Improving the Supply, Distribution and Use of Antimalarial Drugs by the Private Sector in Tanzania

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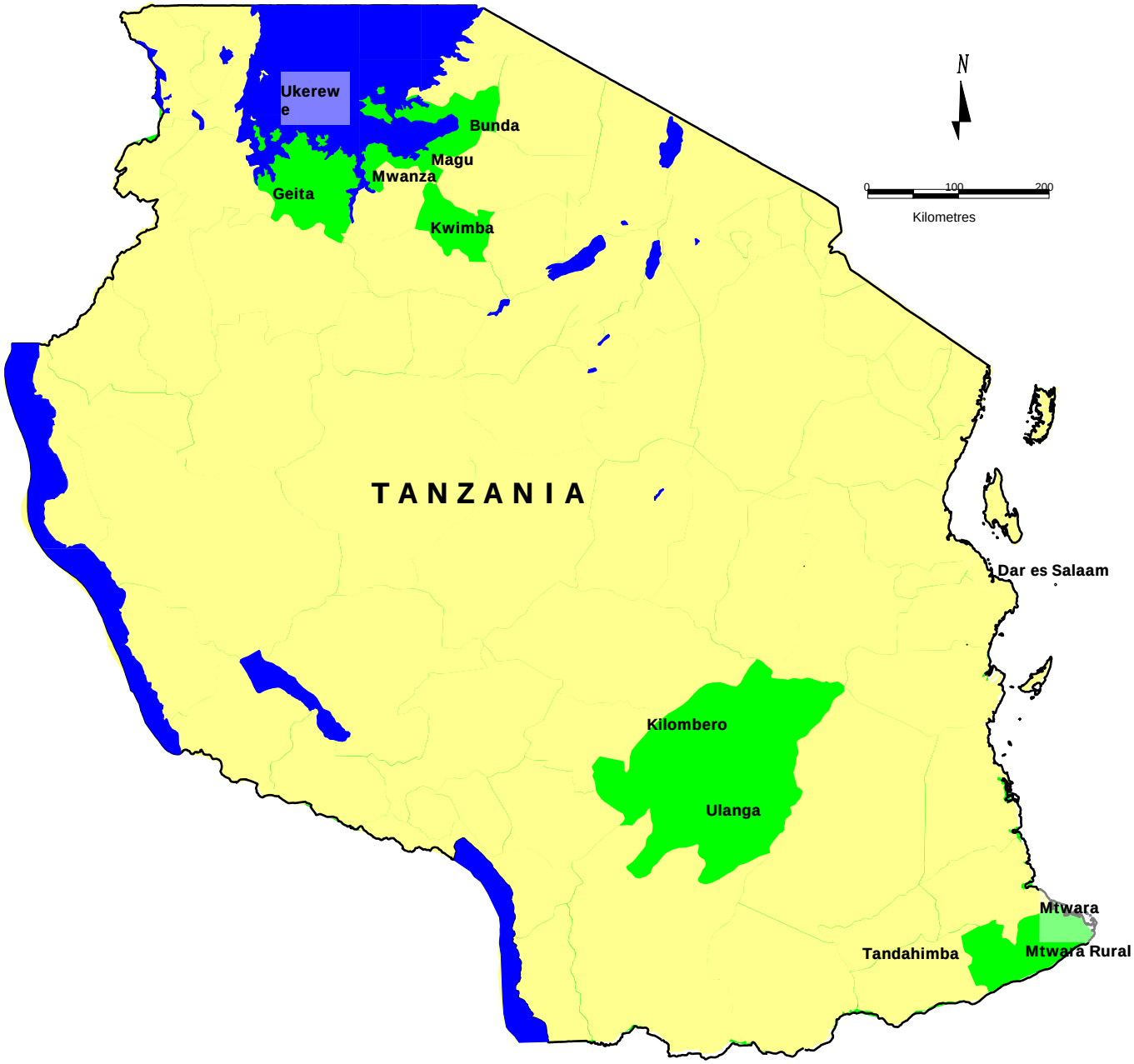
25 February – 22 March 2003

malaria consortium



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Acronyms

ADDO	Accredited Drug Dispensing Outlet
AQ	Amodiaquine
ART	Artemisinin
ACT	Artemisinin-based combination therapy
CDC	Centers for Disease Control & Prevention
CEEMI	Centre for Enhancement of Effective Malaria Interventions
CHMT	Council Health Management Team
CT	Combination Therapy
DED	District Executive Director
DLDB	Duka la Dawa Baridi Part II pharmacy
DFID	Department for International Development
DMO	District Medical Officer
ELCT	Evangelical Church in Tanzania
FIFO	First In First Out
FINNIDA	Department for International Development Cooperation (Finland)
GMP	Good Manufacturing Practice
HMIS	Health Management Information System
HMM	Home Management of Malaria
IEC	Information, Education and Communication
ITN	Insecticide Treated Net
LSHTM	London School of Hygiene & Tropical Medicine
Mfr	Manufacturer
MSD	Medical Stores Department
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
MTEF	Medium Term Expenditure Framework
NDQCL	National Drugs Quality Control Laboratory
NMCP	National Malaria Control Programme
NMMTSP	National Malaria Medium Term Strategic Plan 2002-2007
OTC	Over The Counter
PB	Pharmacy Board
Part I	Pharmacy staffed by a pharmacist dispensing part I and part II registered drugs
Part II	Duka la Dawa Baridi, A pharmacy staffed by a person with basic knowledge of pharmaceutical or medical science e.g. pharmacy assistant dispensing part II registered drugs
PSI	Population Services International
PST	Pharmaceutical Society of Tanzania
QN	Quinine
RDT	Rapid Diagnostic Test

RH	Relative Humidity
RBM	Roll Back Malaria
SADC	Southern African Development Community
SEAM	Strategies for Enhancing Access to Medicines
SMP	Sulphamethoxypyrazine Pyrimethamine
SP	Sulphadoxine Pyrimethamine
TAPI	Tanzanian Association of Pharmaceutical Industries
TPMA	Tanzania Pharmaceutical Manufacturers Association
TLC	Thin Layer Chromatography
Tsh	Tanzania Shilling, US$1=1,000Tsh
/=	Abbreviation for Tsh
TV	Television
UNICEF	United Nations Children's Fund (formally United Nations International Children's Emergency Fund)
WHO	World Health Organisation

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Executive Summary

Private pharmacies or shops are the source of 60% of the drugs bought to treat suspected cases of malaria. At the same time 59% of children fail to be treated within 24 hours of onset. The private sector is the primary source for antimalarials, but parents and carers are failing to administer those drugs sufficiently early to minimise morbidity and mortality.

This review focused on the way in which antimalarial drugs reach the patient. It also examined ways in which the delivery system could be improved and how the private facilities can become more effective sources of both drugs and advice. It has found that there are many problems with the way that drugs are distributed. Many unregistered drugs are readily available, and poor storage conditions are likely to reduce the efficacy of drugs even if they were of good quality at the time of manufacture. For many people the cost of even the cheapest antimalarial is an issue and purchase of part doses is common. The knowledge of the staff in pharmacies is poor and in shops woefully inadequate. Nonetheless most people use shops and private pharmacies as their source for drugs.

There are two overarching requirements:

- First of all the needs and capabilities of the private sector must always be taken into account before any decision is made about how to make antimalarials more available.
- Secondly, educating the staff and public will only be achieved through a subtle communications package regularly repeated and brought up to date. For example we found that many workers in Part II pharmacies remain in post for no more than one year. Unlike their counterparts in the public sector, staff in the private sector do not find incentives in attending training courses. Staff in the public sector spend so much time on courses that their time to actually implement what they have learned is limited. To reach the private sector staff will require subtler and more cost effective methods.

The report is full of detailed recommendations for the improvement of the supply systems and for educating both staff and public.

Section 3 covers issues concerning the quality of drugs, especially the control of unregistered drugs and the usefulness of minilabs to assure quality at point of entry and their limited use for testing drugs within the country. The section also makes recommendations on how to improve the poor quality of storage, handling and distribution of drugs.

Section 4 considers labelling and instructions on drugs, which generally are poor. For example there is no requirement to print in Swahili despite the fact that Swahili is the primary language and often the only language for many rural people.

Section 5 proposes ways in which general shops can be made more effective as outlets for drugs, and considers making both SP and amodiaquine available in shops.

Section 6 reviews the steps necessary for the control of restricted products. It concludes that all those involved in inspection need to be supplied with lists of which items may be held by which types of shop and that inspectors must be assisted in buying suitable transport. Inspectors should not go out of their way to try and prevent Part I drugs being stocked at Part II outlets, unless supply of antimalarials to the public facilities can be guaranteed, because the public sector often relies on the Part II outlets as a source of drugs when the public sector is out of stock, and enforcing compliance to the letter of the law is too onerous for the limited number of inspectors available.

Section 7 reviews the functioning of private laboratories and finds considerable cause for concern in some of them. There is particular concern over the way parenteral procedures are carried out and a more detailed assessment needs to be made of how these procedures are performed. This should be the subject of a separate consultancy in the near future.

Section 8 assesses the ways in which consumer and retailer knowledge can be improved and concludes that the task of developing a coherent communications strategy needs to be contracted out to a professional communications organisation.

Section 9 describes the need to reduce the price paid for antimalarials and proposes that a campaign be launched to force the manufacturers to reduce their prices and especially to reduce the markups made by wholesalers. At the same time the government should drastically reduce the price of antimalarials in public facilities where at present they are sold (including the consultation fee) for eight times the price paid by the government.

Section 10 considers the role of training and concludes that while basic training is a prerequisite, training itself is not the mechanism to be used to convey the information and skills needed. The reason for this is that there is already so much training being carried out that responsible officers hardly have time to carry out their duties. In addition, for the private sector harvesting the per-diems that are paid to public servants to attend training is less attractive because attending training takes time, which they prefer to spend on their business.

Section 11 reviews the options for combination therapies, which will have to be introduced in due course if malaria is to be controlled. It concludes that there is no easy solution to the fact that ACT is very expensive, and even with the subsidy proposed by one manufacturer, will be far beyond the reach of the ordinary Tanzanian. Whichever solution is chosen it must be applied to both the public and the private sector; if there is a price differential between the two sectors it will result in massive levels of theft.

Section 12 considers the options for funding and implementation. There are many tasks in the work plan for which NMCP will inevitably be responsible. It was clear to the team that NMCP is seriously under staffed and does not have the capacity or authority at the moment to meet these responsibilities. Unless there is significant investment in staff and resources at NMCP then progress on strengthening the private sector will be very limited.

The cost of a major investment in promoting the private sector will be substantial. Population Services International (PSI) plans to spend in the order of two million dollars a year on their insecticide-treated net promotional activities. A national communications package for antimalarials is likely to cost substantially more than this.

Unless there is a greater commitment by the MoH to strengthening the delivery mechanisms for malaria control in private sector, malaria will remain a major cause of morbidity and mortality in the young children and pregnant women of Tanzania.

Section 13 illustrates the work plan for the next two years and lists all the action points described in this report.

The stakes are high; unless the private sector becomes the purveyor of cheap, potent antimalarials, taken at the right time by the right people, malaria will continue to be a major cause of morbidity and mortality. This is an economic burden that Tanzania cannot afford to carry. Malaria morbidity and mortality can be reduced if the focus is concentrated on the private sector from which most people get their drugs.

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Introduction

Improving prompt access to effective first-line antimalarial treatment for children under the age of five years, when they have fever, is one of the priority strategies identified in the National Malaria Mid-term Strategic Plan for Tanzania.

Prompt access means having treatment available as near to the home as possible. Information and experience from countries in Sub-Saharan Africa have shown that improved home management of malaria (HMM) is possible but that the best way of achieving this improvement depends on the particular circumstances of different countries. In Tanzania, where up to 40% of child deaths occur in the home, achieving prompt effective HMM is a particular challenge.

The delay in seeking care for fever from health facilities averages two and a half days for Tanzanians and the use of private sector suppliers of drugs by rural and urban populations is widespread. Antimalarials of different types and of variable quality are available in small and large general stores (duka la kawaida) as well as registered Part I and Part II pharmacies (duka la dawa). However, adherence to the national antimalarial drug policy is patchy and access to information on correct dosing and recognition of early symptoms of malaria, that might result in improved HMM, is limited.

In 2001, the Ministry of Health, as an interim response to increasing antimalarial drug resistance, recommended SP as the first line drug of choice for the treatment of uncomplicated malaria to replace chloroquine. A move to an artemisinin-based combination therapy (ATC) is probable within the next three-four years.

Improving appropriate treatment of malaria for children under five years of age within 24 hours requires that quality antimalarial drugs are easy to obtain and adequately distributed everywhere. People must also take the correct dose and comply fully with the treatment, even more challenging when considering a move to combination therapy. Key to this is training and providing information to all those involved in the process from the manufacturer to the caregiver, including the private sector retailer or the community volunteer.

To this end the National Malaria Control Programme (NMCP) has prioritised the need to identify appropriate and feasible ways in which private sector involvement in the delivery of antimalarials can be improved. This includes the promotion of positive behaviour change among customers using drug retailers.

The NMCP now wishes to define its strategic approach to improving private sector involvement and identify other private sector initiatives with which there might be opportunities for collaboration and from which lessons might be learned. Preliminary materials for shopkeeper training, as yet untested, have already been prepared by NMCP.

This consultancy was designed to:

- Assist NMCP find ways to make the private sector more effective at the supply, distribution, storage and use of antimalarials.
- Prepare a strategy and design a set of activities that will deliver improvements in retail sector provision and client use of appropriate, quality, first line antimalarial drugs to customers who seek treatment at retail outlets for symptoms that might be due to malaria.

In Part 1 the report highlights the problems faced by the private sector, and by the Government authorities regulating the private sector. In Part 2 it sets out ways in which the situation can be improved.

Part 1 Background and description of the system for the supply, distribution and use of antimalarials in the private sector

1 Malaria Treatment and the Retail Sector in Tanzania

1.1 Malaria Disease Burden

1.1.1 Epidemiological Stratification

Within the fragile Health Sector, malaria continues to burden the overstretched health services in Tanzania. Malaria is a serious public health problem and remains the major childhood killer in Tanzania and ranks number one in inpatient and outpatient statistics. Over 80% of the country - Coastal belt, lake region, Central Plateau and Isles - the transmission is stable perennial or stable seasonal. The remaining 20% of the country is either mountainous or fringe highlands with altitudes up to 2000 meters above sea level and temperatures of 20^0 C and is prone to malaria epidemics**.** The expected pattern of transmission has changed in recent years with increasing reports of malaria epidemics. About 25% of the population live in epidemic prone areas, generally with little immunity; these people are susceptible to severe malaria in all age groups.

Children under five years of age (7.1 million) constitute a high-risk group for malaria infection and disease. Because of the severity of the disease and the complications of persistent asymptomatic infection, malaria in under fives should be promptly and appropriately managed using effective anti-malaria drugs. Malaria also inflicts a huge burden due to anaemia, especially in pregnant women (1.69 million).[1] The number of clinical malaria cases per year is estimated to be between 14 and 18 million with a mortality rate that ranges from 140 to 650 per 100,000 people. The estimated number of deaths per year due to the disease is 100,000-125,000 of which about 80,000 are children under the age of five years.[2] The development and spread of malaria parasites resistant to the effective, cheap and easily available anti-malaria drugs worsens the situation.

1.1.2 Summary of Epidemiological Indicators

Table 1

Population at Risk in various transmission zones

Transmission season	Zone	Population
Over 6 months stable (perennial)	Coastal	14,000,000 (42%)
4-6 months (stable seasonal)	Central Zone	11,300,000 (33%)
1-3 months (strongly seasonal or epidemic)	Fringe highlands Rift Valley	2,600,000 (8%)
Less than 1 month (Epidemic potential or no malaria)	Highlands	5,800,000 (17%)

(Source: Mapping Malaria Risk in Africa – MARA)

1 Ministry of Health, National Malaria Medium Term Strategic Plan, 2002, Dar-es-Salaam, Tanzania

[2] Ministry of Health, National Malaria Control Programme, Tanzania Essential Health Project Mapping Malaria Risk In Africa (MARA), September 2000

Table 2

Burden of malaria disease

Estimated number of malaria cases per year	14-18 million
Estimated number of deaths per year due to malaria	100,000-125,000 (70-80,000 < 5yrs)
Annual incidence:	400-500 per 1000 (double in < 5yrs)
Reported annual malaria mortality rate, all ages	141-650 per 100,000
Reported annual malaria mortality in 0-4 year olds	300-1,600 per 100,000

Source: National Malaria Control Programme, DPS, MOH

1.2 NMCP targets and objectives for early diagnosis and treatment at community level

Improved malaria case management is one of the main strategies advocated for malaria control in the National Malaria Medium Term Strategic Plan 2002-2007 (NMMTSP). In the strategy challenges for quality anti-malaria services at the health facility and community level have been well articulated. The NMCP and collaborating partners have set targets and operational targets for improvement of malaria case management at all levels of delivery of health services.

The role of the community, and particularly the household, in health improvement, particularly with reference to malaria case management, is well recognized by the Ministry of Health, National Malaria Control Programme and its collaborating Partners. This is important because effective early diagnosis and treatment at household level requires people and communities to have knowledge about the appropriate actions to take when a member of the household gets sick, especially children under the age of five years. They also need access to quality treatment. Decisions made and actions taken at the household level are critical for the overall achievement of the NMMTSP targets.

1.2.1 Target on improvement of malaria at community level

Use of appropriate treatment within 24 hours for febrile episodes in children under the age of five years, will be raised from 19% to 60% by the year 2007.

