons Board
PSK	Pharmaceutical Society of Kenya
RBM	Roll Back Malaria
RDT	rapid diagnostic test
SHEF	Sustainable Healthcare Enterprise Foundation
SP	sulfadoxine-pyrimethamine
UK	United Kingdom
WHO	World Health Organization

BACKGROUND

One of the four pillars of the Roll Back Malaria (RBM) initiative is prompt treatment of malaria fevers among vulnerable groups, including children under five years of age, with effective antimalarial medicines. One of the targets in the Kenya National Malaria Strategy (Government of Kenya [GoK] 2001) is to ensure that up to 60 percent of fevers among children under five years of age would be treated with effective antimalarial medicines within 24 hours of fever onset, as close to the home as possible, in accordance with the Abuja declaration. This target was revised from 60 percent to 80 percent in accordance with RBM's global target for scaling up access.

Following the rapid decline in the efficacy of sulfadoxine-pyrimethamine (SP) in 2004, Kenya changed its first-line antimalarial drug treatment policy to the more efficacious artemisinin-based combination therapy (ACT), with artemether-lumefantrine (AL) being the recommended ACT. The GoK the Ministry of Health (MoH) (which has subsequently been divided into the Ministry of Public Health and Sanitation and the Ministry of Medical Services) launched the new policy in September 2006 (Amin et al. 2007) by providing AL free-of-charge at government and mission sector health facilities using resources from the Global Fund to Fight HIV, Tuberculosis and Malaria (GFATM).

The World Health Organization (WHO) guidelines for malaria treatment state that “to optimize the benefit of deploying ACTs, and to have an impact on malaria, it will be necessary to deploy them as widely as possible—this means at most peripheral health clinics and health centers, and in the community. Ultimately, effective treatment needs to be available at community or household level in such a way that there is no financial or physical barrier to access” (WHO 2006, 29). Given that about 80 percent of Kenya's population lives within 5 kilometers of a public health facility (Noor et al, 2006) (and 60 percent lives within one hour of a health facility) the majority of patients and caretakers in Kenya and, indeed Africa, access treatment for malarial fevers in private retail outlets (Pagnoni 2008). So the widespread use of ACTs is likely restricted by poor availability outside of the public sector. To address these issues, stakeholders put a provision in the ACT rollout plan to conduct operational research to see how the community could better access ACTs, including through retail outlets. In addition, the Affordable Medicines Facility for Malaria (AMFm) has committed to increasing access to subsidized ACTs in Kenya, particularly through the private sector.

However, the prescription-only medicine (POM) status of ACTs constrains their availability at the community level. Of the 44 malarious countries in Africa, 30 include home-based management on malaria in their national malaria control strategy. Of these, only Nigeria has officially changed the legal status of their first-line treatment to OTC to facilitate community access.

In Kenya, ACTs cannot be officially provided without a prescription issued by a duly qualified medical practitioner, dentist, or veterinary surgeon which legally restricts their distribution to government facilities, private clinics, and registered pharmacies. Under current regulations, ACTs may not be distributed by retail medicine shops or community health workers. Despite

these barriers to access, the GoK is cautious about changing the legal status of ACT to over-the-counter (OTC) because of limited safety data outside of a clinical trials setting. Concerned stakeholders argue for the need for a functional pharmacovigilance system to ensure appropriate monitoring of any adverse drug reactions (ADRs) before scaling up ACTs at the community level. In addition, it is unclear what other actions the Division of Malaria Control (DOMC) and other stakeholders should carry out to change the legal status of ACTs from POM to OTC, as there are no formal guidelines or application templates that currently exist.

This paper describes the process of changing the regulatory status for ACTs from POM to OTC in Kenya plus the actions and inputs required by key stakeholders within and outside the MoH, including the DOMC.

Methodology

A literature review using Medline and Popline included articles and guidelines related to making regulatory changes of medicines from POM status. The review included official MoH documents, literature on the pharmaceutical sector, roles and responsibilities of the various actors, and critical processes and requirements to institute the change. Semi-structured key informant interviews at the central level were carried out in January and February, 2009. Follow-up interviews conducted in March 2009 addressed information gaps.

Definition and Characteristics of Self-Medication

Medicines available OTC may also be termed as medicines to be used for self-medication. Self-medication “involves the use of medicinal products by the consumer to treat self-recognized disorders or symptoms....In practice, it also includes use of the medication of family members, especially where the treatment of children or the elderly is involved” (WHO 2000).

Self-medication places almost all the responsibility of treatment on the patient or caretaker. To use a non-prescription product safely and effectively, the patient or caretaker must perform functions normally carried out by a qualified provider treating a patient with a prescription drug. These functions include accurately recognizing symptoms; selecting a product to use; determining an appropriate dosage and dosage schedule; assessing possible contraindications, concomitant diseases, and interactions with concurrent medications; and monitoring treatment response and possible adverse effects.

In the case of nonprescription medicinal products, all of the information required for safe and effective use must come from the labels, patient information leaflets, the individual’s personal experience, media, advertising, and advice from any health care provider, including pharmacists and medicine sellers. In malaria-endemic settings, many providers often have limited or no training.

Assessing Suitability of Medicines for OTC Status

Most POM products that are considered for OTC have usually been on the prescription market for a number of years. The amount of time a country markets a prescription medicine before considering a switch varies; for example, the European Medicines Agency (EMA), the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), and the U. S. Food and Drug Administration (FDA) do not set a minimum timeline, while New Zealand requires 3 years; Japan, 6 years; and the Philippines, 10 years. On average, five years is considered to be acceptable in most settings.

When assessing a medicinal product's suitability for use in self-medication, the following points should be evaluated (WHO 2001)—

- The product should have a safe profile. The active ingredient should have low reproductive toxicity, a wide margin of safety, even if used incorrectly, and a low incidence of ADRs that has not increased unduly during the marketing period. The product should have a favorable benefit/risk ratio—that is, its benefits outweigh potential adverse effects.
- The indication for which the product is intended is common in the target population and appropriate for self-diagnosis, self-medication, and self-monitoring.
- The product does not have undesirable properties, such as interacting with common medicines or food or causing serious adverse reactions that require medical supervision.
- The product's risks are low in sensitive patient groups (e.g., elderly, children under five years, pregnant, and lactating women).
- The product does not contribute to increased antimicrobial resistance.
- The product's risk of masking symptoms of underlying serious disease is low.

In addition, the product must—

- Be easily administered and available in an oral formulation
- Have a simple dosage schedule, with clearly defined dosage strengths for pediatric and adult use
- Have a package size, labeling, and package inserts which are appropriate for self-medication and provide adequate information on how to correctly use the product

In all cases the switch is made because it can bring unique new benefits to consumers.

Potential Benefits and Risks of Changing the Status of ACTs to OTC

Treatment with OTC ACTs presents a number of benefits to malaria management—

- ACTs are highly efficacious and when used correctly, eliminate infection within three days.
- Resistance to ACTs is minimal.
- Clinical trials and subsequent postmarketing surveillance have shown ACTs to have a good safety profile when used as recommended. Although manufacturers have not removed the warning of use during the first trimester of pregnancy, trials in pregnant women that have inadvertently taken ACTs have not illustrated any untoward side effects (White 2009).
- ACTs have an acceptable risk even when used for a longer duration, at a higher dose, or somewhat differently than recommended (Bosman 2009).
- ACTs give patients greater treatment choices. Most individuals choose products that experience has shown to be suitable. Currently, patients and caretakers purchase ineffective antimalarials in the private sector, which has serious public health consequences.
- Wider availability of ACTs ensures that patients and caretakers have more rapid access to treatment and allows them to take an active role in health care.
- Purchasing treatment close to home is more convenient than traveling long distances to health facilities or pharmacies or waiting in long lines at public facilities. In addition, it may reduce absenteeism from work due to symptoms or travel.
- Fewer medical consultations save scarce resources such as staff time, facility use, and individual expenses related to travel or user fees.
- The scope and duration of self-medication can be kept within safe limits by the appropriate selection of approved indications, label text, dosage strengths and forms, and package sizes.

Self-medication always carries potential risks. Most patients and caretakers have no specialized knowledge of the principles of malaria disease or treatment, which may result in some potential risks—

- Incorrect self-diagnosis (pneumonia, typhoid, fevers of unknown origin)
- Failure to seek appropriate medical advice promptly for other conditions or if symptoms do not improve
- Incorrect treatment choice

- Rare but severe adverse effects
- Failure to recognize or act on contraindications, interactions, warnings, and precautions
- Failure to recognize that the same active substance is already being taken under a different brand name (products with different brand names may have the same active ingredient)
- Failure to report self-administered medication to a prescribing medical practitioner (risk of double medication or harmful interaction)
- Failure to recognize or report ADRs
- Inadequate or excessive dosage
- Excessively prolonged use
- Storage in incorrect conditions or beyond the recommended shelf-life

At the community level, improper self-medication could result in increased drug-resistance and wasteful public expenditure. However, many of these risks are not unique to self-medication; they can also occur with prescription drug use.

Self-Diagnosis of Malaria and Self-Medication with ACTs

Most people in endemic countries diagnose malaria themselves and often first seek treatment for fever in the private sector. ACTs are considered good candidates for self-medication or OTC use because they are highly effective at treating malaria and reducing overall mortality. They are safe within approved indications, have a low toxicity index, and have acceptable risks, even at higher doses and longer durations of treatment. They are also available in pre-packaged treatments according to patient age.

INTERNATIONAL EXPERIENCES WITH CHANGING MEDICINE STATUS

United Kingdom

The sale and supply of medicines in the United Kingdom is controlled by the Medicines Act of 1968. The current relevant legislation is given in Directive 2001/83/EC relating to medicinal products for human use, amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC, and 2004/27/EC (MHRA).

The United Kingdom has three classes of medicines—

- *Prescription-only medicines*: can only be supplied with a prescription issued by a medical practitioner.
- *Pharmacy-only medicines (P)*: can only be sold under the supervision of a pharmacist.
- *General sales list (GSL)*: appropriate for medicines which can with reasonable safety be sold or supplied without a pharmacist's supervision.

A formal Application for Reclassification of Medicines was introduced in 2002 (MHRA). Before that, switching involved a legislative change, whereas now, once the Committee on Safety of Medicines has recommended that a change can be made, it is done on the order of the Secretary of State for Health.

The Post-Licensing Division of the MRHA handles requests for changing the legal classification of a medicine, which is determined by its marketing authorization. The marketing authorization holders or other interested parties can file applications to change a medicine's status. Applications may be classified as "complex" or "standard." A complex application, which entails higher fees, will be referred to an advisory committee. "Me-too" applications are based on analogous products and are treated as variations of those products with reduced fees and rules for applications. Products are usually reclassified from a POM to a P, and after a suitable period of marketing as a P product, a subsequent application to a GSL may be made. However, some products have been reclassified directly from a POM to the GSL (Blenkensopp 2004).

An applicant must supply the following information for reclassification—

- Completed reclassification application form.
- Applicant details; product details; rationale for reclassification; support and written endorsements from experts or organizations; specific OTC requirements (safeguards to prevent irrational use); and safety profile (utilization, patient exposure details).
- Safety/efficacy summary with supporting evidence, which may include spontaneous reports of ADRs, postmarketing studies, clinical trials, published literature, or safety reviews. Comparison with other products available without a prescription may be helpful.

- Patient information; full details of labels, leaflets, and advertising plans including mock-ups of patient information leaflets; instructions for diagnosis; and action to be taken when no response is obtained from treatment.
- Training and education, including details on training plans to enable health professionals to monitor patients.
- A clinical expert report which demonstrates that the prescription criteria do not apply. This may include a risk-benefit analysis, potential drug interactions, and any potential for indirect danger, including increased development of drug resistance. In addition, the ability for self-diagnosis and risk of misuse must be discussed.

Once the advisory committee has recommended reclassification, a 4 to 6 week public consultation period opens. If issues arise during the public consultation for a standard application, the application may be submitted for formal review by the advisory committee. Straightforward applications can take 120 days (not including public consultation), while complex applications can take 180 days. The MHRA lists reclassified products on its website and publishes them in the *Medicines Act Information Letter*. In cases of rejection, the applicant will receive the assessment report with reasons for rejection. Applicants have a right to appeal rejections to the Medicines Commission which is the appellate system.

Between 1994 and 2004, over 50 products have been deregulated from the POM status and made more accessible (Blenkinsopp 2004). Since 2002, 12 products have been reclassified; 9 from P to GSL and 3 from POM to P.

Box 1: Recent Examples of Reclassified Medicines in the UK

- Simvastatin
- Chloramphenicol eye drops
- Zantac® (ranitidine)
- Zovirax® (acyclovir)
- Claritin® (loratidine)
- Neurofen® (Ibuprofen)
- Pepcid AC®
- Tagamet® (cimetidine)
- Voltarol (diclofenac) emulgel (2002)
- Omeprazole (2002)

United States

In the United States, the FDA governs the sale and supply of medicinal products. A company files a New Drug Application or an Abbreviated New Drug Application with the FDA to change their regulatory status. Drugs used to treat chronic, serious, or asymptomatic conditions are less likely to gain regulatory approval to switch to OTC. A viable candidate would be a product that is safe, effective, has relatively few side effects, is used to treat a self-diagnosable condition, and

provides advantages for consumers over existing OTCs. The FDA assembles a panel of experts to study the evidence and make recommendations.

In making the decision to changing the schedule, the FDA considers the following (Aschenbrenner 2007; Brass 2001; Mahecha 2006)—

- Does the prescription marketing experience show that the product has an acceptable margin of safety?
- Does it have little potential for misuse or abuse?
- Does it have a wide therapeutic index?
- Can the condition for which the drug is used be easily diagnosed and treated by the patient with minimal health provider intervention?
- Do the drug's benefits outweigh its risks when used correctly?
- Is the drug safe and effective when used without a prescription?

In most cases, the manufacturer or other applicant presents data on the product's safety and efficacy and use (including clinical trial data, literature review, and postmarketing reports) and the findings of label comprehension studies. FDA officials familiar with the drug also present data summarizing what the agency knows. Committee members, the application sponsor, and FDA officials discuss the evidence to ensure that committee members have a clear understanding of the information presented. The advisory committee also holds a hearing to allow public testimony before voting on whether the drug should be granted OTC status. The committee presents its recommendation to the FDA commissioner who normally accepts it. In exceptional circumstances, the FDA may require additional clinical trials to evaluate the switch. The Durham-Humphrey and Kefauver-Harris Amendments define the statutory basis and specific criteria that the FDA should use to evaluate a new drug application for a proposed OTC drug (Spencer 2002; Brass 2008). The process may take up to 12 months (Mahecha 2006), however longer periods have been noted for the FDA to grant final approval.

The switch to OTC status in 2002 of Claritin[®] (loratidine), a non-sedating antihistamine, and in 2003 of Prilosec[®] (omeprazole), a proton pump inhibitor for the management of ulcers, are two of the most important recent switches in the United States. Indeed, the Claritin (loratidine), Allegra[®] (fexofenadine), and Zyrtec[®] (cetirizine) switches were seen as an unprecedented FDA response to a citizens' petition in 2001.

Box 2. Recent Examples of Reclassified Medicines in the United States

- Claritin (loratidine): 2002
- Prilosec (omeprazole): 2003
- Allegra (fexofenadine)
- Zyrtec (cetirizine)
- Tagamet TB (cimetidine):1995
- Plan B Emergency Contraceptive: 2006

Case study: Uganda

Uganda had been implementing a successful home-based malaria strategy using prepackaged chloroquine+SP (Homapak[®]) since 2002.

Uganda changed its first-line malaria treatment to AL in 2006. Given the limited use of ACTs at community and household levels in Uganda, the Department of Sociology at Makerere University, the National Malaria Control Program, and WHO's Uganda Office are implementing a study of the feasibility, acceptability, and safety of using ACTs in the community before considering a status change to OTC. The current study is being implemented in Iganga and Bugiri districts of Eastern Uganda. The study started in December 2005 with a baseline survey to establish key indicators.

A midterm evaluation held between February and March 2007 (Uganda MoH 2007) showed positive outcomes to most of the intervention objectives. For example, caregivers' and community leaders' attitudes towards the new medicine were very positive; 97 percent of caregivers accepted it as a medicine that can be used to treat their children whenever they get a fever. Promptness in seeking treatment (defined as 24 hours within fever onset) for febrile children improved from 56 percent at baseline to 87 percent at midterm, and 79 percent of mothers complied with treatment instructions. Community Medicine Dispensers (CMDs) were also knowledgeable about the treatment instructions.

Findings indicated that 6 percent of children treated with the AL had minor side effects such as itching, rashes, and vomiting. As a result of six months of intervention, Uganda's malaria control program concluded that it may be feasible to distribute ACTs through CMDs.

Uganda requires a medicine to have the following properties to be rescheduled to OTC status—

- Well-known safety profile
- Indicated for a condition easily recognized by the public
- Easy and well-known dosage regimen
- Administration requiring little expertise or no supervision
- Known good adherence and acceptability
- Low potential for diversion or abuse
- Pharmaceutical properties supporting community use (dosage form, packaging, stability)

Case Study: Nigeria

As in Uganda, Nigeria had also been implementing a successful home-based malaria strategy using prepackaged chloroquine since 2002. First-line treatment for malaria was changed in 2005. The new malaria strategy had a full private sector component to the ACT distribution, which later included the medicine vendors. Despite some resistance to the deregulation of ACTs to OTC, prepackaged ACTs are made available close to the home through a network of trained community-based providers backed by a community strategy for behavior change. The national malaria program coordinates the training of Role Model Mothers and Community Oriented

Resource Persons on the implementation of home management of malaria (HMM) at the state and national level.

There is no official document in Nigeria that outlines the process of the policy change to OTC. However, the national parastatal in charge of regulation, the National Agency for Food and Drug Administration and Control (NAFDAC) provided the NMCP with some guidelines on the information needed to change the status. Among the criteria were safety data in Nigeria and in other parts of Africa as well as studies on use of ACTs in Nigeria. NAFDAC required safety data from places where ACTs had been rolled out on a large scale, specifically in Africa. The NMCP enlisted the assistance of RBM partners to collect safety data to support their application on ACTs to NAFDAC and the Food and Drug Division of the FMOH for a change in status, as limited data was available from Nigeria. However, NAFDAC already had some data from ACT studies in Nigeria on ACTs' use, efficacy, and safety in the country that was submitted during the registration process. Furthermore, the findings of pilot studies on the feasibility of HMM in Nigeria were submitted. Ultimately, an analysis of risk and benefit for the change and the contextualization of POM for ACTs within the Nigerian context was a crucial factor in amending the status of ACTs in the country. Since the official change in 2007, NAFDAC continues to maintain surveillance on the use of ACTs through sentinel sites and general pharmacovigilance.

Case Study: Ghana

The process for reclassification ACTs in Ghana started with an overarching review of the current classification of essential medicines in Ghana by a technical committee. Based on the available evidence, the need to increase access to ACTs as part of the malaria policy and the fact that ACTs were already ostensibly available in these lower levels as OTCs, the technical committee proposed that ACTs be made OTCs. In particular, the three ACTs adopted in the malaria drug policy in Ghana—artesunate/amodiaquine, arthemether/lumefantrine, and dihydroartemisin/piperaquine—were recommended for reclassification. A meeting involving a wide variety of stakeholders including the MoH, Ghana Health Service malaria program, Pharmaceutical Society of Ghana, and the Ghana Medical Association was convened to review the reclassification. Participants agreed to make a recommendation to the Food and Drugs Board to ratify the reclassification, advise the Minister of Health to approve it, and have it finalized with publication in the Gazette. Unfortunately, there has been little progress on these steps. Ghana has approval for the home management of malaria as part of its malaria strategy and may be applying for the AMFm. If this proposal is approved, there will a need to fast-track these processes. In the meantime, there is evidence that ACTs are available in the lower levels of the health care, e.g., licensed chemical sellers as OTC.