1.2.2 Operational targets

Operational targets as indicated in the NMMTSP are to ensure attainment of the above-mentioned target on early detection and appropriate treatment of malaria in the community.

- 60% of children under five years of age, with fever / malaria, to receive correct treatment according to national guidelines within 24 hours of fever onset.
- 80% of households to receive targeted IEC messages on severe malaria and appropriate actions to be taken at home, including referral, according to national guidelines.
- Drug stores, retail shops and kiosks to only sell high-quality first line antimalarial drugs and correct doses are to be dispensed.
- The proportion of shopkeepers that are knowledgeable about antimalarial treatment to be raised from 15% to 60%.
- 50% of key community owned resource persons, including traditional healers and village health workers, to be able to provide correct advice on early detection and treatment of malaria in their communities.

In order to achieve the above targets, partnership at all levels of implementation is imperative. The private sector, in view of its involvement in the delivery of antimalarial drugs,

is a key partner in the overall undertaking of the strategy. It is essential for CHMTs to make provision for the above collaboration in the Comprehensive Council Health Plans. It is expected that the private sector providers will play a key role in malaria case management and deliver services appropriately according to therapeutic standards as defined by the Ministry of Health. Supervision is critical; the CHMTs are required to supervise service delivery and performance in their respective districts, including sensitisation in communities and promotion of judicious antimalarial drug dispensing practices by the informal sector.

1.3 National Malaria treatment guidelines[3]

High levels and degree of chloroquine resistant falciparum malaria have necessitated the change of treatment guidelines for malaria in Tanzania and other sub-Saharan African countries.

In Tanzania chloroquine resistance in semi-immune Tanzanians was reported for the first time in the 1970's. During the 1980's many surveys confirmed the increase and spread of the problem. Conventional methods were used to test the efficacy of antimalarials, mainly in asymptomatic school children. Results from such studies had some limitation for use in policy development, mainly due to unstandardised methods used to gather data.

Results from the therapeutic efficacy studies carried out in four sites in 1997 and in six sentinel sites in 1998/1999 clearly showed high levels of chloroquine resistance, with on average a total treatment failure of 52% (range 28-72%). The new WHO protocol for therapeutic efficacy testing was used. Consequently, despite the fact that about 80% of Tanzanians live close to health facilities that provided chloroquine, statistics from such facilities through the Health Management Information System (HMIS) still showed that malaria was the first cause of outpatient attendances, admissions and death. On the other hand, the cost for malaria treatment using chloroquine also increased, mainly due to re-treatment costs.

In view of the above and also in view of the limited practicable antimalarial options, the Ministry of Health changed treatment guidelines for malaria and introduced an **interim strategy** selecting sulfadoxine-pyrimethamine (SP) as the first line anti-malaria drug, amodiaquine as second line and quinine as third line and first choice in severe malaria. (See Table 3). Tablet formulations are preferred; syrup formulations are only recommended where a child is unable to take tablets.

Table 3

National Guidelines for Management of Uncomplicated Malaria at all Levels

	Drug	Formulation	Duration	Contraindications	Notes
1st line drug	SP or SMP*	Tablets	Single-dose	Sulphonamide hypersensitivity Premature babies and children aged one week to two months Late pregnancy	Should be given with an antipyretic
2nd line drug	Amodiaquine	Tablets	Three days	Hypersensitivity to amodiaquine Hepatic disorders	
3rd line drug	Quinine	Tablets	Seven days		

Source: National Guidelines for Malaria Diagnosis & Treatment, 2000

[3] National Guidelines for Malaria Diagnosis and Treatment – Malaria Control Series no.1, 2000

*SMP or sulphamethoxypyrazine pyrimethamine is an alternative SP formulation with the same indicators and dosage as sulphadoxine pyrimethamine.

SP was deployed as the first line antimalarial despite the reported average total treatment failure of 9.5% from the sentinel sites. In this regard it was obvious from the outset of the strategy that the useful Therapeutic Efficacy of SP would be limited. It was therefore deemed necessary to continuously monitor the changes in the pattern of resistance to SP and also to prepare for a more effective strategy - Combination Therapy - as soon as it becomes available. Since the introduction of the new treatment guidelines, routine monitoring of SP resistance in sentinel sites shows an increasing trend up to 15%.

1.4 Malaria Treatment Seeking Behaviour

1.4.1 Consumer Knowledge and Beliefs

The biomedical concept of uncomplicated malaria overlaps with the local illness concepts of "homa" (usually translated as fever, although it can include other symptoms), and "maleria" or "homa ya maleria". These terms generally relate to common and easily treated fevers, and "malaria" is frequently associated with mosquitoes[4]. The biomedical concept of severe malaria can be linked with several local terms for the symptoms of severe disease: **"**degedege" (convulsions), "homa kali" (high fever) and "bandama" (splenomegaly). While some people link these symptoms with malaria, alternative explanations are also identified, for example involving supernatural intervention via spirit possession or magic spells[5].

Antipyretics/painkillers and antimalarials are seen as appropriate therapies for fever or mild malaria, but knowledge of dosing is generally very poor. For instance, only 20% of shoppers at drug stores in Dar es Salaam knew the correct dose of chloroquine for adults when it was still the first line drug[6]. There is wide confusion over the difference between antimalarials and antipyretics, and between brand name and generic products. Consumers may perceive two different brands of an antimalarial to be different drugs, or switch from tablets to injections without realising that they are different formulations of the same medicine.

1.4.2 Treatment Sources

Potential sources for malaria treatment include Government, mission and private facilities (dispensaries, health centres and hospitals), Part I pharmacies, Part II drug stores, general stores, and traditional healers or home remedies.

The vast majority of suspected malaria cases treated in facilities and shops are diagnosed on the basis of clinical symptoms alone, most commonly just the presence of fever. Microscopy is only available in a minority of facilities and a few private laboratories; in government facilities its use is often reserved for suspected treatment failures. A high proportion of clinically diagnosed cases are not parasitaemic. The percentage of children clinically

[4] Minja, H., J. A. Schellenberg, O. Mukasa et al. (2001). *Introducing insecticide-treated nets in the Kilombero Valley, Tanzania: the relevance of local knowledge and practice for an information, education and communication (IEC) campaign.* Trop Med Int Health 6(8): 614-23.

Winch, P. J., A. M. Makemba, S. R. Kamazima, et al. (1994). *Seasonal variation in the perceived risk of malaria: implications for the promotion of insecticide-impregnated bed nets*. Social Science and Medicine 39(1): 63-75.

[5] Hausmann Muela, S. and J. Muela Ribera (2000). *Illness naming and home treatment practices for malaria - an example from Tanzania.* Paper presented at workshop on People and Medicine in East Africa.

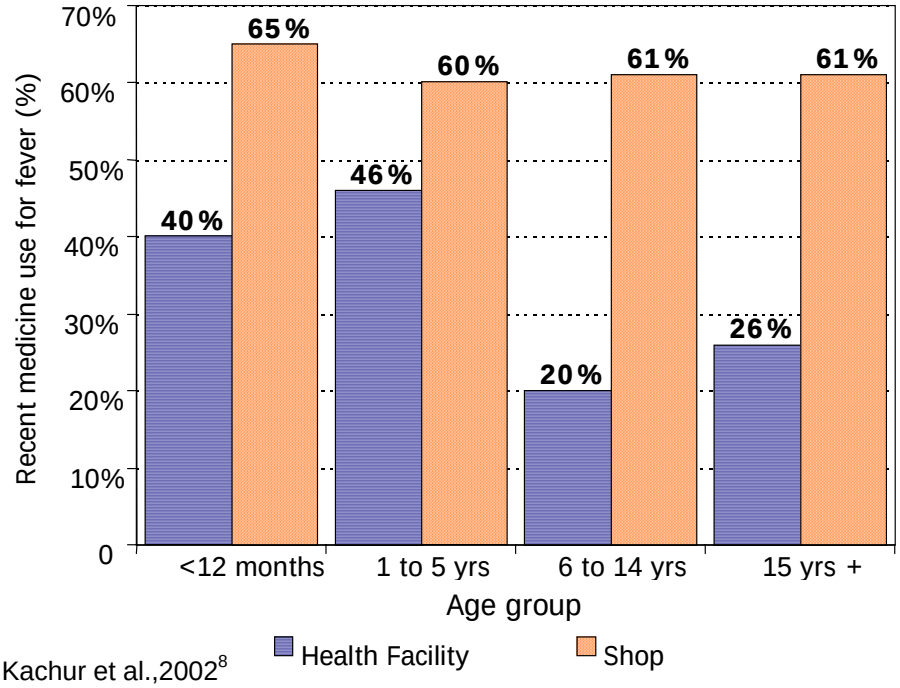
Winch, P. J., A. M. Makemba, S. R. Kamazima et al. (1996). "*Local terminology for febrile illnesses in Bagamoyo District, Tanzania and its impact on the design of a community-based malaria control programme.*" Soc Sci Med 42(7): 1057-67.

[6] Massele, A. Y., J. Sayi, S. E. Nsimba et al. (1993). "*Knowledge and management of malaria in Dar es Salaam, Tanzania*." East African Medical Journal 70(10): 639-42

diagnosed with malaria who were actually parasitaemic was 62% in Kilombero District and 38% in Kibaha District[7].

The most common source of treatment for fever is shops, which include general stores and pharmacies/drug stores. In southern Tanzania 29% of recently febrile people sought care from a health facility, while more than 60% bought medicines from shops (Figure 1)[8] 30% bought drugs from drug stores, and 34% from general stores, showing that both types of retail outlet are important.

Figure 1
Sources of medicines used for fever by age group



Source: Kachur et al.,2002[8]

The frequency with which infants and children under five were taken to health facilities was significantly higher than that observed for older children and adults. However, shops remained the most important source across all age groups. Reported use of traditional healers, herbal remedies, community health workers and unregistered providers was rare for fever[8], although use of traditional practitioners is more common for severe disease[5].

Frequent use of shops has also been demonstrated in other regions, such as Dar es Salaam and Same District[9]. Recourse to multiple providers during a single episode is common. Patients often begin with self-treatment using drugs purchased through the commercial sector, and then only seek care from facilities if their symptoms do not resolve.

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[7] Font, F., M. Alonso Gonzalez, R. Nathan et al. (2001). "*Diagnostic accuracy and case management of clinical malaria in the primary health services of a rural area in south-eastern Tanzania*." Trop Med Int Health 6(6): 423-8.

Nsimba, S. E., A. Y. Massele, J. Eriksen et al. (2002). "*Case management of malaria in under-fives at primary health care facilities in a Tanzanian district.*" Trop Med Int Health 7(3): 201-9.

[8] Kachur, S. P., R. Khatibu, C. Goodman et al. (2002). *Prevalence of malaria parasitemia and recent pharmaceutical medicine use by age in rural Tanzania: Implications for a multi-year evaluation of artemisinin-containing combination therapy.* Proceedings of the Third MIM Pan-African Malaria Conference, 17-22 November, 2002. Arusha, Tanzania.

[9] Mnyika, K. S., J. Z. J. Killewo and T. K. Kabalimu (1995). "*Self-medication with antimalarial drugs in Dar es Salaam, Tanzania*." Tropical and Geographical Medicine 47(1): 32-34.

Alilio, M. S., M. L. Kamugisha, F. K. Msuya et al. (1997). "*Availability and utilization of anti-malarial drugs at community level in Same District North Eastern Tanzania*." Malaria and Infectious Diseases in Africa 6

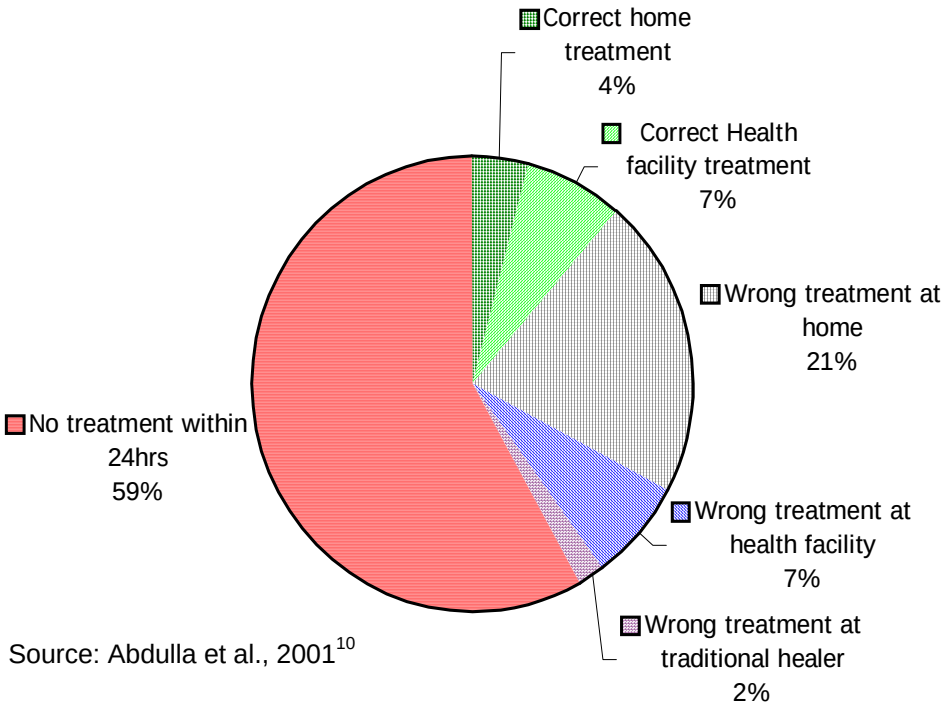
Drugs are officially provided free in most government primary health care facilities, but changing has been introduced in some districts. Even where services are free patients often choose to pay at private facilities and shops because they are nearer to where they live. Common reasons for not visiting a government health facility include long journey times, rude and insensitive staff, limited opening hours, long waiting times, lack of diagnostic facilities and poor building conditions. However, by far the most common complaint is the frequency of drug stock outs. Other reasons for preferring shops are that service is much faster and other family members can be sent to collect the drugs. They are also more likely to sell an incomplete dose of antimalarial drugs, which may be appreciated by the patient when cash is not available to buy a full course of treatment.

1.4.3 Adequacy of treatment

Having sought some kind of treatment in no way guarantees that the treatment received will be prompt or appropriate.

In a household survey of seven sentinel districts in 2001 it was found that in only 42% of under fives was action taken within 24 hours of fever onset, and only 11.3% had received appropriate treatment within 24 hours[10]. Inappropriate treatments were obtained from both health facilities and at home (Figure 2).

Figure 2
Treatment of children with febrile illness within 24 hours



Source: Abdulla et al., 2001[10]

A household survey in southern Tanzania found that only 43% of children with a history of fever had received antimalarials. Children in the "least poor" quintile were twice as likely to have received antimalarials as those in the "most poor" quintile (Table 4), demonstrating that the poorest groups are least likely to obtain appropriate care.

[10] Abdulla, S. et al. (2001). *Assessments of malaria situation and control activities in Tanzania – Preliminary Report.*

Table 4

Socio-economic differences in treatment for fever

	Socio-Economic Status Quintiles					
	Most poor	**Very poor**	**Poor**	**Less poor**	**Least poor**	**Average**
Child with fever received an antimalarial	31%	33%	49%	35%	62%	43%

Source: Armstrong Schellenberg et al., 2003[11]

Where an antimalarial is used, it is frequently taken at a sub-optimal dose, and care-takers are often unaware of important side-effects or the danger signs for severe disease.

1.5 Retail Market Structure

1.5.1 Manufacturers, Importers and Wholesalers

There are four local manufacturers of antimalarials in Tanzania: Shelys Pharmaceuticals Ltd (the market leader), Interchem Pharma Ltd, Keko Pharmaceutical Industries Ltd, and Tanzania Pharmaceutical Industries Ltd. A few other local manufacturers produce antipyretics that may be used for fever treatment, but they do not produce antimalarials.

Registered antimalarials are imported from a wide range of countries in Africa (Kenya, Uganda, Senegal), Asia (India, China, Korea), the Middle East (Egypt), and Europe (France, Switzerland, Italy, Cyprus, Belgium, Germany, Malta).

A total of 113 importers are registered with the Pharmacy Board, although this covers both medical and veterinary products. 48 of these importers are also registered as Pharmacy wholesalers, five or six of which are reportedly the market leaders, responsible for the largest shares of imported drugs. There are 167 registered private pharmacy wholesalers, geographically distributed as shown in Table 5 (excludes MSD). They are highly concentrated geographically with two thirds based in Dar es Salaam, and 80% in either Dar es Salaam, Mwanza or Arusha. They are also geographically concentrated within Dar es Salaam, with most located within a few hundred yards of one another in the Kariakoo area. All those registered to import are based in Dar es Salaam.

[11] Armstrong Schellenberg, J., C. J. Victora, A. Mushi et al. (2003). "*Inequities among the very poor: health care for children in rural southern Tanzania*." Lancet 361: 561-566.

Table 5

Registered wholesale and retail pharmacies in Tanzania

Region	Part I Wholesalers*		Part I Retailers		Part II Retailers	
	n	%	n	%	n	%
Dar es Salaam	110	66%	205	60%	1,300	23%
Kilimanjaro	4	2%	14	4%	270	5%
Mwanza	10	6%	22	6%	500	9%
Arusha	13	8%	25	7%	400	7%
Mbeya	5	3%	13	4%	226	4%
Morogoro	5	3%	14	4%	298	5%
Dodoma	3	2%	6	2%	255	5%
Mtwara	1	1%	2	1%	90	2%
Singida	2	1%	1	0.3%	185	3%
Coast	0	0%	6	2%	85	2%
Tanga	3	2%	9	3%	220	4%
Iringa	1	1%	4	1%	400	7%
Kagera	1	1%	3	1%	138	2%
Mara	3	2%	4	1%	200	4%
Shinyanga	3	2%	7	2%	323	6%
Rukwa	0	0%	1	0.3%	75	1%
Tabora	0	0%	5	1%	200	4%
Ruvuma	1	1%	1	0.3%	150	3%
Kigoma	2	1%	0	0%	60	1%
Lindi	0	0%	2	1%	291	5%
Total	**167**	100%	**344**	100%	**5,666**	100%

* Excludes MSD depots

Source: Pharmacy Board

1.5.2 Health Care Facilities

The government has three tiers of formal health facilities: hospitals, health centres and dispensaries. They are all supplied with SP, amodiaquine and quinine. In addition there are mission facilities run by a range of denominations, and a growing number of private commercial hospitals, dispensaries and laboratories.

Government health facilities receive their drug supplies through the Medical Stores Department (MSD) that procures from a range of local and international sources. MSD also sells to mission/NGO facilities, but not to commercial businesses.

1.5.3 Retailers

Retail outlets for drugs include Part I and Part II pharmacies and general stores (including kiosks and small stalls). Part I pharmacies must be run by a registered pharmacist, and are allowed to sell any drug registered or licensed in Tanzania. There are 344 registered Part I retail pharmacies (Table 5). This figure includes the 167 wholesale pharmacies, which are all also registered to sell retail. Sixty percent of the retail pharmacies are in Dar es Salaam, and the rest are distributed unevenly throughout the regions and are always located in urban areas.

However, drugs are also widely available in both urban and rural areas from general retailers and Part II drug shops. The pharmacy board has records of 5,666 registered Part II stores (Table 5), but accepts that the total number may be considerably higher, including some unregistered outlets. Part II pharmacies tend to be located on main roads or in market centres. They can be run by anyone with a basic knowledge of pharmaceutical or medical science, such as a pharmacy assistant or a nurse. In practice they are typically staffed by nurse assistants who have just one year's training, but give a vast amount of advice to customers, and are treated much like a doctor by the local community. They have only been allowed to sell OTC products (Part II poisons), but often illegally sell Part I drugs as well, such as antibiotics. All Part II stores stock Part II antimalarials (SP and/or amodiaquine) and many stock some Part I antimalarials, generally quinine. The government plans to phase out Part II drug stores and replace them with Accredited Drug Dispensing Outlets (ADDOs). (See Section 2.4).

The general retailers range from large permanent shops to small temporary roadside stalls, and stock a wide range of household products such as soap powder and cooking oil. They may be in market centres or remote areas, and can be staffed by anyone (See Figure 3). They generally stock a few common painkillers, and a minority have antimalarials, with just a few stocking antibiotics. Mobile vendors and markets are not a common retail source of drugs.

Figure 3

A child selling Part I drugs from a general shop

General retailers are by far the most accessible source of drugs for the rural population. For example a study of rural areas in southern Tanzania in 2001 found an equal number of primary health facilities and Part II drug stores, giving a population ratio of around 5,200 people per health facility and 5,200 people per drug store. By contrast there were only 273 people per general retailer stocking drugs (Goodman, unpublished data).

The distribution chains for drug shops and general stores are distinct. Drug shops obtain their supplies from drug wholesalers or pharmacies, which in turn buy from other drug wholesalers or importers. General retailers buy most supplies from general sub-wholesalers in the nearest district/regional town, who then buy from general wholesalers or distributors. At the top of the distribution chain two national general distributors (Nufaika and DG Traders), together with Shelys Pharmaceuticals are responsible for most of the drugs supplied through the general traders distribution chain[12].

2 Regulation and inspection

2.1 New act and drug classifications – Tanzania Food, Drugs and Cosmetics Act

The regulation of pharmaceuticals in Tanzania is in the process of change with the introduction of a new Tanzania Food, Drugs and Cosmetics Act, which should become law in 2003. The Act makes provision to deal with food, medicines, drugs, poisons, cosmetics and medical devices, their control and regulation. It repeals the Pharmaceutical and Poison Act 1978 in order to separate the functions of regulating, supervision and control of matters related to the pharmacy profession from others dealing in pharmaceuticals. A new Tanzania Food and Drug Authority will be established to regulate all matters covered by the act.

[12] This was the case in the areas we visited, and we expect their dominance to be nationwide, but were not able to verify this during our visit.

The new act is also aimed at empowering the Pharmacy Board to execute its activities more efficiently. It also makes provision for the Pharmacy Board to appoint inspectors down to community level.

Under the new Act, drugs have been re-categorized from Part I poisons and Part II poisons to the following groups:

- Controlled Drugs
- Prescription
- General sale drugs

It is now being proposed that an additional category should be created:

- Pharmacy only – Prescription and non prescription drugs only available from a pharmacy

It was reported that the categorization reflects a consensus among SADC countries.

The difference between prescription and pharmacy only groups is not clearly defined and may give rise to considerable confusion. It is unclear why the additional category is deemed necessary.

2.2 Drug registration

Until the year 1997, regulations and laws governing registration of medicines in Tanzania was non-existent. Mechanisms to establish/ascertain the quality of all medicines imported as well as manufactured within the country were lacking. The Chief Government Chemist analysed drug samples collected from different outlets. In 1997 the important regulation and process for drug registration started, including construction of the quality control laboratory. In 1999 drug registration came into force. Since then all medicines/drugs are in theory required to be registered before they are made available for consumption.

The requirements for drug registration require that::

- the availability of the drug is in the Public interest;
- it is safe, efficacious, and of acceptable quality;
- the premises and manufacturing operations comply with the current Good Manufacturing Practice, including Internal Quality Control Assurance.

Guidelines on Good Manufacturing Standards and Practices have been developed and shared with all in country manufacturers. The head inspection Unit of the Pharmacy Board is required to inspect manufacturing premises at least once every year.

A team of experts from the Pharmacy Board is required to inspect the premises overseas for Good Manufacturing Standards and Practices at the manufacturers' cost before the drugs are registered. A total of 67 imported antimalarial products have been registered (Table 6).

Table 6

Registered imported antimalarial drugs

Drug	Tablets/Capsules	Suspension/liquid	Injection	Total
SP	12	0	1	13
SMP	1	0	0	1
AQ	8	4	0	12
QN	10	1	9	20
ART	11	1	3	15
Others	5	1	0	6
Total	47	7	13	67

Source: Pharmacy Board

Registration of locally manufactured drugs should also follow the same procedure. The Pharmacy Board also organizes meetings with manufacturers that mainly focus on GMP. At the time of this consultancy none of the local manufacturers had met the required GMP standards. However, some locally manufactured drugs, including antimalarials, had been

given temporary approval for distribution pending registration, and it is expected that registration will be possible later this year when standards are met. During this interim phase it was reported that the Pharmacy Board is carrying out close monitoring of the manufacturers and their products.

Despite these arrangements that are intended to ensure availability of quality drugs in the country, the study team identified plenty of unregistered drugs of unknown quality in the market.

2.3 Part II pharmacies Registration

Part II pharmacies have to be registered through the Regional board and then have to re-register once a year. The board issues its permits annually after it is satisfied that the facility meets requirements. Thus if a new Part II pharmacy opens up it may function informally for a period without a permit. The team found unregistered Part II pharmacies. It is not clear if the unregistered Part II pharmacies are just ones that are in the process of registering or are in fact ones that do not intend to register.

2.4 Inspection

The Inspection Unit within the Pharmacy Board has the mandate to inspect premises where drugs are sold. The Regional Pharmacist and Council Health Management Teams, particularly the District Pharmacist, are all responsible for inspection.

2.4.1 Manufacturers

A team of experts from the Pharmacy Board is required to visit and inspect premises that manufacture drugs both nationally and internationally.

2.4.2 Wholesalers

It is the responsibility of the Inspection Unit at the Pharmacy Board or the Regional Pharmacist to routinely carry out inspections of wholesalers. The study found that this important activity is not well done.

2.4.3 Part I and Part II Pharmacies

The regional Pharmacist or CHMTs are required to routinely inspect Part I and Part II facilities. The implementation of this activity was found to be sporadic in most of the areas visited due to lack of transport.

2.4.4 General stores

General stores sell a variety of essential commodities, for example, sugar, salt and soap. A variety of drugs ranging from analgesics, antimalarials - mainly amodiaquine (Amodar) - antibiotics - Shetrim syrup (Cotrimoxazole) - to sedative hypnotics like Diazepam were also found in some shops. Anybody in the family, however unskilled he/she is, can provide service in such shops. (See Figure 3.)

Health Assistants carry out supervision for General stores, mainly focusing on hygiene issues and tax revenue collection. Discussions with a Health Assistant revealed that they visit every general store at least once per annum using whatever means of transport is available, for example bicycle. Transport was found to be the main obstacle for efficient undertaking of the supervisory activity. Health Assistants lack knowledge about drugs and they are not allowed to confiscate illegally sold drugs.

2.5 Planned phasing in of Accredited Drug Dispensing Outlets (ADDO)[13]

The 1978 Pharmaceutical and Poisons Act allowed Part II pharmacies (Duka la Dawa Baridi) to sell non-prescription drugs.

[13] The Pharmaceuticals and Poisons (Standards for Accredited Drugs Dispensing Outlets –ADDO) Regulations, 2002

However, from the data available the major issues related to the quality and cost of care provided by duka la dawas are:

- Insufficient number of qualified staff
- No assurance of drug quality
- High drug prices charged to patients
- Insufficient variety of drugs legally available to meet consumer needs.

Each of these problems are exacerbated by:

- Inadequate enforcement of regulations
- Difficulty in finding reliable, and legal, sources of drugs and supplies.

The ADDO programme is designed to address each of these problems.

Management Sciences for Health (MSH) and the MOH collaborated in conducting an assessment of the pharmaceutical sector in Tanzania in 2001. On the basis of that assessment a proposal was developed to improve access to essential drugs and health supplies in Tanzania through developing public-private partnerships. The objectives of the proposal were to:

- Improve the availability of cost-effective essential drugs and health supplies in public and mission hospitals;
- Promote competitive pricing for selected essential drugs in the private sector in rural Tanzania;
- Improve the quality of pharmaceutical services in the private sector in rural Tanzania;
- Improve the quality of selected imported and locally manufactured essential drugs in the Tanzanian market.

The MOH and MSH agreed to accomplish these objectives through:

- Designing, implementing and monitoring a network of Accredited Drug Dispensing Outlets (ADDOs), licensed and regulated by the Drug Regulatory Authority, with monitoring and enforcement carried out in collaboration with local government and community health structures;
- Approving alternative suppliers to serve hospitals supported by public finances;
- Implementing a system of screening, monitoring, and reporting on the quality of selected essential drugs under the Authority of the Drug Regulatory Authority.

Regarding each of the objectives listed above:

The official launch of the ADDO programme as signified by the opening of the first ADDOs is planned for August 2003.

A confidential discussion document prepared by MSH that describes an alternative supplier system for hospitals supported by the public sector is under study by the MOH. In addition MSH has developed, in conjunction with the Evangelical Church in Tanzania (ELCT), a pilot alternative supplier programme for church hospitals located in the Northern Zone of Tanzania. This programme is scheduled to be launched in November 2003.

A comprehensive drug quality programme for assuring product quality, including a range of components, including the review and analysis of documentation, visual inspection, product testing using both qualitative and quantitative methods, monitoring of products and manufacturers and effective enforcement of regulations, was launched by the Tanzania Food and Drug Authority in October 2002.

A minimum list of prescription essential drugs consistent with the yellow, Indent system and life saving potentials will be allowed at the ADDO. A registered wholesaler will distribute registered drugs to ADDOs. Inspection and monitoring will be the responsibility of the Ward Health Committees, District Technical Advisory Committee, Regional Technical Advisory Committee and the Pharmacy Board.

A marketing approach will be used for improvement of appropriate practices through communication, training and support.

The ADDO scheme is ambitious and its chance of success hinges on the adequacy of inspection at the ward level. Given the inability to inspect the existing Part II pharmacies it seems unlikely that adequate inspection will be achieved unless a major investment is made to provide a large number of inspectors with enough transport to enable regular inspection to occur.

Part 2 Key Concerns and Action Points

Thus far this report has described the system used for the supply of antimalarials through the private sector. The rest of the report sets out the team's main concerns and identifies the actions that need to be taken if the systems are to improve.

3 Ensuring Product Quality

The impact of all efforts to ensure appropriate use of antimalarials will be severely compromised if the drugs themselves are not of good quality.

Unfortunately there is substantial recent evidence of poor quality antimalarials in Tanzania. In 2001 the Pharmacy Board tested 16 different brands of SP/SMP on sale in Dar es Salaam, and found only six were of good quality. A local brand that failed this test was purchased by MSD for distribution in drug kits for government facilities, and had to be recalled in late 2001 when it was discovered that certain batches were of poor quality. Risha et al.(2002) examined the quality of chloroquine and SP from Dar es Salaam wholesalers collected between 1998 and 2000[14]. All samples passed the pharmacopoeia requirements for drug content, but two of the four SP products failed the dissolution test. Although all chloroquine samples passed initial dissolution, two out of seven failed to meet dissolution tolerance limits after being subjected to an accelerated stability test under simulated tropical conditions (75% RH/40˚C) for six months.

These incidents relate to substandard products which have been poorly manufactured. Counterfeit antimalarials deliberately manufactured without the appropriate active ingredient also circulate widely in the international market, with many occurrences reported in South East Asia[15]. While the prevalence of counterfeits on the Tanzanian market to date has been rare, the increasing use of more expensive antimalarials, such as artemisinin derivatives, may increase incentives for producing or importing counterfeit products in future.

Quality assurance encompasses ensuring both that the drugs entering the market are of high quality, and that they are still of high quality when they reach the consumer. The Pharmacy Board is in the process of implementing a number of important strategies to improve quality assurance:

- **Local manufacturers and GMP**. As mentioned in Section 2.2 the Pharmacy Board is working with local manufacturers to support the introduction of Good Manufacturing Practice (GMP) and internal quality assurance in all Tanzanian pharmaceutical factories. This process aims to balance the needs to both enforce more stringent quality standards and promote local industry. It has involved the development of GMP guidelines, repeated consultation and inspection of local plants, with a final inspection planned in the second quarter of 2003. Factories passing this inspection will acquire GMP status and will be able to register their products[16]. Any failing the inspection will have to cease production.

- **Drug quality testing at ports of entry**. In collaboration with MSH/SEAM, the Pharmacy Board has established quality testing facilities at major ports of entry: Namanga and Sirari on the Kenyan border, Dar es Salaam harbour and Dar es Salaam airport (temporarily located at headquarters). The Pharmacy board hopes in future to restrict the importation of drugs to ports of entry with testing capacity. Testing began in late 2002. The sites use minilab testing kits based on Thin Layer Chromatography (TLC), but plan to move to stand alone TLC testing systems in the

[14] Risha, P. G., D. Shewiyo, A. Msami et al. (2002). "*In vitro evaluation of the quality of essential drugs on the Tanzanian market*." Tropical Medicine & International Health 7(8): 701-707.

[15] Newton, P. N., N. J. White, J. A. Rozendaal and M. D. Green (2002). "*Murder by fake drugs*." BMJ 324(7341): 800-1.

[16] To date no locally manufactured antimalarials have been registered because production does not meet GMP standards. However, a number of products have been given a temporary licence to distribute, pending GMP inspection.

future. Any products failing the test will be sent to the National Drug Quality Control Laboratory (NDQCL) for confirmatory testing within a 14 day period. No failures had been identified in the first four months of implementation. The minilabs have the capacity to test the following antimalarials: artesunate tablets, quinine bisulphate tablets, quinine sulphate tablets and sulphadoxine/ pyrimethamine (SP) tablets. This list will be extended to include amodiaquine, sulphamethoxypyrazine/ pyrimethamine (SMP), and other artemisinin-based drugs once appropriate methods have been developed.

- **Post Marketing Surveillance**. Minilab testing facilities have also been introduced at the regional level (Dodoma, Mtwara and Mbeya), to undertake market surveillance through routine sampling and quality testing of products from MSD, wholesalers, Part I and Part II pharmacies.

Important strides have been taken in improving quality assurance, which will be of great benefit to antimalarial consumers. However, some important gaps remain in both policy design and implementation.

3.1 Ensuring Quality of Registered Antimalarials at Factory Gate/ Point of Entry

Key Concerns

Lack of quality control for locally manufactured antimalarials. All imported antimalarials must be tested at port of entry. Such routine quality testing is not required for locally manufactured drugs, which only require Pharmacy Board testing prior to registration. It is argued that the systems of internal quality assurance currently being established by local manufacturers will be sufficient for routine monitoring. This is inappropriate and inadequate. The internal quality assurance systems are new and there are likely to be teething problems. Moreover, quality testing is required of all imported brands, even though they must also come from factories with GMP standards. Finally, as a general rule, in any context it is extremely unwise to rely entirely on private market self-regulation.

Lack of quality control for several key antimalarials. The quality control of imports currently only covers artesunate, quinine and SP tablets. Although there are plans to introduce amodiaquine, SMP and other artemisinin derivates in the future, their exclusion represents a major gap at present, as does the absence of any syrup or injectable formulations from the tested list.

Action Points

Include locally manufactured products in routine quality control. As well as testing imported antimalarials, government capacity should be established to test all batches of locally manufactured antimalarials.