Box 3: Feasibility Studies for ACTs in HMM

A multicountry study was performed in Ghana, Nigeria, and Uganda (Ajayi et al. 2008). CMDs were trained in each village to dispense pre-packaged ACTs to febrile children aged 6-59 months. A community mobilization campaign accompanied the program. Artesunate-amodiaquine was used in Ghana while AL was used in Nigeria and Uganda. CMD performance, caregiver adherence, and treatment coverage were analyzed. The findings indicated the following—

- Rate of correct prescription by CMDs: 98%
- Rate of promptness of treatment (< 24 hrs): 90%
- Rate of correct dose and duration of treatment: 85%
- Rate of overall adherence by caregivers: 77%
- Treatment coverage: 59%

Caregivers perceived ACTs to be effective with no serious side effects being reported. The authors concluded that ACTs can be successfully integrated into the HMM strategy.

In the same study area, Ajayi et al. assessed the extent to which ACTs were correctly administered. Cure rates of 90 to 97 percent were recorded and adherence varied from 81 percent in Uganda to 97 percent in Ghana. This study provided additional evidence for the usefulness of HMM and for scaling up implementation of HMM with ACTs.

Other related TDR studies include—

- The use of RDTs for malaria within the context of the HMM strategy: Ghana, Uganda, Burkina Faso, Cameroon, Malawi, and Ethiopia
- Home management of Malaria in urban settings in sub Saharan Africa: Ghana, Uganda, Burkina Faso, Cameroon, Malawi, Ethiopia
- The impact of HMM with AL on childhood mortality: controlled study in Burkina Faso
- Integrated management of malaria, pneumonia, and diarrhea at the community level: Uganda, Ghana, Burkina Faso

PHARMACEUTICAL LEGISLATION AND REGULATORY FRAMEWORK IN KENYA

The legislation and regulatory framework for pharmaceuticals in Kenya is covered by the National Drug Policy and is legally enacted by the Pharmacy and Poisons Act (GOK 2002, revised). The Pharmacy and Poisons Act applies to all locally manufactured and imported medicines available on the Kenyan market and covers legislation and regulations, the drug regulatory authority, drug registration, licensing, and scheduling, pharmaceutical quality assurance, good manufacturing practices, postmarketing surveillance, and regulation of prescriptions and distribution. There has been no recent comprehensive review of the Pharmacy and Poisons Act—changes have been made through miscellaneous amendments. The Pharmacy and Poisons Act is operationalised by the Pharmacy and Poisons Board (PPB) under the Ministry of Medical Services. The PPB oversees the trade in medicines and poisons as well as the registration of pharmacists and premises.

Pharmacovigilance/ADR Monitoring

Kenya's MoH has recently created a Pharmacovigilance Department responsible for developing a nationwide system for reporting adverse drug reactions (ADRs). Currently, prescribers are supposed to report problems on pharmaceutical products to the PPB through the Pharmacovigilance Department; however, the reporting rate is practically zero. The Pharmacovigilance Department also documents product quality and substandard and counterfeit medicines, and collects information on clinical trials in Kenya. In compliance with the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use protocol, ADRs on products experienced outside of Kenya but available on the Kenyan market are also recorded by the Pharmacovigilance Department. In recent times, the pharmacovigilance department has issued recalls of medicines through manufacturers and distributors and publications in the national newspapers (for example, counterfeit Duo-Cotecxin in 2007 (Daily Nation, 2007)). However, these have been passive recalls and not very effective. There is currently a limited capacity in the system to institute an effective widespread recall.

Scheduling Medicines

Chapter 244 of the Laws of Kenya (the Pharmacy and Poisons Act) regulates all medicines. Medicines are classified into various categories or schedules according to the level at which the drug can be prescribed and dispensed. Medicines are described as Part I Poisons or Part II Poisons based on the level of handling and care required, which are then further classified into schedules. It must be noted that while this document uses the acronyms POM and OTC, Cap 244 of the Laws of Kenya does not use these terms. Nevertheless, some prescribers and pharmacists use the POM, OTC, and GSL nomenclature from the United Kingdom.

Part I medicines may be dispensed only by a registered pharmacist—

- **Schedule I** medicines require a prescription from a registered medical practitioner, dentist, or veterinary surgeon. *They may be dispensed without a prescription only by a pharmacist in small quantities in an emergency, when a registered practitioner is not available.*
- **Schedule II** medicines require a prescription from an authorized prescriber such as a registered medical practitioner, dentist, veterinary surgeon, or a nurse.

In general, schedule II can be handled by less skilled persons.

Part II medicines may be dispensed by pharmacists and other authorized persons—

- **Schedule III** medicines may be dispensed by a registered pharmacist without a prescription or by a pharmaceutical technologist with prescription from an authorized prescriber.
- **Schedule IV** medicines may be sold in authorized outlets without a prescription.

In Kenya, there is little practical difference between Schedule III and IV medicines. Schedule III medicines are also available at lower levels of the health care system as OTC medicines.

Roles and Responsibilities of Relevant Stakeholders in Kenya's Pharmaceutical Sector

Department of Pharmacy

The Department of Pharmacy has recently been established when the Ministry of Health split into the Ministries of Medical Services and Public Health and Sanitation, respectively. The major activity for the new department will be the creation of an appropriate framework to facilitate the implementation of the revised drug policy, which has been renamed the Kenya National Pharmaceutical Policy (KNPP). As part of this framework development, the department has been organized into six functional divisions and draws its mandate from the KNPP (1994), now revised, and the Pharmacy and Poisons Act (Cap 244). The KNPP outlines Kenya's strategy for ensuring effective and efficient management of pharmaceutical services. In addition, the department ensures that all drugs entering the country are registered and meet the stipulated quality and safety standards, and that there is proper management, storage, and use at the health facility level. The Department of Pharmacy is headed by the Chief Pharmacist who reports to the Director of Medical Services.

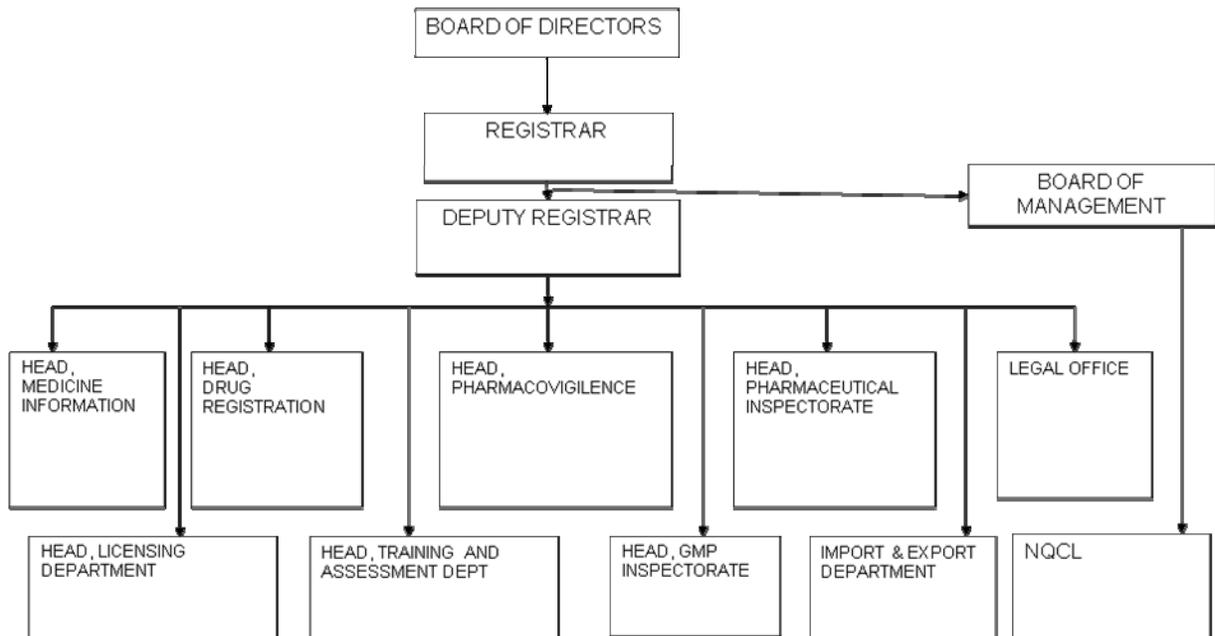
Pharmacy and Poisons Board

The PPB is the regulatory body mandated to ensure compliance with the Pharmacy and Poisons Act. The board is appointed by the Minister for Medical Services and is chaired by the Director of Medical Services, Dr. Francis Kimani. The PPB approves protocols for clinical trials for new products, establishes guidelines for trials involving registered drugs, and registers new

medicines. However, the PPB has been constrained by the lack of a legally enacted secretariat. The secretary to the PPB is the Registrar, Dr. Kipkerich Chumo Koskei who is also the Chief Pharmacist. A new board with nine members was appointed in December 2008 (*Kenya Gazette*, 16th January, 2009, Vol. CXI – No. 5), and will meet quarterly. The PPB has a legal department that advises the registrar on all legal matters, including drafting *Gazette* notices on issues such as regulatory revisions.

Structure of the PPB

MINISTRY OF MEDICAL SERVICES



Pharmaceutical Inspectorate

The Pharmaceutical Inspectorate falls under the PPB and ensures compliance with laws and regulations regarding storage and dispensing pharmaceutical products. Although the office of the Inspectorate is staffed, its functional capacity is limited.

PPB Committees

The PPB has two standing committees that are relevant to pharmaceutical registration, approval, and scheduling: the Committee on Drug Registration and the Expert Committee on Clinical Trials. The PPB's Registrar appoints members to both committees. Other committees also exist; however, they do not have a defined role in the scheduling process.