Expand the range of products tested at minilabs. The inclusion of amodiaquine and SMP tablets in routine quality control checks at ports of entry must be prioritised. The potential to add syrup and injectable antimalarial formulations to the products tested in mini-labs should also be investigated.

Antimalarials not tested by minilabs should be tested routinely at NDQCL. While waiting for appropriate methods to be developed for other antimalarials, these products should not go completely unchecked. Capacity exists at the NDQCL to test all of these drugs. While it may not be possible to test every batch produced or entering the country, batches should be sampled at the factory gate or port of entry, and the samples transferred to the NDQCL on a routine basis. In Dar es Salaam in particular this should be relatively easy to implement, as the port of entry testing for Dar es Salaam International Airport is currently done at the NDQCL.

3.2 Preventing Distribution of Unregistered Antimalarials

Key Concerns

Widespread availability of unregistered antimalarials

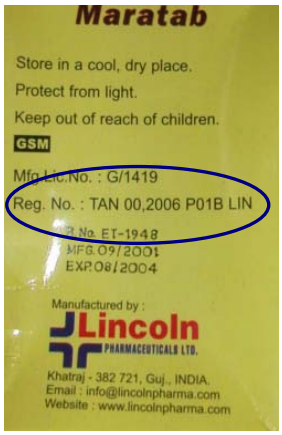
As described in Section 2.2 a drug registration system was established in Tanzania in the late 1990s. In theory only registered antimalarials should be imported and distributed in Tanzania. In practice, unregistered drugs are widely available. A recent SEAM survey found that 46% of drugs circulating in the market were not registered. This was clearly still common during our field work in Feb/March 2003 when in visits to retail outlets in just a few regions we saw over a dozen unregistered antimalarials, examples being chloroquine products (registration withdrawn), SP syrups (formulation not registered), and a product being sold as an SMP which contained the wrong sulphonamide component[17]. Unregistered products had been imported from a range of countries, including Kenya, Uganda and India. (See Figure 4)

Figure 4

Some of the unregistered drugs collected by the team

Lack of knowledge about registered drugs. A key cause of this problem is that very few people know which products are registered. The Pharmacy Board is trying to address this by requiring that the registration number be printed on outer packaging (See Figure 5). They are also providing port of entry inspectors with up-to-date registration information. However, this is clearly still inadequate and will not address those products that are imported through unofficial channels.

Figure 5
Registration Number



Action Points

Print registration number on inner and outer packaging. As drugs in blister packs often become separated from their outer packaging/box before use, it would be prudent to require that the registration number be printed on both the inner and outer packaging of the product.

Checklist of registered products. A clear checklist of all currently registered general sale products should be prepared by the Pharmacy Board. The list should be clearly presented, and ordered alphabetically by brand name, so that any product found in a Part II Drug Shop or general store can quickly be checked against the list. The list should be distributed to all drug inspectors, wholesalers, and retailers. It would be particularly beneficial for health assistants, who are the only inspectors of general stores, but do not have expertise in pharmaceuticals and are often unable to judge whether the drugs they encounter are permitted. It could also be produced in the form of a poster for display in Part II outlets to enable consumers to check the registration of products before they buy. The list must be reprinted and redistributed regularly to ensure that it is up-to-date.

[17] A drug called **Alpakelfin** from India that contained sulphamethoxazole instead of sulphamethoxypyrazine. (See Figure 4).

Education campaign on registration. The message that you cannot be sure of the quality of any unregistered product must be clearly conveyed to retailers and consumers. This should form an important component of the communication package (see section 8), in tandem with information on how to find out which products are registered.

3.3 Ensuring the Maintenance of Drug Quality during Distribution and Sale

Key Concerns

Poor stock management by wholesalers. There is considerable variation in the quality of stock management by drugs wholesalers. While some have well organised stores, run on a strict first in first out (FIFO) basis, others are verging on the chaotic, with drugs from different therapeutic groups jumbled together, not sorted by expiry date, and only intermittent use of air conditioners. The failure to follow a FIFO regime means that products sit for long periods at the wholesaler level. For example we found a Tanzanian SP product in a Dar es Salaam wholesaler already 14 months beyond its date of manufacture. (See Figure 6). While products beyond their expiry date are very rarely found in retailers, it would be preferable for drugs to reach the consumer as soon as possible, especially in view of the likelihood that they will be exposed to high temperatures and high humidity at some stage during the distribution chain.

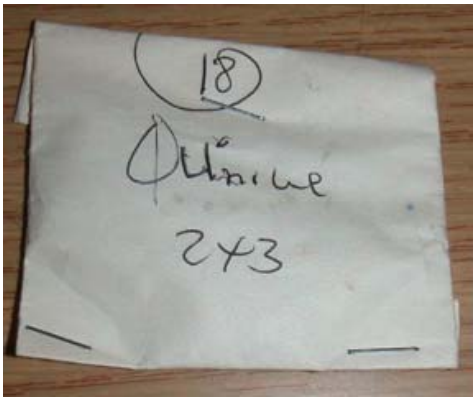
Figure 6
Poor Stock Management by Wholesaler

Poor packaging for transportation of drugs from wholesaler to retailer. Again there is considerable variation in practices, with some wholesalers packing drugs in a well ordered manner in sealed boxes, and others allowing retailers to pack products as they pleased, often carrying them away in loose carrier bags.

Figure 7
Selling SP from a tub

Widespread use of tubs/tins in shops: According to the regulations all drugs in Part II outlets and general stores should be sold in unit dose packs, meaning they should be pre-packaged by the manufacturers in blisters, foil or paper. In practice drugs are often sold from tubs/tins containing 500 or 1000 tablets, and dispensed in home-made paper envelopes or even just a twist of newspaper. (See Figure 7). This is a dangerous practice for several reasons. Many shops do not have sufficient turnover to use the contents quickly, so tablets are liable to sit on the shelf for extended periods in tins that are not air-tight. Their quality may also be damaged because the drugs are unprotected and are at risk of being spoilt or contaminated. There is also concern about the quality of the dosing instructions provided with drugs sold from tins. (See Figure 8). Many tins intended for facility use do not have any instructions, saying merely “Dosage as directed by your physician”. Even if the instructions are written on the tin, they are not taken away by the consumer, who either gets no instructions or a hastily scribbled note that they are unlikely to understand.

Figure 8
Poor Dosing Instructions



Finally, it is easy and common for tablets to be decanted from one tin to another, either to hide their true origin (e.g. because they have passed their expiry date or are stolen from health facilities) or just for convenience (e.g. an owner who splits the contents of one tin between the three drug stores he owns). This makes it impossible for consumers or inspectors to verify the true identity of a product, or whether it is in date.

Action Points

Working with wholesalers to improve their practices. The Pharmacy Board is working with local manufacturers to assist them in implementing internal quality assurance. A similar relationship should be established with the main drugs wholesalers, perhaps through one of the professional associations (Pharmaceutical Society of Tanzania (PST) or Tanzanian Association of Pharmaceutical Industries (TAPI)). The interaction should focus on the importance of good stock management and storage, packing for distribution, knowledge about regulations and drug registration in particular. As with the manufacturers, a timetable for improved practice should be established, with strict sanctions if these targets are not met.

Eliminating tins of antimalarials from Part II drug shops and general stores. The regulations banning the sale of drugs from tins should be strictly enforced for antimalarials. The issue should be highlighted with retail drugs inspectors, and wholesalers and retailers should be alerted to the intended clampdown and its rationale. The Pharmacy Board could also work with local manufacturers to encourage them to produce all their antimalarial tablets in blister packs. A concern is that this may increase the cost of antimalarials to consumers, although tablets in tins and blisters are frequently sold for the same price in retail outlets.

3.4 Post Marketing Surveillance

Key Concerns

Accuracy of tests performed at regional minilabs. At the regional minilab visited during fieldwork, the technician clearly failed both to follow the testing instructions correctly and to interpret the results accurately. It was not possible to assess how representative this was, but the standard of tests performed at these sites it likely to be a concern, because technicians are inexperienced, they do each test relatively infrequently, and lack appropriate technical supervision.

How can information from regional minilabs be used? Even if tests are performed well at regional minilabs, it is not clear how knowledge of the quality of a sample from one particular outlet will add value to a national quality assurance system. If the problem arose during manufacture it should be picked up by minilabs at the factory gate or port of entry. If it arose due to poor distribution or storage, it will not be possible to prove where the problem arose. Moreover, by the time a retail sample is taken, tested and verified at NDQCL, a high proportion of the drugs in question will probably already have been dispensed to the population.

Action Points

Abandon post marketing surveillance role for minilabs. We recommend that random routine testing of drugs in retail outlets in the regions be abandoned. The activities of minilabs should be focused on checking the quality of drugs at the top of the distribution chain (factory gate or point of entry). The energy of inspectors at national and regional level should be invested in ensuring that the distribution chain meets the operational standards for appropriate transportation and storage. Such a quality assurance system should then guarantee that only good quality drugs enter the distribution chain, and that their quality is maintained until the point of retail sale.

4 Appropriate and understandable labelling and instructions

The quality of labelling and the clarity of instructions is varied; there are five aspects that cause concern.

Key Concerns

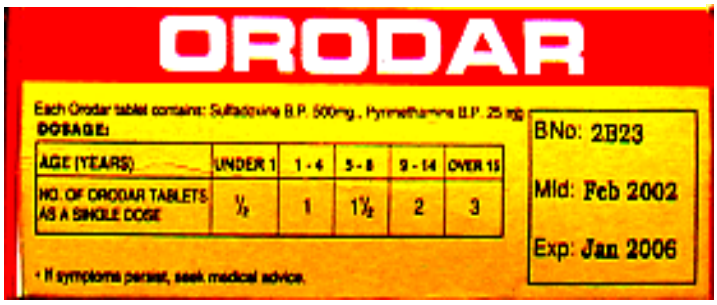
Labelling on blister packs: Labelling is often quite inadequate with writing so small that it is impossible to read. Manufacturers print their brand name larger than the generic name and dosing information may be incomplete, e.g. information for paediatric doses not provided. (See Figure 9). As a result, consumers believe that various brands of the same product are different products. The products are not easily recognizable, resulting in confusion even among retailers. Blisters are packed as adult doses and some blisters are sold without an outer packing. Consequently if a paediatric dose is sold the adult dose is cropped and the dosing information is lost. Even if the blister comes in a box with clear dosing instruction on the back, there is only one copy so when a dose that is less than an adult dose is sold the dosing information is lost or the remaining tablets lose their outer box.

Figure 9

Examples of labelling

Inadequate labelling on a blister pack

Good labelling on a blister's outer box



Lack of measuring devices. Most of the packs for syrups and mixtures found in the outlets visited specified a dose based on a standard 5ml teaspoon but did not include a measuring device in the packet. Mothers whose children require treatment with antimalarial syrups therefore use domestic teaspoons, which come in different sizes and are not of standard measure (5ml). This results in either over doses or under doses depending on the sizes of the teaspoons used. A minority of manufacturers do include a measuring cap (See Figure 10) and when one manufacturer was asked if he could include a spoon or cap with every syrup he confirmed that there would be no significant cost implications.

Figure 10

Syrup with a measuring cap

Language. The regulations specify that instructions can be in English and/or Swahili. Most antimalarial manufacturers only include English, which is a major problem for OTC drugs as the majority of Tanzanians are not fluent in English

Use and Labelling of tubs/tins. Drugs supplied in tubs or tins do not usually include dosing information. In addition, the team found on a number of occasions that tubs had been recycled; at best the batch number and expiry date did not relate to the present contents and at worst the description on the outside did not match the contents.

Dosing instructions. There is inconsistency in the dosing instructions provided for two general sale antimalarials. Confusion has arisen regarding to the manufacturers' dosing instructions given on the labels of brands of sulphamethoxypyrazin/pyrimethamine (SMP). Some overseas and local manufacturers recommend a single dose of two tablets for all adults while others recommend three tablets. Others recommend two tablets for adults below 70kg in weight and three tablets for those above 70kg in weight. The National Malaria Control Programme recommends three tablets as a single dose for adults and this is clearly indicated in National Guidelines for Malaria Diagnosis & Treatment. The recommended dosage for amodiaquine is not consistent. Table 7 shows the three options found by the team. Option 2 is the one recommended by the NMCP in the National Guidelines for Malaria Diagnosis & Treatment. Option one and three are those recommended by different manufacturers.

Table 7

Different dosing regimens for Amodiaquine – number tablets for adult dose

	1st day	2nd day	3rd day
Option 1	3	3	3
Option 2	3	3	2
Option 3	3	2	2

Action Points

Ensure that the products sold in Part II shops and general stores are sold in their original packs as closed by the manufacturers as required by the PB guidelines for Part II poisons to avoid use of wrong labels for the right drug.

It would be relatively straightforward to address these issues through the leverage the Pharmacy Board has through its registration process, for example by stating that in 2004, only amodiaquine, SMP and SP products conforming with the following regulations on improved labelling and packaging will be registered.

Inclusion of dosing information in Kiswahili as a requirement for registration, at least for antimalarials. This will enable all Tanzanians to follow dosage instructions easily, communicate without message distortion, be motivated and encouraged to read the instructions on the label.

All dosing information to conform to National Malaria Treatment Guidelines. This will eliminate confusion over SMP and amodiaquine dosage regimens.

Dosing information must be supplied for all age groups.

Manufacturers should include measuring devices in all syrups/mixture packages.

Generic names must be in large clear letters (larger than brand name).

Because packs often need to be split for paediatric doses, **enough extra cards repeating the instructions printed on the back of the packet should be inserted into the box so that one card could be taken away with each tablet** .

Improved labelling and packaging instructions must be a pre-requirement for re-registration.

5 Increasing the Availability of General Sales Antimalarials

5.1 The Importance of General Stores for Rural Households

If households living in remote rural areas are to have easy access to outlets selling antimalarials, these drugs must be widely available through general stores.

Figure 11

Shamba shop selling drugs

Although Tanzania has a relatively good network of primary health care facilities, much of the population remains more than 30 minutes travel time away. Part II drug stores provide an important alternative source of drugs, but are generally located in market centres or on main roads, often close to health facilities. Demand for drugs is rarely high enough to encourage the establishment of drug stores in remote areas. By contrast, the network of general shops and kiosks has the potential to reach even the most remote populations, providing an effective distribution chain for a wide range of consumer goods, with long opening hours and no waiting time. Figure 11 shows a shamba shop located far from permanent settlement yet selling drugs, including antimalarials (although out of stock when we visited).

5.2 Drugs Stocked by General Stores

Most general shops and kiosks stock a limited range of general sale antipyretic analgesics such as paracetamol, aspirin, and various combinations of the two, such as Hedex™ and Action™. Only a minority stock antimalarials, and this share has fallen since the change in national first line policy. In rural areas of southern Tanzania 29% of general stores stocking some drugs had antimalarials in 2000, which had fallen on 24% in 2001 (Goodman, unpublished data). Field visits in 2003 indicated that this share has continued to fall. Where general shops do stock an antimalarial, this is now most likely to be amodiaquine; SP is very rarely available in these outlets. The sale of antimalarials is more likely in general stores located far from Part II drug stores. A few remote general stores also stocked some prescription drugs, such as quinine and antibiotics, but this was unusual.

5.3 Regulations on Drugs Allowed in General Stores

The regulation of pharmaceuticals has been revised under the Tanzania Food, Drugs and Cosmetics Act, 2003, which should play an important part in clarifying the situation for general stores. Pre-2003 the situation was very confused. Drugs were categorised as Part I poisons (prescription only) or Part II poisons (over-the-counter), with Part II drug stores only allowed to stock Part II products. However, general stores were not covered under the 1978 Pharmaceuticals and Poisons Act, or perceived to be within the Pharmacy Board's regulatory remit. It appeared that officially general stores were not allowed to stock any drugs, but in practice they were permitted to sell some Part II poisons, such as common painkillers. Chloroquine was generally permitted until it was removed as first line antimalarial and effectively banned in 2001. Subsequently it was very unclear whether general stores were allowed to stock the new first line antimalarial, SP.

The 2003 Act has replaced the Part I/Part II classification with three groups: "controlled drugs", "prescription drugs" and "general sale drugs"[18]. It states "any general sale drug may be sold either by way of retail or wholesale in an open shop". SP and amodiaquine will be designated as general sale drugs, and will therefore be permitted in general stores.

[18] With a fourth category of "Pharmacy only drugs" being considered.

Key Concerns

Poor access to first and second line antimalarials. The patchy availability of antimalarials in general stores, and particularly the limited availability of SP, severely restricts access to first and second line antimalarials for remote rural populations by increasing the travel time and costs associated with obtaining appropriate medication.

Limited price competition. The limited number of retail antimalarial stockists restricts the downward pressure on antimalarial prices that would result from more widespread competition.

5.4 The Causes of Poor Antimalarial Availability in General Stores

The key factor limiting the stocking of antimalarials in general stores is that they are not available at the general sub-wholesalers where retailers purchase the majority of their supplies. Many retailers told us they would like to stock antimalarials but did not know how to get hold of them. This in turn reflects the lack of availability all the way up the general trader distribution chain. There are several possible reasons for this situation:

- There was considerable confusion among retailers and wholesalers about antimalarial regulation. Many owners and sellers believe they are not allowed to stock SP and/or amodiaquine, or are unclear about the regulations, and fearful of incurring regulatory sanctions.
- The capital cost of buying bulk packs of antimalarials was too high for smaller retailers, who were concerned that they would not be fast moving.
- There is a common perception among retailers and consumers that the appropriate place to buy antimalarials is a Part I or Part II pharmacy, and that general stores do not supply these kinds of products. Chloroquine had become an exception to this rule, perhaps because it was such a familiar product, but this perception has not been transferred to SP since the change in policy.

In view of the lack of antimalarials in general wholesale shops, mobile distributors are a common source for general retailers. We heard about a range of distributors, including registered van salesmen from local manufacturers or major importers, independent van salesmen travelling from Kenya, and individuals travelling by bicycle with a large bag or suitcase full of drugs. Mobile distributors have the advantages of reducing travel costs for retailers, and providing a direct channel for manufacturers or importers to communicate with retailers and supply them with promotional material. However they are extremely difficult for local or national authorities to monitor and control, and therefore represent a relatively easy distribution channel for unregistered drugs and the sale of prescription medicines to non-Pharmacy outlets. It would therefore be preferable if the main source of antimalarials for general stores were the static general sub-wholesalers where they already purchase most of their painkillers and non-drug products.

Action Points

Several steps must be taken to encourage the sale of antimalarials in general stores. This will definitely include SP and careful consideration is needed for the reasons outlined in Box 1 on whether these strategies should also encompass amodiaquine.

Effective communication of drug regulations. It is essential that all those involved in the retail drugs market are clear about which types of drug can be stocked in general stores, and which brands are registered (or licensed for distribution) in Tanzania. This information should form a key part of the communication package for consumers, retailers, wholesalers, national distributors and local manufacturers (see section 8.1). Particular emphasis should be placed on reassuring general retailers in remote areas with few or no drug stores, and encouraging them to stock recommended antimalarials.

Encouraging national distributors to stock and promote SP and deciding whether to encourage them to stock and promote amodiaquine. Individual retailers and sub-wholesalers have very little control over the products they stock because the product range is

effectively determined by a small number of national distributors. Discussions should be held with the national distributors to clarify the regulations and encourage them to include SP. The MOH will need to make a decision on whether to encourage them to include amodiaquine (see Box 1). Distributors should be encouraged to stock only products appropriate for general retailers (i.e. blister packed with clear labelling and dosing instructions in Swahili). An alternative (or complementary) approach would be to work through a parallel distribution network, which bypasses the national distributors, as PSI does by delivering products such as Ngao (insecticide re-treatment kit for mosquito nets) and Salama condoms direct to large wholesalers. This, however, raises problems of sustainability.

Encouraging manufacturers to produce smaller bulk packs. Blister packed SP and amodiaquine are generally sold wholesale in boxes of 75 tablets (25 packs of 3 tablets) for Tsh 1700-3000 for amodiaquine, and Tsh 3500-4500 for SP. The introduction of smaller bulk packs (e.g. 30 tablets per pack) should encourage more small retailers with limited capital to stock antimalarials.

Link with communication package for consumers. These interventions on the supply side will be complemented by the communication package for consumers (see section 8) to encourage early treatment of febrile illness with appropriate antimalarials and to raise awareness about local sources of antimalarials.

6 Controlling availability of restricted products

The Pharmaceuticals and Poisons Act and Pharmaceuticals and Poisons Regulations have governed the provision of pharmaceutical services in Tanzania.

This law provides control of the pharmacy profession and matters relating to dealings in pharmaceuticals in Tanzania under the Pharmacy Board.

The law recognizes two categories of drugs; “prescription drugs”, legally described as Part I poisons, and “non- prescription drugs”, legally described as Part II poisons.

Currently, there is a transition to change to the new act called the Tanzania Food, Drugs and Cosmetics Act under the administration of Tanzania Food and Drugs Authority. The new act will soon be applied to introduce the Accredited Drug Dispensing Outlets (ADDOs) to replace the current Part II pharmacies on a pilot basis. The ADDOs will be allowed to stock a limited number of approved antibiotics and other Part I drugs including injectables.

Areas of Concern

There is already widespread availability of restricted Part I drugs including antibiotics and Part I antimalarials in Part II outlets, which is against the current regulations. Government healthcare workers in various dispensaries and clinics often send patients to buy Part I drugs such as antibiotics, injectable presentations of various products and anti-diabetics from Part II outlets.

Unregistered products such as various brands of sulphadoxine/pyrimethamine, quinine, amodiaquine syrups and tablets and artemesinin derivatives are also available in Part II stores.

During the fieldwork, a substantial quantity of Part I drugs such as antibiotics and, to a small extent, some sedative hypnotics like diazepam were also found in general stores. A good number of those drugs were available in loose tablets packed in tins.

The availability of the restricted products in Part II and general outlets were attributed to:

- High levels of demand by the community.
- Referral by health workers to the private sector when the public sector is out of stock.
- Inadequate information about regulations at all levels (confusion about which drugs are Part II drugs among inspectors and retailers).
- Lack of drug inspection in general stores. Such stores are not normally inspected by Council Health Management Teams (CHMTs) but by ward level Health Assistants who inspect all commercial outlets for environmental health reasons. They know little

Box 1: Which Antimalarials should be focused on in Retail Outlets?

An important choice must be made about which drugs the intervention package should focus on in retail outlets. SP tablets and amodiaquine tablets and syrup will be designated as general sale drugs, and therefore legally available for sale by all retailers. According to the National Treatment Guidelines amodiaquine should only be used as a second line antimalarial, or where treatment with SP is contraindicated. However, in reality it is widely used as the first line drug for febrile illness treated with shop-bought drugs, and is often the only antimalarial available in general stores. This reflects both the demand and supply conditions in the market. On the supply side, amodiaquine is much more widely available in the general trading distribution chain, but SP is rarely seen and often believed to be prohibited. On the demand side, many consumers have been affected by the adverse publicity surrounding SP, in particular media stories about the effects of Steven Johnson Syndrome and reports about poor drug quality of locally manufactured brands.

It is clear that the intervention package must be proactive in promoting SP tablets through general stores. A choice must be made about whether to promote the correct use of amodiaquine tablets through general stores, or to try and discourage their use as a first line. Discouraging amodiaquine use will be very difficult. As a general sale drug, it is likely to continue to be widely available and widely used. Without appropriate promotion, it will continue to be poorly used. Moreover, by trying to work against the flow of demand, the overall communication strategy will be more challenging. It could be argued that amodiaquine should not be promoted in retail outlets because of the small risk of serious side-effects, but it is possible that this risk will increase if amodiaquine is widely available but inappropriately used. Some would therefore argue for the joint promotion of appropriate use of both SP and amodiaquine in general stores[19]. On the other hand increasing resistance to amodiaquine, which may develop more quickly since withdrawal of chloroquine and greater use of amodiaquine, may lead to more frequent dosing of children, which could increase the frequency of severe adverse reactions.

Similarly, the national guidelines focus on the use of tablets, because of concern about the accuracy of dosing and stability of syrups. However, syrups are favoured by many caretakers of young children due to the ease of administration, and the long history of using chloroquine syrup for children. Several registered amodiaquine syrups are very widely available in Part II drug stores. No SP syrups are currently registered in Tanzania because of concerns about the formulations, but some may be registered in the near future, and unregistered products are available in some outlets. Again there is a need to decide whether to attempt to discourage their use by explaining the dangers of inaccurate dosing to consumers, or to accept and work with the popularity of syrup formulations by, for example, providing appropriate dosing information in the communication package and forcing manufacturers to include a measuring device in each pack (see section 4).

about drugs and have no authority to take remedial measures like confiscating any drugs found in general stores.

While it is against the letter of the regulations for these Part I drugs to be supplied by Part II outlets for the above reasons it would not be prudent to invest a major effort to stop the practice.

Injectables and syringes are currently widely available in Part II drug outlets and will continue to be so in ADDOs. They are usually bought and taken with the drug to the health facility where a health worker administers the injection. The current disposal procedures of used syringes and needles by health institutions are however extremely worrying because safety boxes are not universally used, disposal areas are not protected and there is no equipment

[19] in contrast to the NMCP IEC materials targeted at retail outlets prepared in 2001 for the change in first line drug policy, which focused solely on SP tablets.

for destroying the used syringes in a safe and environmentally acceptable way. As a result there is:

- An opportunity for the re-use of syringes.
- The possibility for used syringes to be picked up and played with by children.
- The chance for people to buy their own syringes and use them at home. In countries where sale of disposables is long established, home medication with a "family syringe" is common.
- An opportunity for unqualified staff at the Part II pharmacy to administer injections. The team found some evidence of this during the fieldwork. (See slide 37 in Appendix 11).

Action Points

Clear alphabetical list of Part II registered brands should be supplied to all Part II outlets, general shops, pharmaceutical and general wholesalers and those involved in their inspection (Regional Pharmacists, District Pharmacists, CHMTs and Health Assistants) so that they can quickly check and ascertain if the products in stock are registered.

Inspectors should be provided with lists of the drugs that are allowed by the various outlets so that over time they can encourage the outlets to stock only the categories of drugs that the regulations specify.

The public sector must improve its stock management to ensure that Part I drugs are always available.

Information to consumers and inspectors should highlight that quality of unregistered drugs is not guaranteed and that checking to ensure that the drugs are registered is in the interest of the consumers.

A detailed assessment of injection safety needs to be carried out.

Areas of Concern

With regard to supervision and inspection, two regions visited had different approaches to supervision and inspection of drug outlets. In Mwanza region, the Regional Pharmacist is in charge of the Regional Drug inspectorate. She works closely with the District Pharmacists. The District Pharmacists work in collaboration with the health officers and health technicians who perform the actual inspection at the ward level. In Mtwara Region, The Regional Pharmacist is the sole Drug Inspector and carries out the inspection with his team up to ward level every quarter. No inspection is done in his absence. He faces transport problems as he uses a pool vehicle only when the other departments are going out for supervision or inspection. The inspectors in Mwanza use pool cars as well and the technicians more often than not use their own bicycles.

With the introduction of ADDOs the PB will be directly involved as opposed to the current situation where the Regional Commissioners and their committees are responsible for registration and control of Part II outlets. The PB will ensure that all inspectors are trained up to ward level and that there is uniformity in carrying out the inspection as opposed to the current situation where most of the health assistants have no knowledge about drugs.

Transport is and will continue to remain a major constraint.

Action Points

Health assistants should be provided with bicycles on a lease/purchase basis.

CHMT staff be provided with motorcycles on a lease/purchase basis.

7 Safety of Private Diagnostic Laboratories

It was also observed that private laboratories are being established with increasing frequency. They offer malaria microscopy at Tsh. 200.00 per test, a service rarely available at public facilities.

Figure 12

A Private Laboratory with dangerous practices

Areas of Concern

- While some laboratories are safe and well managed, some appear quite unsafe. In one laboratory two hypodermic needles were being used to make finger pricks and a blood filled syringe was being kept in the same box as new syringes. (See Figure 12).
- Some are in the same building as Part II pharmacies, contrary to Part II poisons guidelines.
- The owners of Part II shops own some laboratories. The diagnostic result may be biased. This may be deliberately done to encourage the patient to buy from his/her outlet.

Action Points

Close laboratories which are in the same buildings as pharmacy outlets.

Introduce stringent inspection of private laboratories.

Educate the inspectors to recognise unsafe practices.

Conduct a safe parenteral procedure survey of laboratories and Part II pharmacies.

The owners of Part II outlets should not own laboratories.

8 Ensuring consumers and retailers have adequate knowledge

Many studies have shown that the majority of early treatments for childhood illness are given at home using shop-bought brand name drugs in many countries including Kenya and Uganda. Early treatments for children are given at home using brand name drugs bought from Part II pharmacies and general shops.

Although a high proportion of childhood and adult fevers are caused by malaria, patients may only buy antipyretic analgesic drugs. When antimalarials are used, many customers purchase inadequate quantities of the drug. The reasons for this are a combination of ignorance and poverty. Retailers and consumers were found to have little knowledge in the following areas.

Retailers:

- Functions of drugs
- Correct drug dosages
- Division of brands of antimalarials into generic groups
- Danger signs
- Adverse reactions
- Registered Products
- Drugs permitted to be stocked in various outlets e.g. which drugs are allowed to be in Part II pharmacies or general shops

Consumers:

- Information on various brands of the same drug
- Drug dosages
- Recognition of severe symptoms e.g. convulsions
- Importance and benefits of early treatment
- Adverse effects
- Avoidance of injections

There is really a potential to reduce malaria deaths if home treatment can be improved. One way of achieving this is to improve the knowledge of consumers themselves. In addition, train retailers to give good advice on antimalarial use and management of malaria. This can only be done if their knowledge in the above-mentioned areas is improved.

There are therefore two approaches for improving the knowledge of retailers and customers. The two approaches, which have been and continue to be implemented, are:

- Communication
- Training.

8.1 Communications strategy

To enable consumers to acquire appropriate and good healthcare seeking behaviour and at the same time to help the drug retailers acquire and improve their knowledge, strategic communication approaches should be designed to address the above key areas of concern.

Various communication approaches currently being used to influence consumer and retailer behaviour are mainly from manufacturers or their main agents. Although communication strategies have been designed and put in place by various organisations, they do not appear to be as effective as they should be.

To be effective a communication strategy must be designed with specific communications objectives and target segment in mind. The target audience to be addressed by communications strategy includes the following:

- Parents of children under five
- Adults
- Owners and sellers in Part II shops
- Owners and sellers in General shops
- Pregnant mothers
- Health Assistants
- Dispensary/Health centre staff

- Religious leaders
- Teachers.

The National Malaria Medium Term Strategic Plan (NMMTSP 2003) underscores the importance of communication strategies on early diagnosis and appropriate treatment at household level. It emphasizes the following underlying critical issues: Knowledge within the communities which should be followed by timely actions to be taken in ordinary and emergency situations in case of febrile illnesses within the family members, especially for the most vulnerable groups. The major communications objective will focus on consumer and retailer knowledge.

8.2 Advertising Campaign using mass media

Advertising is a popular method of impersonal communications using such mass media as newspapers, magazines and journals, TV, radio, billboards and posters. The role of an advertising campaign will be to educate and evoke and associate specific feelings and emotions about malaria and connect them to the early treatment using quality antimalarials at the right dosage. In other words the campaign would set the right attitude for the management of malaria both at the retailer and consumer level. Focus on attitude is important because attitude influences behaviour and behaviour determines result. Advertising requires heavy repetition to build the associations, hence it is necessary for advertising to be consistent over time if it is to have any meaningful effect.

Our findings during the fieldwork were that:

There was no consistency in advertising nationally because the few organisations in the market have limited their activities to pilot areas, e.g. CARE Tanzania confine themselves to pilot areas around Dar es Salaam. Other organisations include NMCP whose advertising through the posters focuses on the public sector. Posters are mostly placed in public health facilities and are not replaced regularly. The effect of such posters is probably minimal. Advertising through the press is expensive and thus little used.

A review of CARE MALIP IEC strategy (2000-2003) showed that they focused mainly on:

- Bed nets
- Pilot urban and peri-urban areas in and around Dar-es-Salaam
- Use of Posters and occasional use of T.V. and radio media for advertising and rarely any press advertising campaign.

A review of ADDO marketing Plan (January 2003-December 2003) revealed that advertising through various media would be well covered when SEAM project on communication is launched, although they too would focus on a pilot area. The ADDO plan will be prepared annually. A year is a very short period in which to achieve behavioural change so it will be crucial that the ADDO plans are consistent over a number of years, otherwise behaviour change will be limited. Advertising through the radio is planned to run for nine months with a break of three months. It may be more effective if the radio campaign were allowed to run for two years with a three month break in the middle. PSI have wide experience advertising the ITN campaign and have been promoting ITNs successfully for a considerable time.

8.3 Media Strategy

Whether it is an advertising or editorial campaign, careful analysis and selection of appropriate media are fundamental to the success or failure. Deciding to include advertising or editorial campaigns in the communications mix is a relatively easy decision compared to deciding which media and specific media vehicles (e.g. specific magazine title) to use. Should press, T.V., radio, cinema or posters be used? If so, how much of each? Should they be mixed together (media mix)? If press advertising is chosen, which publications should be used – national dailies, daily or weekly regional papers, or magazines? How many times should the audience see or hear the advertisement? (*Optimum frequency*) Even a great advertisement will not work if, a) it is in the wrong place, b) It is placed at the wrong time, or c) it is at the right place at the right time but not enough times (*insufficient frequency*).

Most of an advertising budget is spent on the media (and not on the creative side or production side). For an advertising campaign to succeed careful attention to detailed media planning, knowledge and negotiation skills is very important. Therefore it is necessary to use expert media planners and buyers and get the best out of advertising by finding the right spaces or places for an advertising campaign at the lowest cost.

With this in mind we now focus on the criteria for selecting the various media/channels available that can be used to communicate with the rural community using advertising.

Radio

Information available from various organizations, e.g. Care Tanzania's MALIP IEC Strategy, involved in advertising as a communication tool was that a radio programme or campaign has been and still is effective in communicating basic information to the rural and urban communities and is appropriate to less literate people. During our meeting with PSI senior staff corroborated our finding that radio use is widespread in the community.

Other benefits of using radio cited by the above organisations are:

- Radio allows malaria messages to reach large numbers of people on a national level because radio ownership is widespread and several neighbours can use one radio.
- It can easily be carried to the place of work, particularly to the gardens in the rural areas.
- Listeners have relied on radio and still rely on radio for initial awareness creation. Once they become aware, individuals may seek to validate the radio message, evaluate it and obtain clarification, for example through interpersonal consultations and reading newspapers before they take action on the malaria message.
- Despite the benefits of radio as a medium of communication, not only for advertising campaign but also for other educational campaigns, there are certain limitations, which dictate the scope and content of the subject it can relay effectively. The limitations, which need to be taken into consideration when using the radio as a medium for communication, are as follows:
    - It is a one-way channel of communication without immediate opportunity for asking questions or seeking further clarification.
    - The programmes are impersonal so they stand a risk of not being taken seriously to some extent and may face criticism when certain sensitive malaria issues like adverse effects are discussed.
    - The programmes are sometimes too rushed.
    - It is difficult to know that the message broadcast is the message that the listener understands.
    - The language may not be understood because it is too technical for the average person.