Committee on Drug Registration

The Committee on Drug Registration of Human Medicines meets once a week to help the PPB evaluate pharmaceutical product dossiers presented for registration. The committee's role is to recommend medicines for registration that comply with the criteria for efficacy, safety, and quality as outlined in Cap 244 of the Pharmacy and Poisons Act. It is comprised of eight members from various disciplines and is chaired by Professor C. Maitai of the University of Nairobi's School of Pharmacy.

The Expert Committee on Clinical Trials

The role of the Expert Committee on Clinical Trials is to review information from clinical trials in dossiers submitted for registration. In addition, the committee oversees any clinical trials conducted in the country. It meets once a month and is comprised of seven members, mainly from academia and research organizations.

Kenya National Medicines and Therapeutics Committee

The Medicines and Therapeutics Committee governs drug selection, formulary management, prescription policies, promotional activities, dispensing, and drug utilization review, including revising the essential medicines list. The Director of Medical Services chairs the committee which meets quarterly and the Chief Pharmacist serves as secretary. The committee has been recently reconfigured and comprises 18 members that are appointed by the Director of Medical Services. The members come from a wide range of professional backgrounds and expertise including academia, medicine (Kenya Medical Association and subgroups within it), pediatrics, clinical pharmacology, clinical pharmacy, infectious disease, and pharmacokinetics; in addition to a provincial pharmacist, medical superintendents, provincial medical officers, district medical officer of health, representatives from the offices of the Director of Medical Services and Chief Pharmacist, the Deputy Chief Pharmacist, and a member of the WHO Essential Drug List committee.

Although the national Medicines and Therapeutics Committee works with the PPB, thus far it has not been involved in drug registration or rescheduling. The committee does not participate in the deliberations of the Committee on Drug Registration or the Expert Committee on Clinical Trials. Once fully operational, it may have an advisory role in legally classifying medicines.

Kenya Medical Supplies Agency

The Kenya Medical Supplies Agency (KEMSA) is a state corporation operating under the auspices of the MoH. KEMSA's mandate is to procure, warehouse, and distribute medicines and medical supplies throughout the public health system. KEMSA also participates in compiling the essential drug lists for Kenya with the PPB and Kenya Medicines and Therapeutics Committee.

Professional Associations

The professional body for pharmacists is the Pharmaceutical Society of Kenya (PSK), which has 200 members out of over 1,500 registered pharmacists in Kenya. The PSK also serves as a lobby group to advocate for changes in the pharmacy profession. The PSK ensures a professional code of ethics in all activities related to the practice of pharmacy. The organization is interested in making sure that patients are getting the right information from dispensers and using quality medicines rationally.

The Kenya Medical Association (KMA) oversees the professional code of ethics for medical practitioners and sensitizes them to potential ADRs, using the pharmacovigilance system to report ADRs. The professional associations communicate disciplinary action regarding professional standards to the PPB.

National Quality Control Laboratory

The National Quality Control Laboratory performs assays on products submitted for registration. The Chief Pharmacist's office oversees the quality assurance surveillance framework. Currently, little postmarketing surveillance takes place in Kenya, and there is limited capacity to recall problem pharmaceuticals from the market. Regular quality monitoring only occurs when samples are submitted with dossiers for medicine registration.

Division of Malaria Control

The DOMC, headed by Dr. Elizabeth Juma, falls under the Department of Preventive and Promotive Health Services. The DOMC plans and coordinates inputs and activities for malaria control at all levels and is responsible for providing relevant links within the MoH and with other ministries, development partners, United Nations agencies, and nongovernmental organizations. The division plays a lead role in defining and disseminating the National Malaria Strategy and sets annual milestones for implementing the strategy. The DOMC is the primary source of technical advice to the provincial and the district levels on malaria matters. Information for this task is generated through the various technical working groups (see below) that advise the DOMC and coordinate partners in specific strategy components.

Technical working groups—

- Malaria Inter-Agency Coordinating Committee (MICC)
- Drug Policy Technical Working Group (DPTWG)
- Malaria Clinical Management Working Group
- Working Group on ITNs
- Malaria Information, Education, and Communication Working Group
- Malaria Research Working Group

- Working Group on Monitoring and Evaluation
- Working Group on Malaria in Pregnancy

The DPTWG is a multidisciplinary group of stakeholders involved in malaria policy and implementation. This working group has been instrumental in changing and implementing the first-line therapy for malaria to ACTs. The membership is comprised of the DOMC, KEMSA, Mission for Essential Drugs and Supplies (MEDS), nongovernmental organizations, donors, and research institutions, among others.

The highest decision making body for malaria policy formulation and implementation in Kenya is the MICC that comprises the DOMC, technical partners, and donors. The MICC meets quarterly, but special ad hoc meetings can be called as and when the need arises. The MICC is chaired by the Director of Public Health, Dr. S.K. Shariff.

CHANGING THE REGULATORY STATUS OF MEDICINES IN KENYA

Medicines are classified when a product is first registered on the Kenyan market. Any subsequent change must undergo a separate formal application, which is similar to submitting a dossier for registration although less rigorous.¹ When the new malaria treatment policy of AL was launched in 2005, the Minister did not officially attest to it as a POM. The PPB considering the relevant dossier and information submitted by the applicant, scheduled it to be a POM. To make a POM into an OTC or P requires administrative collaboration between stakeholders and the PPB. Then, the PPB, the chief pharmacist, and registrar to the PPB are responsible for implementing this change.

There are no written guidelines on the rescheduling process; therefore, the following information comes from a combination of stakeholder interviews, grey literature searches, and past precedents.

The manufacturer or any other stakeholder acting in the interest of public health, such as the DOMC with written permission from the manufacturer, can apply for a schedule change. The applicant should submit a formal letter addressed to the PPB Registrar with copies to the Committee for Drug Registration and the Expert Committee on Clinical Trials. This letter should state the rationale for requesting the change. The letter should also include any new evidence, information, and supporting documentation related to the product's efficacy and safety and suitability for sale as an OTC. Any evidence on stability under actual storage conditions would be useful. A change in legal status or schedule would be considered an amendment, for which the processing fee is 200 U.S. dollars (USD).

Any rescheduling, safety, efficacy, or quality concerns are discussed at the Committee on Drug Registration or at the Expert Committee on Clinical Trials level. Upon receipt, the registrar will formally submit the information package to the Committee for Drug Registration and the Expert Committee on Clinical Trials and any other experts that may be required to review the information.

The PPB's practice subcommittee may also be involved as well as other experts from WHO, PSK, academia, research institutions, or the MoH's Medicines Information Department or Pharmacovigilance Department.

The experts in these committees review the information and submit comments. The review is deliberated at formal committee meetings with recorded minutes. The PPB and its committees may ask for more information from the applicant. The committees' recommendations are forwarded to the PPB registrar, who then records them as part of his or her report to the full Board. In the interim, the registrar may communicate the decision directly to the applicant depending on the recommendation. Final ratification and adoption would occur at the quarterly PPB meeting, and the PPB would most likely pass along the final application outcome.

¹ Registration requires the submission of a dossier comprising a completed application form for registration accompanied by supporting documentation including information on the manufacturing process of the product, the stability of the product, and data on efficacy and safety and bioequivalence in the case of generic products.

Once adopted by the PPB, the registrar then prepares and sends a list of products to the Minister of Medical Services to put into the *Kenya Gazette*. The legal department drafts the gazette notice which the Minister signs. The Minister then sends the signed notice to the Attorney General for publication in the *Kenya Gazette* under Cap 244. The change does not have to go through the parliament, but is legalized through the publication of a notice in the *Kenya Gazette*, after which it is enforceable as law. The final authority for the process lies with the Minister of Medical Services. A change would be recorded as an amendment to the registration dossier, and the conditions on the certificate would be changed.

Chapter 244 identifies some medicines which cannot be reclassified to OTC in the section on regulations for registration of medicines. ACTs do not fall within this category, and although they are registered as POMs, artemisinin and lumefantrine do not currently exist on the list of medicines in any of the Cap 244 schedules; however, they would fit into the same schedule as other antimalarials. The DOMC and other stakeholders need to investigate whether the medicine can easily be renewed and registered as OTC without having to go through a rescheduling process once the five-year drug registration period has expired. In any case, key stakeholders should still be engaged and involved in the process.

Kenya has other ways of changing scheduling laws, for example, through the parliament or through Ministers' rules and regulations. Occasionally, extremely political proposals may be taken up at ministerial level including the Director of Medical Services or the Permanent Secretary for Health and the change would be from the top-down. Under the category of miscellaneous amendments, the Minister has the power to bring to regulation anything with the aim of public good. For example, the Minister of Health could resolve to make the ACTs widely available and would then write an official letter to the PPB requesting them to make the change. In response, the Board would gazette the change and amend the list of registered products accordingly. Usually, the Minister will consult the PPB before taking such a step. The PPB can provide a supplementary brief or information to the Minister to consider his action. In most cases, the Minister's decision is considered to be final and there are no precedents where the PPB may have challenged a Ministerial decision.

In some cases, the recommendation may be to move the medicine from POM to available from a pharmacist (P), and as more information is obtained, the medicine may be rescheduled once again from P to OTC. However, in other cases, a medicine may be directly scheduled from a POM to OTC if deemed appropriate.

Once an application has been submitted, the process may be completed within three to six months. The Committee on Drug Registration meets once a week while the Expert Committee on Clinical Trials meets monthly, after which the application would go back to the PPB for adoption. Some exemptions are made during outbreaks. Advocacy at the ministerial level may shorten the process to two months. Generally, antimalarials tend to be fast-tracked.

If the application is denied, the applicant has a right of appeal; however, the Board usually specifies the reasons for the rejection, so it would only consider an appeal in the case of misinformation or a change in information including new evidence.

Changing SP to OTC

Kenya changed its first-line treatment policy for malaria from chloroquine to SP in 1998. SP had been a POM and could therefore only be dispensed by qualified clinical and pharmacy staff with a prescription, so community health workers or dispensers at peripheral facilities were not included. However, to be fully effective, SP needed to be available at the lowest levels of the health system. To institute the change, the Medical Supplies Coordinating Unit (now KEMSA) approached the MoH's Pharmacy Division to discuss how to make SP more widely available.