The above limitations support the fact that for subsequent sources of information, people rely on a combination of other information, education and communication sources.

The radio programme alone, though a very effective one, does not therefore provide the rural population with all the information they need in order to make major decisions leading to behaviour change on home treatment of malaria.

Television

Television has sound, colour and movement, which makes it an ideal medium for demonstrations but its ownership is restricted to urban and some peri-urban areas . T.V. ownership in rural areas is very limited. The current providers in the market use it and have planned to use it to a very limited extent. It would therefore offer limited effect since the main target is the rural population.

Other channels available for advertising campaign:

Newspapers

A review of various documents e.g. MALIP IEC strategy and a discussion with Shelys pharmaceuticals and PSI staff revealed that the use of newspapers as a medium of communication has not been exploited fully. No explanation seemed to have been forthcoming from them. The assessment made during our fieldwork indicated that this is due to:

- Irregular availability of newspapers in remote rural areas.
- Poor people cannot afford a daily newspaper.

Despite the above limitations of the newspapers, they are still a useful way of communicating the malaria messages because:

- Information can be referred to or retained for future sharing.
- Useful sources for information for those who are not able to listen to the radio or watch T.V.

Posters

It was established that all organisations use posters extensively as a medium of communication as they are visual and can be retained for a long time for reference. They are a good channel of communicating information to the community. The unfortunate thing is that the messages reaching the rural population through posters with regard to information on antimalarial drug dosages is conflicting. This is because the majority of the posters prepared by the NMCP in accordance with their guidelines goes to the public facilities and rarely reach the private shops. Many of the posters in Part II pharmacies and general shops we encountered were either faded, torn or defaced (see Figure 13) indicating that they had been in place for a long time and were not printed on sufficiently robust media. The retailers rely mainly on manufacturers' posters, some of which do not give dosage instructions as required by the National Guidelines, hence confusion in dosing.

Figure 13

Counterproductive Advertising

Bill Boards

These are used mainly by PSI for mosquito nets and insecticides for treating nets. They are highly visual but with limited space for conveying messages in the case of malaria knowledge and management. It would not be effective as a channel of communication in the first year but it would be very useful as a reminder in the second year.

Table 8 below gives an idea of media characteristics . It gives a guide as to what media should be used and about how much it would cost to use them. Other cost estimates can be derived from communications activities budget (MALIP IEC strategy (2000-2003).

Table 8

Summary of Media Characteristics

	TV	Radio	Press and Media			
			Daily	Regional	Posters	Bill boards
Audience Size	Medium. Limited to urban and peri-urban areas	Very large National coverage	Large national coverage	Small No national coverage	Difficult to coordinate on National scale.	National Coverage
Audience	Wealthier	Mass	National	Geographic	Private and	Mass

Type	Urban and Peri-urban	audience. Many house wives. Commuters and rural people	mass audience but less likely amongst the poor people	mass audience but less likely amongst the poor	Public Health workers.	audience
Cost of Production	High	High	Low-medium	Low	Medium	Very high
Minimum Cost of space	High	Low	Medium	Low	Low medium	Medium
Cost per 1000 population reached	More than Radio	Low	Low-Medium	Medium	Variable depending on the size of posters	Very Low
Extra Advantages	Adds credibility to the Message	Transportable medium	Retained message	Retained message	Retained message. Can be used for various purposes e.g. road shows	Highly visual

- Cost of Production. Development and production of messages, actors involved and the right colour required depending on whether it is for T.V., radio or posters.
- Minimum cost of space. Advertising space is rarely bought in single units. The space is normally bought over a period of time and not one-off.
- Average cost per thousand. This is the cost of reaching at least 1000 of the population audience.

8.4 Publicity

Publicity is a communications technique that uses print and electronic media to convey messages without being paid for. Positive publicity is dependent primarily on good relationships with the media. Publicity should be integrated with the other communications elements: e.g. follow up of advertising campaigns with press launches and publicity campaign to maintain the visibility generated by the public relations people.

During the fieldwork, all the communication plan documents reviewed were found to have totally ignored publicity. As a tool which should be integrated with other communications elements, omitting it in the said plans and even ignoring it, as is the case in those plans, denies other communications techniques synergistic effect. The only organization that has so far considered this area is CEEMI. It organized a workshop on malaria and the media. This workshop was organized on 28th October–1st November 2002 with the aim of bringing the media closer to NMCP as partners. According to the workshop report (December 2000) the meeting aimed to enhance a multi-directional advocacy and education programme aimed at promoting malaria as a newsworthy topic amongst those working in the media at all levels, and to improve policy and practice concerning the depiction of malaria in the print and broadcasting media. It was quoted in the report that the journalists who attended the meeting had a number of questions and concerns, focused on:

- Lack of transparency by the Ministry of Health.
- Uncooperativeness and slow response by the MOH when it comes to releasing information.

This was an excellent start to using publicity. It appears that no follow up is being done to ensure that there is consistent contact using a public relations agency to enhance this very important communications tool. Identifying one individual at NMCP to play the role of a public relations person would promote the use of this communications tool effectively by:

- Ensuring immediate response to media houses.
- Ensuring that any information worthy of publicity is conveyed to the media houses.
- Quarterly meetings/workshops between NMCP and all journalists from the media houses mentioned under media strategy are held to review performance and relationships.
- A public relations firm is engaged and contacted at least once a quarter to review the outcome generated by publicity and to put in place what should be done in the next quarter.

This approach will ensure that negative publicity like the one currently dogging SP[20] is controlled and managed effectively.

8.5 Interpersonal Communications as a strategic option

An interpersonal communications approach, although conventional, is one of the most effective ways of disseminating information to consumers and retailers. It is considered appropriate because it reinforces the impersonal communications approaches as follows:

- Provision of an opportunity for the consumers and retailers, and even the health workers, to have a two-way dialogue where people ask questions which they would not be able to ask while listening to the radio or in a group discussion.
- Provision of reassuring personal touch.
- Provision of instant feedback from the consumers and retailers.
- Opportunity to respond to consumers' and retailers' changing needs, moods and questions.

During the discussions with PSI it was established that they have effectively used their field representatives to provide information and educate clients on malaria management and prevention using ITNs. Their clients include pharmacy retailers and wholesalers, general shop retailers and general wholesalers. Other organizations like CARE have gone further to use their staff to disseminate information not only on the use of ITNs but also to pass information on antimalarial dosages, importance of earlier treatment and the management of malaria at the consumer and Part II pharmacy levels.

However, interpersonal communication is expensive, as it requires extensive manpower mobilization and training, despite the fact that it is a tool that ought to be used to augment impersonal communications. Because PSI and CARE have the manpower and the capacity and a wide network in the country, they have and continue to use interpersonal communications, using their personnel effectively: Other channels which could be used effectively for interpersonal communications include:

- Field Health educators
- Religious organizations
- Health Personnel
- Teachers.

The above people were cited as the most appropriate groups to handle interpersonal communications due to the respect they command in the community. Following are some suggested activities which could be implemented using the above channels.

For teachers to be effective, ensure that:

[20] There have been a number of articles highlighting the adverse effects of Stevens Johnson Syndrome linked to SP. These have been very damaging and discourage people from using SP.

- Teachers participate in malaria seminars.
- Ensure that posters with full malaria information are distributed to teachers in schools.
- Provide a slot for malaria programmes in school radio programmes.
- Health officials visit schools at least once a term to give short lectures on malaria and replenish the posters where necessary.

Ensure that religious organizations have posters and encourage them to talk regularly to their congregations about malaria and its management.

We found out that the most popular interpersonal communications channels being used by PSI and CARE are:

Folk Media

Folk media, which includes songs, poems and plays, was another channel of communications identified as an effective means of communicating malaria information. Popularity of the folk media was identified as the single most important advantage in using the channel. It was cited as the medium that would bring messages to the community without offending anyone. Composed songs, plays and poems could be acted, recited or performed during traditional festivals and national functions. Various events like soccer matches could be sponsored and folk media used to convey malaria messages to the community during such occasions. It is cost effective as the actors are normally found in the community and do not have to be transported from one place to another. Unlike many other suggested channels of interpersonal communications the community sees no disadvantages in using the media to communicate malaria information.

Exhibitions/Road shows

This media was cited as growing very fast in popularity amongst the community and health workers and is compatible with folk media. It is dynamic and combines the benefits of interpersonal communications, plays, visual and audiovisual aids. It involves the mounting of music systems, videos, on a track as well as posters with various performers performing different plays as they move from one place to the other. It is quite infectious and pulls a very large crowd particularly in the rural areas. The cost is a bit high, hence some organisations use it cautiously. PSI has implemented this strategy successfully. It is recommended that this medium be used to launch a campaign and thereafter for follow up.

8.6 Communications agencies, firms, and organisations currently involved in communications

8.6.1Organisations

NMCP

NMCP has produced a series of malaria control booklets that spell out malaria policy guidelines with full information on malaria, its prognosis, diagnosis and treatment. There are also comprehensive training manuals that are focused and clear. Distribution of these materials has mainly been confined to the public institutions. Unfortunately many of these materials, including the National Guidelines, are now out of print.

IEC materials were also produced by NMCP in sufficient quantities in the year 2001 for policy change. The main limitation is that their availability in Part II outlets is very limited and they are rarely seen in general shops.

A concerted effort should be made to ensure that adequate malaria posters are available in the private sector.

Although comprehensive information and education and fair communication efforts have been made by NMCP, the influence on provider behaviour seems to be skewed towards public healthcare providers, leaving the private healthcare providers in the hands of the manufacturers and /or their agents. Since the majority of the consumers seeking malaria treatment first go to the private healthcare providers, particularly Part II retailers, the consumers' awareness and knowledge are influenced by them. Consequently, there is a gap in the private sector that needs to be filled if home management of malaria is to be effective.

The following organizations have striven and continue to strive to fill the gap using various communications strategies and approaches.

CARE TANZANIA

They run Malaria Intervention Project (MALIP), a project limited to four Districts in Dar es Salaam Region and focused mainly on urban and peri-urban areas.

In their project implementation report (July 2001-2002) three important communication activities dominated the activities:

- Collecting of IEC materials that carry malaria intervention messages from NMCP and PSI and distributing them to the community members.
- Using mass media (mainly posters) to disseminate malaria messages to the community in the project area.
- Using plays, songs and poems to pass malaria messages across to the community members in the pilot areas.

CARE has made attempts and continues to work with NMCP and PSI and to use communication interventions to reach the community. However, their activities are limited to the pilot areas. In addition the pilot areas are within urban and peri-urban areas, hence their activities do not address the problems facing the rural population.

CARE Tanzania MALIP Project phase two is planned to cover Mwanza, although this has not been finalized.

CEEMI

CEEMI recognises media houses' mainly electronic and print media as one of the most effective ways of getting to the targeted audience. Because of this recognition, it recently organized a workshop for journalists. The participants came from all over East Africa.

This is a commendable step forward as media relationship strategy is a key approach to managing some of the damaging reports that can otherwise create a permanent damage to consumer and retailer behavioural change efforts, e.g. recent print media negative report on SP. Besides, maintaining such a relationship is a sure way of ensuring that the correct and clear messages on malaria reach the people. NMCP should therefore work closely with CEEMI towards this goal.

PSI

PSI uses high profile integrated social marketing techniques with regard to insecticide treated nets and their insecticide brand used for treating nets.

During the discussion with the PSI management the following key areas of their activities were cited:

They have divided the country into zones. This has been done not only for ease of product distribution purposes but also for ease of interpersonal communications, e.g. road shows, theatre and sponsorships. The zones are:

Lake Zone
Southern Zone
Central Zone
Dar es Salaam Zone

They said that they work closely with Medical Stores Department. MSD store their products centrally in Dar es Salaam. They then use their own trucks to transport the goods to MSD zonal stores from where the products are moved to regional wholesalers and finally to the District sub-wholesalers.

It was cited that this arrangement is also convenient for communications purposes because it allows for ease of transporting IEC and promotional materials to all parts of Tanzania.

During the discussion, we were informed that PSI has commissioned a consultancy firm called Research International which works with the PSI research team to handle issues like the management of demand pattern, stock and market structure, and more so consumer behaviour, and assessment of the impact of IEC. With a research consultancy firm and a

research team in place, PSI has a good understanding of Tanzania's consumer market and is well placed to assess the impact of IEC on a continuous basis.

They did spend time on product positioning, pricing, distribution policy development and finally the development of promotional or marketing communications strategy. The main strategic communications options currently being used by PSI are as follows:

- **Interpersonal communications using field health representatives**

  The four marketing zones have given them an easy way of reaching their clients with interpersonal communications effectively. The health representatives work with general and pharmaceutical wholesalers, drug and general retailers and the community by offering expert advice. This is viewed as a longer-term strategic partnership win-win scenario. This strategy is working extremely well.

  It is expensive, as it requires extensive manpower mobilization and training. However PSI has a well-trained field force and a good network of distributors, hence they can reach as many retailers and community members as possible.

- **Communication through folk media**

  Use of songs poems and plays is an effective way of communicating to the rural people. PSI uses this approach effectively to reach the community. It is very effective in various cultures and can have an immense impact on the community. During our meeting they said that they normally use theatre groups. They said that the groups were available locally and that they need not spend money to transport them to different locations.

- **Exhibitions/Road shows**

  This is an effective and efficient way of reaching the rural drug retailers and the community at large. It combines the benefits of interpersonal communications, plays and visual aids. PSI has implemented this strategy successfully. They use three different organisations across the country.

  They explained that they would use 600 road shows in the year 2003.

Impersonal Communications Media (Mass Media)

It was cited that radio and posters are used extensively and that they use the services of various communications agencies for:

- Planning/strategy
- Creativity
- Media Choice.

It is important to note that the agency selection procedure is a time consuming, tedious process involving the following:

- Definition of the requirements
- Developing a pool list of attractive agencies
- Credentials pitch by the agencies
- Issuing of brief to shortlisted agencies
- Full agency preparation or pitch
- Analysis of pitch
- Selection of winner
- Agreeing on contract details announcing a winner.

Apparently, PSI has selected and tested the competence of the agencies it uses.

They seem to have developed good relationships with the selected agencies over a period of time. This good relationship coupled with being a large client has attracted a reasonable discount.

PSI's communication model is the most successful one because of the following:

- The success of using one communication tool is normally hampered by its constraints. PSI integrates all communications elements to minimize individual strategy constraints.

8.6.2 Communications Agencies

Appendix 9 lists the communications agencies which can be contracted for communications purposes through a transparent tendering process.

Although it is not listed as one of the communications agencies, Dunia Promotions Ltd. was mentioned by PSI as one of the most effective agencies in Tanzania, having successfully been used by PSI themselves, Vodafone, Tanzania and Kibo Breweries.

According to PSI, selection was based on the rigorous agency selection procedure and that the agencies selected are specialized in certain areas of communications, e.g. Momentum Exp. DMC and Group Africa is specialized in road shows.

When we met the top management of PSI for the second time, they were asked what they thought about funding of communications activities. They responded as follows:

- The public health sector has more than they can manage. To get more involved in the private sector initiative will be fertile.
- Funding must originate from NMCP and not from the districts. Not much will happen if funds are to originate from the Districts.

There are two options for using organizations to implement communications activities:

- NMCP directly hiring a range of Communication Agencies.
- Using one agency with media planning, knowledge and negotiation skills to manage the project and subcontract the various specialised communications agencies needed.

The latter approach may appear expensive, but may end up being cost-effective, because NMCP does not have the in-house capacity to select and manage the diverse range of communications agencies needed.

The process of designing and implementing the communications strategy would be as follows:

1. Identify and fill key gaps in evidence/information to develop the strategy, for example, in different users' behaviour, media habits, provider behaviour.
2. Develop a coherent communication strategy.
3. Develop partnerships taking account of complementarity and comparative advantages.
4. Set campaign objectives and strategy.
5. Divide Terms of Reference into lots
    a. Behavioural studies
    b. Provider behaviour
    c. Media habits
    d. Creative development
    e. Road shows
    f. Training
    g. Communications.
6. Campaign Management and monitoring and evaluation including media monitoring.

Areas of Concern for patients

In summary:

Inadequate information/Knowledge by consumers on:

- Drugs
- Drug dosages
- Prices
- Recognition of severe symptoms e.g. convulsions
- The importance and benefits of early treatment
- Adverse effects
- The avoidance of injections.

Action Points

Use commercial marketing strategic approaches described herein to be run by outside agencies.

Use road shows to be conducted in each area on an annual basis (not one-off push). Integrate these shows with other media in a co-ordinated and sustained campaign.

Involve sellers in Part II and general shops, healthcare workers fully in road show activities.

Discuss the need to redesign NMCP IEC materials to include amodiaquine tablets and syrup as well as SP on the basis of MOH decision on this issue. A brochure and price list of activities and materials should be sent to the Districts. They can then order the materials through NMCP and pay for them out of the basket fund.

Laminate IEC posters for Part II and general shops (paper posters are counter productive because they are easily destroyed).

Develop and produce "top pocket" size laminated dosing cards and promotional material like T-shirts, kangas, caps etc. for consumers.

Work closely with manufacturers and encourage them to step up their poster and appropriate dosing campaigns.

Work with CEEMI to cultivate and sustain media relationship with the aim of creating an avenue for sustained publicity and editorials as well as damage control.