The Malaria Control Unit requested that the Chief Pharmacist deregulate SP from POM status, and the legislative changes allowed SP to be dispensed by recognized medical and paramedical staff without prescription after October 1999. However, SP was only deregulated to a Part II/Schedule III poison, still making it illegal for manufacturers to actively distribute to informal outlets. In Kenya, these informal shops are a major source of antimalarial drugs to the community (Mwenesi 1994). Therefore, to achieve maximum levels of access, SP was further deregulated to a Part II/Schedule IV which legalized its sale in retail outlets without a prescription.

Following a similar process, chloroquine was subsequently rescheduled from OTC to POM to discourage its use as first-line therapy when SP was introduced (Cap 244, p. 91). Currently, discussions are ongoing to change the legal status of SP back to POM to preserve its effectiveness for use in intermittent preventive therapy in pregnancy.

Current Status of Increasing Access to ACTs

Increasing access to ACTs in Kenya involves a number of components including garnering stakeholder support for changing the ACT schedule from POM to OTC, conducting research in the private sector to support the change, and bolstering the pharmacovigilance system to be able to detect ADRs when access increases.

Changing the Schedule for ACTs

The DOMC's Drug Policy Technical Working Group began discussing a change in the legal status of ACTs when the treatment policy change to ACTs was implemented. The plan was to roll out ACTs to the community level two years after initial implementation, using evidence from operational research. It was intended that these pilots would be scaled up in the third year of implementation. This would then be followed by training and capacity building of the health workers with advocacy at the community level to inform them of the change. Toward year four, it had been envisioned that there would be an evaluation of distribution systems to understand their capacity to implement the change, and full deregulation was expected in year five, based on widespread monitoring.

As a member of the Drug Policy Technical Working Group, the PPB has been aware of discussions on ACTs and their status. Other involved stakeholders include the PSK, KEMSA,

and MEDS. The working group has a subcommittee on community access to ACTs, which reopened discussions on the regulatory status of ACTs at the end of 2008.

Stakeholders, including the permanent secretary for medical services, have subsequently discussed the schedule change at various forums. In February 2009, the Kenya NGO Alliance Against Malaria (KeNAAM) convened a forum bringing together partners from the DOMC, KeNAAM, PPB, Kenyan Red Cross Society, Merlin, Sustainable Healthcare Enterprise Foundation (SHEF), Population Services International, MoH, Novartis Pharma, KEMSA, Medical Assistance Programs International, and Churches Health Association of Kenya to consolidate their experiences and share their insight into the current policy work towards deregulation of ACTs. However, the DOMC has not officially applied to the PPB requesting a review of the legal status of ACTs because it is unsure whether an application will be made before any operational research data on selling ACTs in the private sector is available.

Stakeholders have not agreed on either diagnosis strategy or a strategy to enhance community access to ACTs. Currently, hospitals and health centers with laboratories use microscopy, but lower levels of the public health sector use rapid diagnostic test (RDT) kits. Anecdotal evidence suggests that a provider will often administer SP or a combination of artemether/doxycycline in the case of a negative RDT test result when they are used. It is unclear what diagnostic or access strategy stakeholders will recommend for the private sector.

Novartis, the current manufacturer of artemether-lumefantrine (Coartem) will not apply for a change in the schedule of their product (personal communication, Novartis representative, 2009). Indeed, as far as Novartis is concerned, Coartem will remain a POM in Europe and other non-endemic areas because of its original registration with Swiss Medic—the regulatory body in the country of origin. Novartis has also stated that they will not change their packaging or inserts to accommodate any change in regulatory status. The DOMC would have to make any packaging changes. While this may put the DOMC in a difficult position, previous switches to OTC have involved a similar situation, Roche Pharmaceuticals did not change the packaging or POM status for Fansidar (SP) when it was deregulated in Kenya in 1998. However, the product had been on the market for a long period of time with a widespread availability of generics.

Novartis has also been collecting data on ADRs for Coartem; however, reporting has been slow.

Finally, changes in regulatory status are made by individual product and not by therapeutic class; deregulating one brand will make deregulation of others simpler. However, ACTs as a class of drugs cannot be deregulated; each ACT will need a separate application to change its regulatory status.

Community Studies for Private Sector Sale of OTCs

Pilot studies on community distribution of ACTs are planned but two of them have not begun yet because researchers have not received needed approvals (table 1). In addition, researchers need to get temporary OTC status (also referred to as a PPB waiver or special dispensation) for ACTs, which has not been received yet for the two pilot projects due to commence this year. However, communications and training are already underway.

Table 1. Pilot Studies on Community Distribution of ACTs

Intervention Organization	Approvals Received to Date
Population Services International/KEMRI Wellcome Trust	<ul style="list-style-type: none">• Ethical approval only• Expert Committee on Clinical Trials approval
Kenya Red Cross	<ul style="list-style-type: none">• Ethical approval only
Sustainable Healthcare Enterprise Foundation	<ul style="list-style-type: none">• Ethical approval only

Preliminary findings from the CFW/SHEF study indicated that access to treatment had increased by 10 percent as a result of the pilot. CFW/SHEF has scaled up the pilot from 9 facilities in 3 districts to over 62 facilities in 10 districts.

ADR Monitoring of ACTs

As mentioned, the MoH's Pharmacovigilance Department has just developed a system for reporting ADRs. Plans are in place to collect information on ADRs through an active surveillance system, which has been submitted to the PPB for approval. ADRs will be classified according to severity and type. Sentinel sites have already begun small-scale ADR monitoring, and some manufacturers and license holders have begun reporting directly to the PPB. The Pharmacovigilance Department also prepared a detailed curriculum for training all public and private sector health care professionals in Kenya on pharmacovigilance issues. The department has submitted these training documents to the MoH for approval.

The Pharmacovigilance Department suggested that they would follow WHO guidelines on the quantity of evidence needed to support the switch to OTC. The guidelines recommend a minimum of 10,000 patients treated by the ACTs. Within this cohort, there must be at least three cases of each serious ADR for it to be considered. However, in general, the higher the number of patients exposed and the more heterogeneous the population is, the more reliable the findings will be considered.

Novartis has supplied 200 million treatments of Coartem globally since 2001. Novartis has collaborated with WHO in Zambia and maintains a global database on all ADRs reported for Coartem. Thus far, they have not received any reports of serious side effects that may raise any concerns. In 2008, Novartis received five reported cases of rashes and headache, which could have been attributed to the disease itself. In addition, some reports of treatment failure in Uganda were later proven incorrect.

Perceptions of Select Stakeholders on Changing ACT Status

Box 4 lists possible Kenya stakeholders to involve in the process of changing the legal schedule of the first line ACT.

Box 4. List of Possible Stakeholders to Involve in Deregulation of the First Line Therapy in Kenya Ministry of Health

- DOMC
- PPB
- KEMSA
- Health Education Department
- Medicines Information Department
- Pharmacovigilance Department
- Provincial and District Medical Officers of Health
- Director of Reproductive Health Program
- Director of Child Health/the Integrated Management of Childhood Illness Program
- Diagnostics and Laboratory Board
- Medical Training College
- National Quality Control Laboratories
- Community health workers

Private Sector

- Manufacturers of antimalarials and diagnostic products
- Importers and wholesalers
- Private hospitals and pharmacies
- Drug shops
- Traditional healers

Research departments and institutions

- Kenya Medical Research Institute and its affiliate programs such as Wellcome Trust UK, U.S. Centers for Disease Control and Prevention, U.S. Walter Reed Army Medical Center
- University of Nairobi, College of Health Sciences (schools of Pharmacy, Medicine, Dentistry and Nursing)

Professional organizations

- Kenya Medical Association
- Kenya Medical Practitioners and Dentists Board
- Association of Pediatricians
- PSK
- Nursing Council

Nongovernmental organizations

- MEDS
- Kenya National NGO alliance against malaria (KeNNaM)
- Mission hospitals
- RBM partners involved in malaria case management

Multilateral and bilateral organizations

- WHO
- USAID
- United Nations Children's Fund
- Department for International Development [U.K.]

Interviews with select stakeholders, which contributed to the development of this guidance document, revealed that while stakeholders generally agreed on the need to improve access to

ACTs and increasing their availability, some had concerns about making them widely available without having appropriate safeguards and risk mitigation strategies in place.

A summary of the concerns follows.