Areas of Concern for retailers

In summary

Inadequate knowledge by retailers about:

- Function of Drugs
- Division of brands of antimalarials into generic groups
- Correct Dosing
- Danger Signs
- Adverse effects.

Action Points

Both Part II pharmacy workers and general shopkeepers must be involved in the road shows. They can be brought in before the road show is presented to the public to be given specific training and then involved in the road show, so that the public see them as being knowledgeable and a part of the health care system.

9 Making General Sale Antimalarials Affordable to the Majority

9.1 Retail Prices for Antimalarials

Table 9 shows current retail prices for commonly available antimalarials. SP (Sulphadoxine Pyrimethamine) is the cheapest treatment on offer, ranging from 120/= to 900/= for an adult dose. Most East African SP brands are sold in the range of 300/= to 500/=, with the originally patented European product, Fansidar, commanding around double this price. SMP has the same action as SP, but a slightly different formulation.

Sulphamethoxazole Pyrimethamine. Often perceived as a different drug by consumers, it is generally sold at a higher price than SP, especially for the originally patented European product, Metakelfin. Amodiaquine tablets are generally slightly more expensive than SP, with a range of 400/= to 800/= per adult dose. Quinine is the most costly, generally over 2000/= for 42 tablets, although this full adult dose is rarely purchased in practice. These figures compare with a standard market rate for an adult dose of chloroquine tablets of 100/= before the change in first line policy. Syrup and injectable formulations are generally more expensive than their tablet equivalents.

Table 9

Retail prices for an adult dose of widely available antimalarials tablets (Tsh)

Antimalarial	Adult Dose[1]	Retail Price Range for Adult Dose (Tsh)
SP	3 tablets	120/= to 900/=
SMP	3 tablets	750/= to 2,100/=
Amodiaquine	8 tablets	400/= to 800/=
Quinine	42 tablets	1,260/= to 4,200/=

Sources:
[1] National Guidelines for Malaria Diagnosis & Treatment
[2] Field visits in February/March 2003

Key Concerns

Antimalarials are not affordable to much of the population. This is demonstrated by two treatment seeking behaviours, both or which have potentially damaging health consequences:

- Consumers frequently purchase less than the full dose, especially for amodiaquine and quinine.
- Consumers with fever often buy only painkillers, such as paracetamol and aspirin, when they have fever, which are much cheaper at an average price of 10/= and 5/= per tablet respectively. This is a particularly common strategy in the early stages of a febrile episode, with a tendency to wait and see if the illness is self-limiting before proceeding to purchase antimalarials.

These two behaviours are not solely related to affordability. Even with cheaper retail prices some consumers may choose not to buy a full dose of an appropriate drug because either they are not aware of its importance, or because they decide to take the risk of developing more severe disease in the hope that they will be able to save their scare resources. However, if the prices of SP/SMP and amodiaquine were reduced, we would expect significant increases in the proportion of febrile episodes treated with an antimalarial, and the proportion treated with a full dose.

9.2 Can SP and Amodiaquine Retail Prices be Reduced?

Possible sources of retail price reduction are listed below, with an assessment of their feasibility in this context[21].

[21] The Pharmacy Board has commissioned a Drug Pricing Study from the Faculty of Pharmacy at the University of Dar es Salaam to investigate different mechanisms for reducing drug prices. Once complete, this should be carefully reviewed to assess the implications of their findings for general sale antimalarials.

- **Reducing manufacturing costs through higher volume production?** While the proposed communication package should increase Tanzanian demand for SP and amodiaquine (see section 8), there are unlikely to be substantial reductions in manufacturing costs, as current production volumes are already high, and many East African manufacturers serve the international market, and will not be heavily influenced by Tanzanian demand alone.
- **Reducing manufacturing costs through a reduction in packaging costs?** This is unlikely to occur, and would not be desirable. In fact several of the recommendations of this report may serve to somewhat raise packaging costs, through the increased use of blister packs and improved labelling and instructions (see section 4).
- **Reducing retailer overheads?** Retailers must recoup a wide range of overhead costs, including staff, transport, taxes, licence and permit fees, and rent. The ADDO programme plans to explore two possible strategies for reducing overheads for drug stores: first of all providing tax breaks to accredited stores, and secondly reducing travel costs for drug sourcing by linking ADDOs with a prime drugs vendor or developing an ADDO purchasing organisation. These initiatives may help to reduce antimalarial retail prices, at least within ADDOs. However, the ADDO programme will take several years to go nationwide, and will not address the costs of general shops.
- **Reducing mark-ups?** In view of the above-mentioned overheads, a significant mark-up is obviously required for shops to cover their full costs. However, there is some indication that mark-ups on SP may be unnecessarily high, allowing shopkeepers to reap abnormal profits. For instance the retail price of locally manufactured SP is between 3.3 and 5.5 times its factory gate price. The breakdown of this mark-up is shown in Box 2, indicating that retailers take the lion's share, with a mark-up of over 100%. This is much higher than the overall mark-up for locally manufactured amodiaquine, for which the retail price is between 2.1 and 2.8 times the factory gate price. This indicates that, at least for SP, there may be potential to reduce mark-ups, particularly at the level of the final retailer.
- **Encouraging use of cheaper brands.** Some consumers are willing to pay two to three times the price of the cheapest brand in order to buy a more valued product, particularly for well known brands from European companies. This reflects concern about the quality of cheaper drugs, especially those manufactured in Tanzania and India. Available evidence on drug quality indicates that this has been justified in several cases in the past (See section 3). However, once a quality assurance programme is fully established in Tanzania, including GMP standards for all manufacturers and routine quality control testing of all antimalarial batches, these problems should be much reduced and hopefully eliminated. Once this is achieved, a communication campaign to explain that the brands belong to the same generic group (i.e. all SP brands contain the same drugs), and that all registered brands are of high quality, will reduce the potential for higher mark-ups on some brands, and help to reduce the economic burden of treatment.

(Prices could also be reduced through government or donor subsidies. Due to the substantial operational difficulties involved in such a strategy this is not considered a viable option for the current first and second line antimalarials, but is discussed in Section 12 in relation to the more expensive combination therapies that the government plans to introduce.)

Box 2: Tracking the Price of SP through the Distribution Chain

The table shows the price at which an adult dose (3 tablets) of a locally manufactured SP changes hands as it moves down the distribution chain, and the mark-up obtained at each stage.

Table 10

Mark-up on SP

Transaction	Price (Tsh)	Mark-up
Manufacturer to 1st wholesaler	90/=	-
1st wholesaler to sub-wholesalers	133/=	48%
Sub-wholesalers to retailers	150/=	13%
Retailers to customers	from 300/=	from 100%
	to 500/=	to 233%

Source: Field visits Feb/March 2003

Action Points

Strategies should be adopted to push down mark-ups where they are excessive by providing information to consumers and increasing competition in the market:

Publicity campaign to push down SP prices. A key component of the communication package should be increased awareness of appropriate prices to pay for the first line drug, e.g. "don't pay more than 200/= for three tablets of SP". This must be combined with IEC materials and packaging that indicates clearly which brands fall under which generic category. The publicity campaign should include posters giving recommended retail prices for general sale antimalarials. This is already done for cigarettes. (See Figure 14). Although most drug manufacturers or importers provide distributors with schedules of recommended wholesale and retail prices, these are treated as suggestions only, and are not enforced. Retailers are generally totally unaware of the recommendations. This could be addressed by printing recommended prices on product packaging (as PSI do with their socially marketed products), but commercial manufacturers are unwilling to take this step unilaterally, in case it makes their products less attractive to retailers. An alternative would be to produce generic advertising materials listing recommended prices for SP.

Figure14

Cigarette Price List

The main East African manufacturers may be willing to include their brand names on the poster in return for the additional publicity they would receive, especially as such price maintenance is likely to increase their profitability by increasing sales at a constant factory gate price.

Encourage more general shops to stock SP (and amodiaquine if this is decided). Expanding the range of shops stocking these antimalarials should increase competition and drive down prices where mark-ups are high (see section 10.1).

Reducing Government facility prices for SP and amodiaquine. In many government PHC facilities all services are provided free. However, some districts have begun to introduce "cost-sharing" for drugs including first and second line antimalarials. In a Kilombero dispensary patients were charged 300/= for an adult dose of SP (and in addition were required to pay a 200/= consultation fee). This represented a huge 8 fold mark-up of on the discounted price at which the drugs were purchased by MSD, apparently a deliberate strategy to allow cross-subsidisation of other more expensive drugs, such as Benzyl penicillin. This is an entirely inappropriate strategy for the first line antimalarial in government facilities, and eliminates the potential to exert downward pressure on prices in the retail market. In view of the additional travel and waiting costs incurred by patients visiting health facilities, Government price schedules should be revised to ensure that the total direct cost of treatment is at a minimum not more expensive than care from shops, and is preferably substantially cheaper.

10 Role of training

In 1998 Care Tanzania completed its urban Livelihood Security Assessment (ULSA) for Dar es Salaam, covering low-income households in six wards in Dar es Salaam Region. In undertaking the ULSA, malaria featured prominently as the commonest problem in all the six wards. Based on this, CARE is now managing malaria intervention projects in the six wards. The selected six wards were mostly in urban and peri-urban settings. The overall project goal was to bring about significant reduction to malaria related morbidity and mortality, especially in children under the age of five years and pregnant women. (Training needs for Self-protection and Malaria Case Management, October 2001). The emphasis was on protecting the project target group against malaria using Insecticide Treated Nets and strengthening malaria case management. One of the interventions for accomplishing the above was through training of selected healthcare providers, ward committee members, pharmacists, Part II pharmacies retailers, traditional healers and traditional birth attendants.

The exercise was therefore undertaken in order to identify training needs for the different key groups listed above so that their services could be improved and hence contribute towards the achievement of the desired goals of protecting mothers and their young children from malaria.

The training needs assessment indicated that Part II drug retailers or drug store vendors' training needs included:

- Stocking of the right antimalarial drugs
- Lack of information about the use of antimalarial drugs.

From the information spelled out above, it is evident that lack of knowledge of antimalarials and the management of malaria in general is not only confined to the rural areas but is also present in the peri-urban and urban settings. However, those living in these areas have access to healthcare from numerous sources because of better health infrastructure. Even then, this is a minority and efforts should be made to spread this kind of activity by CARE in the rural areas.

Based on the outcome of the training assessment, CARE continues to run training on malaria management and prevention in six Wards in the Dare es Salaam Region under its Malaria Intervention Project (MALIP). Table 11 shows those people who have so far been trained on malaria case management.

Information derived from the MALIP report of July 2001-June 2002) indicated that the following observations were made during the training:

- Most healthcare providers did not know what the abbreviation SP stood for.
- SP is given as a single dose according to the National Malaria Guidelines, but a good number of prescribers follow some manufacturers' guidelines which recommend repeat dose after one week. Health workers have more faith in manufacturers.
- The use of a teaspoon in measuring the medicine is not an appropriate method.

Table 11

Categories Trained in Malaria Case Management

Non-technical Health care Providers	Number trained
Ward Health and Environment committee members	191
Ward Peer Health Educators	153
Ward Traditional Birth Attendants	82
Ward Traditional Healers	33
Technical Health care Providers	
Ward Laboratory Staff	36
Ward MCH	45
Ward Health and environmental Health Officers	4
Ward Clinicians	57
Ward Pharmacists	14

Source: Malaria Intervention Project (MALIP): Project Implementation Report July 2001-June 2002

The observations actually corroborate our findings during the fieldwork and thus the urban and peri-urban areas face similar problems. Therefore the steps Care is taking to train the health care providers and the key community opinion leaders are relevant to NMCP needs.

CARE uses *Manual for drug retailers* (malaria control series number 9) and *Manual for trainers of drug retailers* (malaria control series number 10), both prepared in the year 2000. They are comprehensive and to the point and thus they are quite suitable for this kind of training.

Although further similar training is planned for the same wards and Mwanza Region as explained during our meeting, there seems to be a slow implementation of the training suggesting that the rural areas may not be covered in the medium term. Consequently, some urgent malaria messages may not reach the rural areas unless communications activities are intensified through the mass media. It is therefore pertinent to implement nationwide communications activities to supplement this very training that is quite relevant to the NMCP requirements.

MSF

MSF Has been running and continues to run training for drug retailers on malaria management in Kigoma. Their training is not only focused on Part II drug retailers but also on general shop drug retailers.

Further similar training is planned for the same region and Mtwara Region.

On reviewing their curriculum for training of drug retailers the following observation was made:

They borrowed heavily from Vicki Marsh's working draft of 8th April 2002 for training drug retailers in Kenya[22]. While this would be applicable to training general shop retailers, its contents are not suitable for Part II drug retailers because they already have reasonable medical back ground. Secondly, Part II retail shops are growing rapidly and they stock a lot of different antimalarial drugs, hence they will form the core of home treatment for malaria. In Kenya, home treatment of malaria is confined to general shops where retailers have no medical background at all. The training approach is therefore different, hence replication of such a training approach to Tanzania may not be relevant to NMCP needs.

[22] Marsh V.M. et al. *Changing home treatment of childhood fevers by training shop keepers in rural Kenya*. Tropical Medicine & International Health. 4 (5) 383-389 May 1999.

While it is appreciated that MSF is doing a commendable job, it is recommended that they tailor their training programme to conform to the National Malaria Guidelines when implementing their planned training programme for Mtwara.

MSH

In the report on the Assessment of the Tanzania Pharmaceutical Sector, co-sponsored by the Ministry of Health and MSH, carried out in April-May 2001, it was proposed that there would be training and continuing education for ADDO drug retailers countrywide. This training would be used as the criterion for accrediting any health worker wishing to work in ADDO.

The accreditation course would involve:

- Education on ADDO drugs in their generic and branded forms
- Common indications and contraindications
- Common dosages
- Adverse effects
- Information to patients on malaria and how to use antimalarial drugs
- Laws governing their work.

Pharmacy Board approved institutions such as the School of Pharmacy would offer such courses.

Certainly, the area of concern intended to be addressed by the communications strategy here is retailers' limited knowledge. Two issues arise from this proposed training:

The question is, how soon will MSH/SEAM implement this training programme for the current Part II pharmacies, which need urgent attention?

Immediate and even medium term consumer behaviour change is not addressed by this training because other healthcare workers closer to the community as well as some key members of the community are not catered for to enable them to address the consumers' areas of concern.

While this training is relevant, it is only addressing one side of the story. Furthermore, this training planned under SEAM Project is only for four Districts in Ruvuma Region and it is not known when this will be replicated in other regions.

There is a need to put concerted efforts in using communications activities to fill this gap in the medium term.

UNICEF

UNICEF has supported a number of training programmes, particularly those of its own resource persons in Kyela and Magu Districts.

It continues to be involved in the development of training modules for health care providers, particularly in the area of malaria management and prevention.

UNICEF produced training modules for management of childhood illness in the year 2002. The manual focuses on various illnesses including malaria. Since it is meant for clinicians it may therefore not be used for drug retailers or consumers for improving their knowledge. UNICEF is currently not engaged in malaria specific activities that focus on the drug retailer and the consumers.

CEEMI

During the meeting with CEEMI the information received was as follows:

CEEMI's main objective is to strengthen Zonal centres and CHMTs in terms of capacity building. Training is delivered in a cascade manner starting from the Regional Medical Officers up to the dispensary level. This kind of training is meant for prescribers/clinicians at the public and private levels and does not therefore address the shopkeepers.

It has submitted a proposal for approval for education and training activities in the prevention and management of malaria in pregnant mothers in Tanga Region. Training will be conducted at the Zonal Training Centre and will take the direction indicated above.

Apparently the training that has been conducted so far has not focused directly on drug retailers. The community however gained from the private and public clinicians trained by trainers who were trained by CEEMI.

Therefore, there is a need to urgently address the plight of the Part II retailers in so far as disseminating information to them on malaria is concerned. The fall back activity is again communications.

The mission was informed that a request is being made for funds to enable CEEMI to conduct training for drug retailers next year and that it will not be a one-off affair.

CEEMI conducted a training workshop for journalists. This strategy towards developing media relationship would be beneficial to NMCP with regard to damage limitation in case of side effects. (This is described in detail under communications strategy.)

CHMTs

CHMTs Training was very patchy. It was actually one-off and was done on the back of training health workers after the change in first line policy. There is no guarantee that it will continue and there are no records of how much has been done anyway.

There is a big gap here and the only way out is to involve them in communications activities.

Areas of Concern

For the training to be effective:

- It will involve a very large number of trainers and trainees.
- It will have to be repeated frequently.
- It will require a comprehensive package including refresher training, the monitoring of which would stretch the capacity of the District-level staff.
- It will involve the development of training programmes, which will take District staff away from routine work, from which they are already away too much.
- The Zonal Training Centres, which are also being proposed to take some of the training, will have to take more training load despite the fact that they are already burdened with heavy workload coupled with acute shortage of resource persons.

Assessment of various training manuals on malaria has revealed that:

- Training messages developed by some organisations are not consistent with the National Malaria Control Guidelines.

Action Points

NMCP should not be involved in training because there would not be adequate capacity to implement separate training programmes since training of drug retailers would also be done through ADDO training. It should however encourage any donor who wishes to implement pilot projects on a small scale in order to learn more about what works to do.

Communications would be a better way to change both consumer and retailer behaviour.

NMCP should be involved in the approval of all malaria-training materials to avoid inconsistency in message delivery.

A seminar should be given whenever there is a change of policy.