Issue or Concern	Stakeholders	Comments
Inadequate stakeholder consultation and discussion	PSK, KMA, manufacturers	KMA and the manufacturers have not been involved in any formal discussions on the schedule change; they believe that more discussions on implications of this change were needed.
Inadequate safety data, pharmacovigilance	PSK, MEDS	DOMC believes that Kenya is ready to make the change and that sufficient anecdotal data exists to confirm its safety. For example, ACTs have been available on the Asian markets for years without reports of any significant adverse drug reactions. PSK and MEDS also emphasized a need for continuing scaled up pharmacovigilance efforts.
Limited use/time on market	PPB	Although widespread use of artemisinins only began in Africa in 2006, they have been widely used in Asia for over 20 years. PPB concerns stem from the unclear safety profile in pregnant women and young children. Some interviewees believed that if a medicine had not been on the market for long, moving it from POM to P and then OTC should be considered; however, this distinction in Kenya is purely academic and does not exist in practice.
Drug resistance	MEDS, KEMSA, KMA	Stakeholders felt that preventing the development of drug resistance required proper supervision and regulation
Suitability for OTC use	PSK, KEMSA	KEMSA felt that more discussion was needed on how ACTs can be regulated to address adherence and resistance. Furthermore, they felt that the need for a high fat diet may decrease its effectiveness. AL has been used in Kenya and other countries in Africa without any evidence of reduced bioavailability and reduced effectiveness or resulting recrudescence.
Adherence	PSK, KEMSA	AL is used in the public sector. Packaging contains simple pictograms to assist providers, patients, and caretakers. Simple information, education, and communication (IEC) in the community may address the issue of adherence and the need to complete the treatment.
Rational use	PSK, MEDS	Packaging contains simple pictograms to assist providers, patients, and caretakers. Simple IEC in the community may address the issue of adherence and the need to complete the treatment.
Increased availability of counterfeits	PSK	In general, some stakeholders believed that once the status of ACTs changed to OTC, counterfeits would increase in the market. This may be true but can be countered by the widespread availability of affordable

Issue or Concern	Stakeholders	Comments
		products (see affordability below).
Limited data on lumefantrine	PSK	Lumefantrine as used in the AL combination has been shown to be safe.
Affordability and cost sustainability	PSK, pharmacists	The AMFm has pledged to make ACTs available to populations, including the private sector, at affordable prices.
Regulation	Novartis, PPB, pharmacists	Stakeholders expressed the need to regulate pharmacies and other retail outlets that would supply ACTs. Others wanted to use the Bamako Initiative approach whereby every village or marketplace has an authorized outlet for ACTs; however, this approach has not been effective in Kenya
Provider training/type of outlet	Manufacturer, Novartis, PPB, pharmacists	Stakeholders expressed the need to train dispensers on the adequate use of ACTs. One manufacturer thought there was a need to define who could sell the medicines and what information would be available to provide to the buyer and the seller.
Others	Novartis	Stakeholders felt that while changing the legal status of ACTs was important in Kenya, eliminating monotherapies on the market is also imperative.

Evidence Needed to Change ACTs from POM to OTC

The following evidence was outlined by the PPB as important to support the shift in the legal schedule of ACTs from POM to OTC—

- Safety data from Kenya should include reported ADRs, particularly genetic, mutagenic, or teratogenic effects. Any scientific information presented should be recent (within 5 years) and not more than 10 years old. While no defined limits exist on the number of ADRs or patients, generally a product may be considered for OTC status once it has been on the market as a POM for five years.
Responsibility: PPB (pharmacovigilance) in collaboration with DOMC should begin to gather this data. Data from other regions and databases need to be incorporated.
- Ideally, safety data from other countries should be where patients are genetically similar, exposures have been widespread, and where there is a functional pharmacovigilance system. This may not be easily available in sub-Saharan Africa.
- Safety data should also come from WHO’s Uppsala Monitoring Centre, including any evidence of sudden unexpected and suspected ADRs.
- WHO endorsement (if available)
Responsibility: DOMC should approach WHO/Kenya to obtain this
- Evidence of use in the general population including susceptible groups, such as children.

Responsibility: Some preliminary results from studies exist and these should be packaged by the DOMC.

- Experiences from other countries that have instituted the change to OTC (see case studies from Uganda and Nigeria).

Responsibility: DOMC and partners need to document these experiences

- Analysis of risk versus benefit.
- International expert opinions, which should be reviewed by in-country experts.
- Risk of the development of drug resistance with widespread use. The ACT Consortium is already working on medicine use and resistance modeling and preliminary findings should be available soon.

Responsibility: DOMC

- Affordability in the private sector and the AMFm.

Responsibility: DOMC and partners need outline the objectives of AMFm for the PPB

- The PPB needs to define clear strategies and mechanisms for an appropriate response to an ADR, such as when the patient should be referred to a health care facility.

Responsibility: PPB with partners

- A strategy to address treatment adherence, including culturally appropriate messages; changes in packaging (outer, secondary, and primary packaging); labeling; and evidence of ease of administration in the absence of instructions from a medical practitioner.

Responsibility: DOMC and manufacturers

- Clear criteria for who will sell ACTs as OTC and their related training needs.

Responsibility: DOMC and partners; PPB

DISCUSSION

It has been estimated that while ACTs account for about 60 percent of the global market for antimalarials in the public sector, they constitute only 5 percent of the total market in the private sector, which means that the other 95 percent of antimalarials are ineffective products such as chloroquine, SP (AMFm 2008), and artemisinin monotherapies which are not recommended for the treatment of uncomplicated malaria. Given that more than half of the population accessing treatment for malaria does so in the private, often informal, sector, a lack of ACT availability in this sector contributes to serious public health consequences including excess mortality.

Evidence demonstrates that making products more available by giving them OTC status has the potential to increase access and use. In the United States, using sales volumes as surrogate measures for patient access to drugs, the sales of hydrocortisone 0.5 percent increased by over 700 percent when it was made available OTC. Similarly, U.S. sales of diphenhydramine quintupled after a similar change in legal status while Sweden experienced a 36 percent increase in sales as a result of deregulating 16 medicines (Brass 2001). These findings indicate that deregulating ACTs has the potential to significantly increase access and use of effective antimalarials at all levels of care. This is paramount to reducing mortality from the disease and reaching the 2010 RBM target of 80 percent coverage of essential interventions (RBM 2005).

Currently, Nigeria is the only countries in Africa that have officially changed the legal status of ACTs to OTC. Policy makers and regulators in the rest of Africa and specifically Kenya are wary of making ACTs an OTC medication independent of the manufacturer because it places the burden of the change entirely upon the country regulators and the MoH. While several precedents for changing the legal status of medicines exist, most recently with SP for malaria treatment, Kenya made the changes after products had been available for a number of years.

Following is a discussion of the criteria for evaluating an appropriate OTC medicine and the context for ACTs in Kenya.

Ease of Self-Diagnosis and Treatment

The ease and ability to self-diagnose is a key factor in determining whether a product should be considered as suitable for OTC use, and people in malaria-endemic countries have been self-diagnosing and treating for years. Similarly, antimalarials such as chloroquine have been available as OTC medicines for over 50 years. Patients and caretakers in Kenya are generally familiar with the signs and symptoms of malaria and prefer to access treatment from their local retail outlet or community health worker. Furthermore, home-based management of malaria has been accepted both globally and nationally as a cornerstone of malaria treatment, particularly for children under five years. In addition, health facilities in Kenya are not easily accessible and medical personnel are in short supply. As a result, the real cost (including travel) of visiting public medical facilities can be prohibitive.

ACTs can be considered good candidates for self-medication or OTC use because they are highly effective at rapidly treating uncomplicated malaria and reducing overall mortality. Nevertheless, ACT use is not without risk, and Kenya should introduce appropriate risk mitigation strategies and safeguards to prevent any potential problems.

Medicine Safety Profile

WHO recommends that a medicine's safety profile be one of the criteria that determines a product's suitability for OTC status. AL has been on the Kenyan market for 10 years, although widespread deployment did not begin until 2006 (White 2009). Some data from the MoH's Pharmacovigilance Department and from the manufacturer, Novartis, illustrates a low incidence of side effects with no unexpected adverse events. Information from Southeast Asia, where ACTs have been in use for over 20 years, suggest that widespread use has not resulted in any unexpected or severe side effects. In addition, a study carried out in Kenya in 2008 revealed that health workers generally perceived AL as being tolerable and efficacious compared to amodiaquine and SP (Wasunna et al. 2008). When completed, the three pilot studies to investigate ACT safety and other criteria will provide additional information.

Stakeholders interviewed during this study indicated that the pharmacovigilance system in Kenya does not have the capacity to detect ADRs. Furthermore, some believed that the product had not been available for long enough to capture adequate data. The newly appointed Pharmacovigilance Department has recently set up a sentinel site reporting system for ADRs for all medicines and is training providers on the reporting process, and plans are underway to scale-up active reporting. Nevertheless, changing ACTs to OTC will require an extensive communication campaign to encourage consumers to report any adverse reactions to the medicine.

It is important to note that prescription status does not necessarily guarantee greater safety. In malaria-endemic countries, antimalarials including ACTs are sold over the counter in the private sector without a prescription, even if they are scheduled as POMs. In these cases, recognizing the actual self-medication status may be in the public health's better interest than merely maintaining a theoretical prescription status. In addition, evidence has shown that changes made in regulatory status of medicines in the developed and less-developed world have generally not altered a medicine's safety profile.

Low Risks in Susceptible Populations

Another WHO criteria is that an OTC product should be of low risks to specific patient groups such as the elderly, children under five years, and pregnant and lactating women. ACTs are indicated for use in adults and children over 5 kilograms. They are not recommended for pregnant women in their first trimester. However, retrospective studies in pregnant women that inadvertently ingested ACTs during their first trimester indicted no unexpected ADRs in the mother or the child, including low birth weight or teratogenic effects (White 2009).

Likelihood of Promoting Antimicrobial Resistance

Widespread use of an OTC product must not promote antimicrobial resistance. In Asia, where ACTs have been used for many years, recently ACT resistance has been reported on the Thai-Cambodian border. However, this area has also seen rampant use of monotherapies and counterfeit or substandard products. There is a risk that ACTs will eventually become ineffective in Africa. However, strategies can be implemented, such as the removing monotherapies from the market, carrying out periodic postmarketing surveillance to ensure that monotherapies are no longer available, and providing patient information to ensure adherence and rational use. Furthermore, one of the objectives of the AMFm is to crowd out the monotherapies and other products sold on the basis of availability and affordability. The AMFm will make ACTs available at USD 0.10–0.20, which is likely to be cheaper than any monotherapy or counterfeit medicine on the market.

Easy Administration

Another criterion is that OTC medicines must be easily administered, available in an oral formulation, have a simple dosage schedule, and have packaging that is appropriate for self-medication, including understandable labeling and package inserts. ACTs are already available in prepackaged treatments according to patient age with simple instructions on use.

RECOMMENDATIONS AND CONCLUSION

The recommended actions should begin immediately—prior to the completion of the community pilot studies.

Engage Stakeholders

Immediately engaging stakeholders in the discussions is critical to successful change. Although the KeNAAM workshop in February 2009 was a step toward this, engagement should also include professional health provider organizations and community health workers. We recommend that the DOMC’s Drug Policy Technical Working Group convene a stakeholder’s workshop to discuss the decision-making process and provide a briefing on the upcoming pilot studies and the new pharmacovigilance program. The workshop can also serve as a forum to define a treatment and diagnostic strategy.

The Pharmacovigilance Department has developed a pharmacovigilance plan for ACTs which includes guidelines for data collection as well as a training curriculum. This plan should cover how to collect safety data from community use of ACTs and where consumers can report any such ADRs. Support should be provided to implement the plan immediately.

Discuss Regulatory Decision Making

In any discussion of regulating medicine schedules, OTC needs to be defined within the Kenyan context. Many stakeholders did not understand the meaning of “over-the-counter.” In Kenya, medicines are classified according to parts and schedules as defined in the Pharmacy and Poisons Act; Part I/Schedule I poisons are the most regulated medicines, while Part-II-Schedule IV poisons are the least regulated. References to deregulation should therefore use the Kenyan terminology of Schedule IV rather than OTC.

Coartem’s registration expires in June 2009. The DPTWG, Novartis, and other stakeholders need to decide whether it will be feasible and preferable to wait and re-register Coartem with a revised marketing authorization or regulatory status, which is likely to be a shorter process, or request an official change in status.

Define a Community Diagnostic and Dispensing Strategy

The major gap in the process of changing the status of ACTs is defining the role of RDTs for malaria. Higher level health facilities currently supply ACTs based on microscopy-based diagnosis, but lower level facilities without laboratories rely on clinical diagnosis. RDTs are available at select facilities only, and while they are a potentially valuable tool to detect malarial parasites and prevent irrational drug use, experience indicates that a negative test may still result in a provider dispensing SP or a combination of artemether/doxycycline.

The DOMC and other interested stakeholders need to develop a diagnosis strategy regarding increased community use of ACTs. Requiring rapid diagnostic testing will affect several components of the strategy, such as the training needed to perform the test and educating consumers about the test including not to expect an ACT with a negative test. Furthermore, providers will need to know what to give patients and caretakers for fevers of unknown origin when the RDT result is negative; providers will need to have adequate stock of an alternative medication or be trained to refer such patients.

The government will also need to make a decision on who can handle ACTs under the potentially reviewed status. While deregulation to a Schedule IV in Kenya means that the medicine can be available from shops and itinerant vendors, stakeholders need to clarify whether any additional training will need to be provided and whether any new regulation and monitoring pertaining to the distribution and sale of ACTs through these outlets needs to be outlined.

Define a Training, Communication, and Information Strategy

Stakeholders also need to decide what training to offer ACT providers, but any training plan should incorporate community health workers. In addition, a communication strategy needs to include consumer messages that showcase the new strategy and the importance of adherence, rational use, and ADR reporting. The MoH should also consider developing secondary product information leaflets that use simple pictograms to communicate dosage instructions. If such material is part of the strategy, stakeholders need to begin immediate discussions with manufacturers to develop, field test, and print these additional materials.

Obtain Waivers to Enable Commencement of Pilot Studies

The DPTWG and the MICC should address the challenges in obtaining the waivers.

Disseminate Pilot Study Findings

The results of the three pilot studies will be available in 2010. The DPTWG can use midterm results to demonstrate and discuss the feasibility of community level distribution of ACTs.

Collect Evidence Needed to Support Schedule Change

The DOMC should collaborate with the PPB to put a system in place to collect the information outlined in “evidence to support the change” immediately.

The DOMC and other stakeholders need to immediately investigate whether the medicine can easily be renewed and registered as OTC without having to go through a rescheduling process once the five-year drug registration period has expired

Stakeholders need to work with the Committee for Drug Registration and the Expert Committee on Clinical Trials to define the safety evidence needed to support an application to change regulatory status before submission to the PPB. In addition, the DPTWG should begin to gather evidence on the safety of and adherence to ACTs. This includes data from the MoH's Pharmacovigilance Department, WHO's Uppsala Monitoring Centre, manufacturers, published and unpublished literature, and anecdotal evidence. The experience of Nigeria should be shared with stakeholders in Kenya.

A theoretical timeline is presented in annex 2 to facilitate the mapping of these processes.

CONCLUSION

Community availability and access to ACTs is essential to significantly reduce mortality and morbidity due to malaria. While the AMFm addresses the affordability dimension, community availability will also require regulatory mechanisms to ensure that ACTs are available at outlets where patients most often seek treatment. Such mechanisms will also require appropriate risk mitigation strategies to prevent any problems. Currently, Kenya's process to facilitate such regulatory changes is not well defined. This document describes the process and highlights some of the gaps and challenges that the DOMC should address in consultation with key stakeholders. Kenya states that home management of malaria is a key component of its malaria strategy and may be applying for the AMFm. If this proposal is approved, it may well act as the catalyst for fast-tracking these processes, garnering political support from the highest levels of the MMS.

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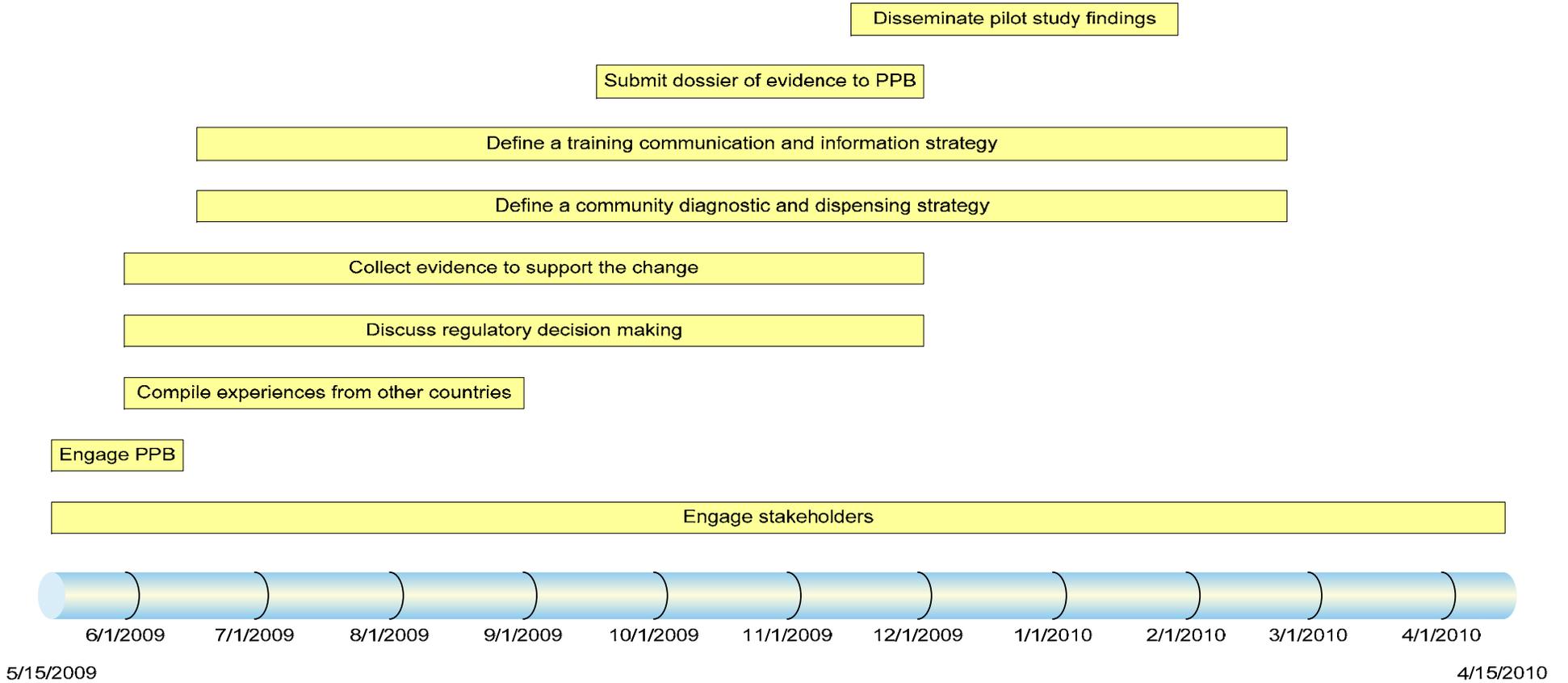
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ANNEX 1: TIMELINE FOR ACTIVITIES



ANNEX 2: INTERVIEWS

Name of Interviewee	Organization and Position	Date of Interview/Discussion
Dr. James Mwenda	Company Pharmacist Mission For Essential Drugs & Supplies (MEDS)	December 11, 2008
Dr. Larry Kimani	Quality Assurance Manager Cosmos Industries	December 11, 2008
Dr. Fred Siyoi	Former Registrar Pharmacy and Poisons Board	December 15, 2008
Dr. Dominic Kariuki	Drug Registration – Pharmacy and Poisons Board	December 15, 2008
Dr. Dorothy Memusi	Case Management Division of Malaria Control	December 16, 2008
Dr. Hezekiel Chepkwony	Director National Quality Control Laboratories	December 18, 2008
Dr. Willis Akwahale	Head, Disease Control	December 19, 2008
Dr. Elizabeth Juma	Head, DOMC	December 22, 2008
Dr Nathan Mulure	Medical Coordinator Novartis East and Central Africa	December 23, 2008
Dr. Elizabeth Ogaja	National Medicines and Therapeutics Committee	January 8, 2008
Dr. Jayesh Pandit	Pharmacovigilance Pharmacy and Poisons Board	January 13, 2008
Mr. George Muthuri	Pharmacovigilance-Pharmacy and Poisons Board	January 13, 2008
Dr. C.N. Chungu	Center for Tropical and Travel Medicine	January 13, 2009
Dr. Margaret Oluka	Lecturer Pharmacology, School of Pharmacy, University of Nairobi	January 13, 2009
Dr. Andrew Nyandigisi	Division of Malaria Control	January 14, 2009
Dr. Wilberforce Wany'ang'a	Former Quality Assurance Manager Cosmos	January 20, 2009
Dr. Stephen Thuita	Director Step Pharmaceuticals	January 21, 2009
Dr. A.J. Suleh	Chairman Kenya Medical Association	January 21, 2009
Dr. Kipkerich Koskei	Chief Pharmacist and Registrar of the Pharmacy and Poisons Board	January 22, 2009
Dr. Joseph Yano	Pharmacist and Legal Adviser, Pharmacy and Poisons Board	January 22, 2009
Dr. John Munyu	Ag CEO, Kenya Medical Supplies Agency	January 26, 2009
Dr. Dominic Karanja	Chairman Pharmaceutical Society of Kenya	January 27, 2009
Prof. A.O. Amayo	Member Committee on Drug Registration Chairman Department of Internal Medicine	January 28, 2009

ANNEX 3. MALARIA WORKING GROUPS AND SUBCOMMITTEES IN KENYA

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
National Malaria Coordinating Committee (Malaria Inter-Agency Coordinating Committee)		<ul style="list-style-type: none"> • To advise and guide MoH on national malaria policy, strategy and priorities, and on RBM in Kenya, including cross-border issues • To advise and support the DOMC and MoH in advocating resources for malaria • To advise and guide the DOMC and partners on content and organization of their workplans • To act as a forum for exchange of information on partners' malaria control and research activities • To identify and advise on areas for coordination nationally and internationally • To define and review the output of technical working groups and sub-committees and take account of their findings in formulating advice and recommending action • To receive and review reports from partners on progress toward objectives • To identify obstacles to implementation of malaria control activities and recommend solutions • To report to the MoH twice a year on achievements and progress toward objectives 	DOMC	Permanent Secretary; Director of Medical Services; Heads of the following—Health Sector Reform Secretariat, DOMC; Preventive and Promotive Health Services, Curative Services; Division of Communicable and Vector Borne Diseases; Division of Reproductive Health, IMCI; Division of Primary Health Care, Division of Health Education; Health Management Information System, Chief Pharmacist; Deputy Secretary Finance; two Provincial Medical Officers (PMOs); Chief Public Health Officer; Deputy Director, Research and Development (KEMRI); Technical Advisor to MoH on Malaria (Wellcome Trust); Ministry of Education, Ministry of Finance; Ministry of Information and Broadcasting; USAID, CDC, AMREF, WHO, DFID, UNICEF
Drug Policy Technical Working Group		<ul style="list-style-type: none"> • Constantly review status of drug resistance and make recommendations on implications • Continually review quality of antimalarial medicines and manufacturing practices and recommend actions as necessary to deal with substandard product • Monitor the implementation of current drug 	DOMC	DMS, DOMC Chief Pharmacist, PPB, PMOs, KEMSA, East African Network for Monitoring Antimalarial Treatment (EANMAT), Kenya Medical Association, University of Nairobi, MEDS, KEMRI, AMREF,

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
		<p>policy, identify problems, and recommend solutions, liaising with case management working group as necessary</p> <ul style="list-style-type: none"> • Advise government policy related to antimalarial medicine donations • Provide regular reports to DOMC 		Pharmaceutical Manufacturers Association, PSK, MSH/SPS
	Case management subcommittee of DPTWG	<ul style="list-style-type: none"> • Review guidelines on malaria case management including diagnostic strategies at all levels of health care • Develop a curriculum for the training of health workers on the new policy including rational use of new regimens both pre-service and inservice • Define responsibilities of health care workers in facilities at each level including home-based management of fever 		DOMC, WHO, KEMRI, Wellcome Trust, University of Nairobi, Maseno University, MSH/SPS
	Drug management subcommittee	<ul style="list-style-type: none"> • To revise and update guidelines on regulatory control of the new drug regimens and advise DPTWG • Mobilize resources and advise on ancillary needs for effective case management under the new drug policy • Advise on cost implications of the drug policy change while exploring possible points of subsidy • Advise on procurement strategies for the new antimalarial drugs and advice on drug needs • Advice on mechanisms to ensure adequate and uninterrupted supply of drugs at all levels 		DOMC, MSH/SPS, GFATM Procurement and Supply Chain Management Consortium, John Snow International, WHO/EDM, PPB, National Quality Control Laboratory, KEMSA, MEDS,
Malaria Research Technical Working Group		<ul style="list-style-type: none"> • Advise on needs for malaria research to support National Malaria Strategy implementation • Mobilize partners and advocate for funds for such research 	DOMC	KEMRI, DOMC, DVBD, KEMRI partners (Kilifi & Kisumu), national universities, EANMAT, Health Sector Reform Secretariat, Health Research Development Council,

Annex 3. Malaria Working Groups and Subcommittees in Kenya

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
		<ul style="list-style-type: none"> Disseminate research needs to national partners Monitor emerging research evidence nationally and international in relation to policy issues in the National Malaria Strategy Report regularly to the MICC 		MSH/ SPS
Monitoring and Evaluation Methodology Working Group		<ul style="list-style-type: none"> Agree on methods for measuring indicators for malaria and malaria control Identify logistical and resource issues associated with applying proposed methodology and recommend ways forward including tendering Advise on methods and routes for disseminating results of M&E Report regularly to MICC Establish modalities of feeding M&E results into revised strategic direction 	DOMC	DOMC, HMIS, Health Sector Reform Secretariat, KEMRI/Wellcome Trust, MSH/SPS, Central Bureau of Statistics, NCPR
MIAS Implementation group		<ul style="list-style-type: none"> To monitor and review progress in the DOMC MIAS implementation process and provide guidance while planning the way forward for all related activities 	DOMC	Representatives of DOMC Units – Case/Drug Management; Monitoring and Evaluation; Operational Research; MSH/SPS
Pharmacovigilance Working Group/Expert Advisory Committee on Pharmacovigilance		<ul style="list-style-type: none"> To evaluate the post-approval medicine safety, quality, efficacy, and effectiveness issues; such evaluations should be relevant to the risk/benefit implications for the use of the medicine(s) in question To make recommendations to the PPB regarding actions that may be taken to resolve issues or concerns related to post-approval drug safety, quality, efficacy, or effectiveness To assess ADR reports, including causality assessments and clinical relevance To assess drug product complaints, failures, and anomalies; and make 	PPB	PPB, Ministry Divisions (DOMC, NASCOP, DRH, TB, DOP), WHO, MSH/SPS, MEDS, KEMSA

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
		<p>recommendations regarding actions to be taken by the PPB</p> <ul style="list-style-type: none"> • To assess drug safety issues related to drug misuse, abuse, or off-label use, and make recommendations regarding actions to be taken by the PPB • To recommend topics for the ADR newsletter, which is to be written and distributed by the PPB. The committee may also recommend publication of case reports, their risk/benefit evaluations, and recommendations and communications arising from EAC meetings that are deemed appropriate for medical or scientific journals • To make recommendations for pharmaco-epidemiological or other research to be commissioned by the PPB or by its partners or stakeholders • To make recommendations for educational programs or other interventions designed to enhance professional and consumer awareness of post-approval drug safety, quality, efficacy, and effectiveness issues • To undertake any additional activities that may complement any or several of the above activities • To carry out any other activities or responsibilities as may be prescribed by the PPB Registrar 		
<p>Clinical Management Working Group</p>		<ul style="list-style-type: none"> • Review pre-service and in-service training needs for case-management and laboratory diagnosis and recommend changes to curricula or training packages to meet these needs • Liaise with WG on drug policy on issues of drug needs and supply 	<p>DOMC</p>	<p>DOMC, IMCI, Chief Nursing Officer, Chief Clinical Officer, Nursing and Clinical Officer National Councils, KEMSA, NPHLs, KMTC, AMREF, Universities,</p>

Annex 3. Malaria Working Groups and Subcommittees in Kenya

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
		<ul style="list-style-type: none"> Review needs and supplies of ancillary supplies for the management and diagnosis of malaria Report regularly to NMCC 		KEMRI, Head Curative Services (chair)
ITN Working Group		<ul style="list-style-type: none"> Provide a forum for private and public sector interest groups to consider and review policy direction against solicited market research Solicit and tender targeted research on market-sizes and consumer behavior in private sector Review modalities and costs of GoK/donor assisted targeted distribution of ITNs to vulnerable groups Liaise with working group on IEC on messages to consumers and communities Provide technical advice to PCPB on new ITN products Advise on policy direction to NMCC 	DOMC	DOMC DOMC, DOMU, Division of Reproductive Health, Division of Primary Health Centers, Division of Health Education, Private sector representation, PCPB, PSI, DVBD, UNICEF, Div. Of Environmental Health, Director Preventive and Promotive Health Services (chair)
IEC Working Group		<ul style="list-style-type: none"> Advise on all aspects of the IEC strategy including research, design, production, dissemination, monitoring and evaluation Contribute to and support the establishment of a network linking all major stakeholders in malaria IEC activity Identify best practices in malaria IEC and advise on updating and dissemination of the same Work with Ministry of Education on life-skills curriculum development Advise on the establishment of IEC resource centers under the DOMC Support and contribute to long-term implementation of national malaria IEC activity, co-ordinated by DOMC with other 	DOMC	Div. Health Education, DOMC, MoE, MIB, UNICEF, WHO, AMREF, PSI, World Vision, MEDS, JHPEIGO and other implementation partners, Head Division of Health Education (Chair)

Committee	Sub-Committee	Terms of Reference/Committees' Mandate	Parent Coordinating Department	Illustrative List of Member Stakeholders
		stakeholders • Report regularly to the NMCC		
Malaria in pregnancy		Agree upon a workplan for the first year of implementation of IPT of malaria in pregnancy setting out activities, time scales, responsibilities and resources required • Agree training packages and information materials needed to implement the policy • Monitor progress against the work plan and identify problems and solutions • Report regularly to Committee on Reproductive Health and NMCC	Division Reproductive Health/ DOMC	Div. PHC, Div. Reproductive Health, DOMC, Kenya Society of Obstetrics and Gynecology, Provincial Gynecologists, KEMSA, MEDS, Population Council, Plan International, JHPEIGO, Head, Primary Health Care (chair)