11 Planning the Introduction of Artemisinin-Based Combination Therapy

The Ministry of Health has indicated that they consider the use of SP as an interim strategy, and that a move to an Artemisinin-Based Combination Therapy (ACT) as first line drug is probable within the next three to four years. The two ACTs being most actively considered at present are Artesunate+Amodiaquine and Artermether-Lumefantrine (Coartem™).

There are three reasons why such a move is planned. Firstly, resistance to SP is already present and expected to grow quite rapidly. Secondly, ACTs have been shown to be highly

efficacious. Thirdly, it is believed that the use of a combination regimen will reduce the rate of growth of drug resistance, so that for example the use of artesunate+amodiaquine will lead to slower development of amodiaquine resistance than the use of amodiaquine monotherapy.

These advantages must be balanced against some important challenges in implementing ACT, not least of which is the cost. With a predicted factory gate price of 1000/= to 3000/= per adult dose, there will be a more than ten-fold increase in the Government's first line drug expenditure alone. The price is unlikely to fall below 1000/= in the short to medium term due to the costs of extracting the active ingredient. In addition it will be necessary to ensure appropriate use of these more complex drug regimens when dispensed by health facilities.

It is also essential to consider the implications of ACT for the retail sector. All the key issues raised so far in this report, concerning drug quality, labelling and instructions, product availability, consumer and retailer knowledge, and affordability, will be of equal or greater importance following a move to ACT. However, a more immediate concern is that the implications for the private market should be incorporated now in choices about a future ACT-based policy. It would be a grave mistake to design a new policy on the basis of the optimal choice for health facilities alone and only then to consider how it should be implemented in the private sector.

The intended role of the retail sector must be taken into account from the outset in relation to three key choices about an ACT policy.

11.1 Choice 1: Which combination should be chosen?

Two issues need to be addressed here: firstly whether resistance will develop to the component drugs through their use as monotherapy in the retail sector, and secondly whether the ACT will be suitable for OTC retail sector distribution.

11.1.1 Preventing Monotherapy with the Companion Drug

Theory and experience from South East Asia indicate that the development of resistance to each component drug will be greatly reduced if they are used in combination, compared with their use as monotherapies. However, if one of the drugs continues to be used widely as a monotherapy in the retail sector this impact is likely to be much diluted. This could allow resistance to develop to that drug, reducing efficacy of the ACT and leaving the other component unprotected, even when used in combination. Most attention has been focused on the dangers of monotherapy with the companion drug to the artemisinin derivative, rather than the artemisinin derivatives themselves. This reflects the evidence that resistance to artemisinin derivatives has not developed in settings where they have been widely used as monotherapies, perhaps because of their very short half-life. Moreover, although artemisinin derivatives are available in urban pharmacies as monotherapies in Tanzania, their retail price of 4000/= to 6000/= currently precludes widespread use.

Two strategies could be employed to prevent the development of resistance to the companion drug:

- Select a combination that does not include a widely available monotherapy e.g. Artermether-Lumefantrine, as Lumefantrine is not available as a monotherapy.
- Select a combination that includes a currently widely available monotherapy and withdraw this monotherapy from the private market e.g. select artesunate-amodiaquine and withdraw amodiaquine monotherapies. This should in theory be possible; the Government achieved a high degree of success in withdrawing chloroquine after it was abandoned as first line drug, with only very small quantities remaining in the market after one year. However, experience might be different with a drug being withdrawn, not because it was no longer efficacious, but in order to protect it from resistance, especially if consumers were dissatisfied with the remaining alternatives on the retail market.

11.1.2 Is ACT suitable for OTC retail sector distribution?

An ideal first line drug would be suitable for distribution throughout the public and private sectors, to ensure maximum accessibility. If it is intended that the ACT be used in the retail sector, a number of issues should be considered:

- **Will the regimen be sufficiently simple?** This will relate to the number and timing of doses, the availability of a co-formulated (rather than just co-packaged) product for all age groups, and any other special requirements (e.g. artermether-lumefantrine must be given with fat). It will be important to conduct operational research prior to the policy change on adherence to the regimen, both when dispensed from formal facilities and when purchased from shops without a formal consultation.
- **Will the safety profile be suitable?** Where drugs have not previously been used on a very wide scale, have potentially severe side-effects, or are contra-indicated for certain groups, such as pregnant women, they may be considered inappropriate for distribution without consultation with a health worker and/or the recording of patient records, effectively precluding OTC retail sector distribution.

11.2 Choice 2: Should ACT be available to confirmed malaria cases only?

To date the vast majority of suspected malaria cases treated in facilities and shops are diagnosed on the basis of clinical symptoms alone. Microscopy is only available in a minority of facilities and a few private laboratories, and in government facilities its use is often reserved for suspected treatment failures. However, in most of Tanzania at least half the suspected cases are not parasitaemic, and in some areas this share is much higher.

It has been suggested that it would be appropriate to restrict ACT to patients with confirmed parasitaemia, possibly through the use of rapid diagnostic tests or “dipsticks”, which require less equipment and experience than microscopy. This could potentially improve the management of both malaria and non-malaria cases, but the prime motive of introducing RDTs in conjunction with ACT would be to reduce the costs of using expensive drugs for aparasitaemic patients. The actual cost savings will depend on the cost of the drugs, the cost of the RDT, the proportion of patients that are aparasitaemic, and whether the treatment protocol is adhered to in practice.

If ACT were to be restricted to confirmed diagnoses across the public and private sectors, it would effectively be necessary to make it a prescription only medicine, i.e. officially available in Part I pharmacies only. It could not be sold legally in general stores or Part II drug stores, severely restricting availability of the first line therapy in rural and peri-urban areas.

11.3 Choice 3: Should you subsidise the combination in the private market?

Substantially reducing the purchase price of artemisinin derivatives will require a concerted international effort. Strategies currently under consideration by WHO and other international agencies include improving price information, bulk purchase, differential pricing for low income countries, voluntary or compulsory licences to manufacture drugs still on patents, and procurement and subsidy through a Global Malaria Drug Facility[23]. The NMCP should use its lobby power to support such macro initiatives. In the short to medium-term the cost price will remain high, and NMCP will be unable to unilaterally alter the price it faces. Full or near-full subsidy of ACT in the public sector is therefore inevitable. In view of the substantial increase in the retail price, one needs to consider whether subsidies should also be provided for ACT in the retail sector.

The two options of an unsubsidised or subsidised private market are explored below.

11.4 Option 1: Unsubsidised private market

As discussed in section 10.1, a retail price of 300/= to 500/= for an adult dose with the current first line drug is unaffordable to many people. Replacing SP with an ACT costing around five times as much would effectively exclude all but the wealthiest citizens. One would expect to see some shift in utilisation from the private to the public sector, but widespread use of shops is likely to continue because of their far greater accessibility and

[23] RBM Partnership Meeting on Improving Access to Antimalarial Medicines, 30th September-2nd October 2002, Draft Report, January 2003, Malaria Control Department, WHO, Geneva.

convenience. Treatment for the vast majority continuing to use shops will therefore inevitably be contrary to the national treatment guidelines.

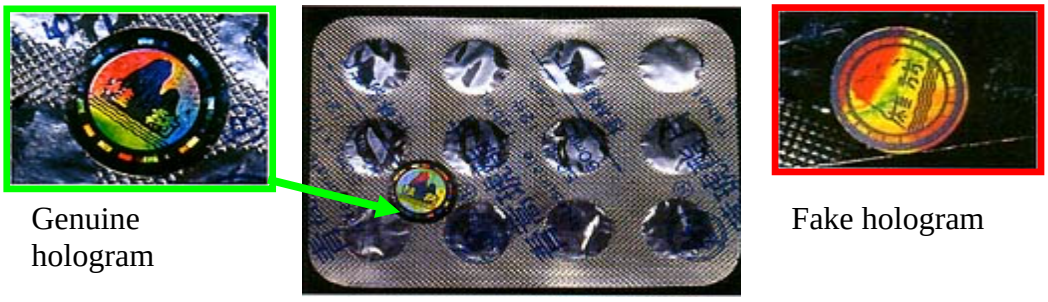
The Government may choose to accept this situation, especially while efficacious monotherapies are available. If they do, they should note that it will remain essential to provide treatment guidelines and an appropriate communication package to ensure appropriate use of these monotherapies in the retail sector. This will lead to a situation where there are effectively two sets of treatment guidelines, one for facilities and one for shops, adding to the complexity of the overall policy.

With an unsubsidised private market, the highly subsidised public provision of a drug with a high retail sector value will provide a powerful incentive for theft (See Box 3) from the public sector and or forgery into the whole market. Although a number of measures have already been taken to prevent theft from drugs kits distributed to peripheral facilities, these may be insufficient to prevent the development of a black market for a product that is both highly subsidised and highly valued by consumers. This in turn would make it extremely difficult to monitor utilisation.

Box 3: Faking Artesunate in Cambodia

The Artesunate pack shown in Figure 15 shows the genuine hologram label enlarged on the right. It also shows an example of a fake hologram that has been found on other packs of Artesunate. Although seen side by side the fake is obvious it does illustrate the sophistication and lengths to which fakers will go when the price of the product is high enough to justify the effort.

Figure 15
Fake hologram used on Artesunate packaging



Source**: Jan Rozendaal**, M.Sc., Ph.D

Faking of drugs in Tanzania was reported to us. It was alleged that aspirin is coated with sugar and then sold as quinine. There is no doubt that wide use of ACT will encourage the fakers to extend their market, so it only a matter of time before the Cambodian experience is repeated in Tanzania.

11.5 Option 2: Subsidised private market

The alternative option would be to extend subsidies to the retail sector. The overall cost of the ACT policy would dramatically increase, although the size of the increase is difficult to predict, depending on both the percentage subsidy, the elasticity of demand, and the administrative costs of delivering the subsidy. The subsidy would need to cover a high proportion of the cost of ACT to have a significant impact on demand, probably bringing it down to below the level current price of SP. If the subsidy is not great enough, even subsidised ACT could be considered unaffordable by the poorest groups. As a result the benefit of the substantial increase in public funding would be captured by the relatively well-off groups.

Increased cost would not be the only problem. There would also be a range of operational challenges to address. Although many people have called for the use of private sector subsidies for ACT, there is no consensus on how these should be implemented. A range of

options exist, which can be distinguished by whether they are targeted or universal subsidies, and the delivery mechanism used.

11.6 Targeted versus Universal Subsidies

Universal or generalised subsidies are potentially available to all members of a community, whereas targeted subsidies aim at increasing the demand of particular groups in society. A key advantage of targeting is that it can reduce the cost of the subsidy (or increase the amount of subsidy that can be provided to recipients). It can also be used as a tool to increase equity (by transferring resources to poorer groups), and efficiency (by channelling resources to those most able to benefit, and by avoiding subsidising people who would have purchased at an unsubsidised price)[24].

The target group may be selected on the basis of biological or economic characteristics. The most biologically vulnerable groups for malaria in Tanzania are generally considered to be pregnant women and children under five, although in epidemic prone areas all age groups are non-immune. Targeting a biologically vulnerable group would not make sense if the aim was to achieve high coverage of ACT across the whole population. However, the desired impact on the growth of drug resistance should be achieved even with partial coverage, as long as monotherapy with the component drugs is not widespread among the rest of the population. Targeting on the basis of economic characteristics is fraught with the difficulties of finding a simple and reliable way to identify the poorest groups. Moreover, in the case of ACT this may be inappropriate if the majority of the population would find it unaffordable.

11.7 Subsidy Delivery Mechanism

Several potential delivery mechanisms exist, which introduce the subsidy at different levels of the distribution chain:

- **Subsidise at the level of manufacturers and importers** by providing a fixed payment or tax break on each unit distributed. This would by default imply the use of a universal subsidy. Some strategy of retail price maintenance might be required to ensure that the lower price was passed all the way down the distribution chain.
- **Subsidise at the level of a national distributor**, which could purchase from a range of potential manufacturers and importers at the market rate, and sell on to wholesalers and retailers at a substantially lower price[25]. The products could be sold on as they were, with the organisation acting merely as a procurement agency, or could be repackaged as a single socially marketed brand, and promoted under this brand name. The subsidised products may be supplied on a universal basis, or targeted to particular groups through the style of packaging, marketing or distribution channels used in a social marketing strategy. Again retail price maintenance would be required to ensure the lower price was passed on.
- **Subsidise at the level of the consumer/retailer through a voucher system**. Targeted and untargeted vouchers systems have been used in the delivery of education, food and public health commodities, including treatment for sexually transmitted infections, and other reproductive health care[26]. Tanzania has experience with a small-scale voucher scheme for ITNs in Kilombero and Ulanga Districts and is planning to begin to roll out a nationwide scheme in 2003. Vouchers will be provided at antenatal care visits in order to target the most biologically vulnerable groups of pregnant women and young children.

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[24] Worrall, E., V. Wiseman and K. Hanson (forthcoming). *Targeting of Subsidies for Insecticide Treated Mosquito Nets*. London School of Hygiene & Tropical Medicine, Health Economics and Financing Programme Working Paper.

[25] In the case of artemether-lumefantrine it would only be necessary (and possible) to subsidise the single product on the market because it is still under patent.

[26] Gorter, A. C. (2003). *Review paper on evidence for using competitive voucher schemes and related methods for ensuring young people have access to health service interventions designed to prevent or provide care for HIV/AIDS*. Background paper prepared for the "Consultation on the health services response to the prevention and care of HIV/AIDS among young people."

The vouchers will cover a substantial proportion of the retail price and will be redeemable in any shop.

While a comparable voucher approach is conceivable for ACT[27], it would be complicated by a number of factors. Firstly the number of episodes experienced by the target group would be difficult to predict, and would probably necessitate a "book" of vouchers, rather than a single one. Secondly vouchers for ACT would be highly transferable between individuals (meaning that they could be used by any family member or sold to other people, and are therefore less likely to "stick" to the target group), and between products (meaning that shopkeepers could redeem the vouchers against other products). Thirdly, distributing vouchers at health facilities would be unlikely to reach the groups that do not have good access to facilities, and are most in need of vouchers for private sector drugs. This would necessitate the use of alternative distribution mechanisms, such as community leaders or NGOs. Finally, the national policy is to encourage these biologically vulnerable groups to visit a facility for treatment rather than a shop, and providing vouchers to be redeemed in shops would send a confusing message. However, the experience of the ITN pilot should be reviewed to assess whether there are any lessons to be drawn for ACT.

In summary, the private sector must be considered at an early stage in all decisions made about an ACT policy. The Government needs to take a proactive stance, deciding what coverage with the ACT first line they would like to achieve, which drugs should be available in the retail sector, and at what price, and then design a policy and set of interventions to achieve these goals.

Action Points

Decide how to make ACT available to the public and private sector.

Identify mechanisms to make it affordable.

Decide on a date for its introduction.

12 Options for Implementation and funding

12.1 National level activities

The Private sector is an important partner in the provision of antimalarial drugs to most of the rural population. The Ministry of Health, through Health Sector Reforms, recognizes and promotes private sector involvement in the delivery of quality health services.

Ensuring the quality of antimalarial drugs that are distributed, and appropriate delivery and utilization by the end user are key areas that would contribute greatly towards reducing development of severe disease and mortality due to malaria. However, the quality of some antimalarial drugs available in the different outlets is questionable. Often the price of such drugs, most of them illegally distributed and unregistered, is lower than registered ones and therefore easily accessible to the majority of the poor rural population. Eventually the parasites might develop resistant strains and also the disease condition might turn into severe form. Conformity in dosing information by manufacturers with National Guidelines is critical to avoid confusion and under-dosing by the public. Optimal packaging and enclosing adequate information about correct drug use is essential to improve understanding by the consumer without underscoring the language used by the majority of the population. Lack of

[27] Vouchers for ACT were tried in Myanmar where a subsidy was introduced for mefloquine through the provision of a voucher, given to care-seekers with the artemisinin prescription, and redeemable at specific outlets. However, post intervention, only 3.6% of patients chose to redeem their voucher, and all of those doing so were being treated at the hospital where both drugs were available. None of the other patients were prepared to put up with the inconvenience of going to another outlet to redeem the voucher (Shwe et al., 1998). This experience would not be directly relevant to a potential voucher system in Tanzania where the voucher would be likely to be for a coformulated or at least co-packaged product.

standard measurement for various syrups available in the different drug outlets is a serious omission that might cause under or overdosing practices by most rural caretakers.

The success of malaria case management mainly depends on many factors, including quality assurance of pharmaceuticals for adequate clinical cure of malaria patients. A robust registration procedure for pharmaceutical products, manufactured in the country or imported, which addresses the above-mentioned concerns, and routine quality assurance monitoring, backed by effective legislation, must be guaranteed in order to protect consumers against counterfeit or substandard drugs.

12.1.1 Ensuring quality antimalarial drugs

The Pharmacy Board has the mandate to ensure drugs sold in the country conform to the laws and regulations set. The Pharmacy Board, in collaboration with partners, has started to address some of the deficiencies in terms of availability of registered and quality drugs through enforcement of GMP, introduction of Minilab and introduction of the ADDO scheme. The National Malaria Control Programme should be proactive, have an advocacy role and work in close collaboration with the Pharmacy Board to discuss and follow up above-mentioned issues that support malaria interventions. Furthermore it will be necessary to strengthen and enforce supervision at all levels to also critically deal with drug stock management.

12.1.2 Promote marketing strategies consistent with the national guidelines, packaging and labelling

It will be necessary for the Pharmacy Board to review regulations for registration to include recommendations made on the above-mentioned issues.

Effective utilization of existing structures, for example the Tanzania Association of Pharmaceutical Industry (TAPI) and Tanzania Pharmaceutical Manufacturers Association (TPMA), to promote marketing strategies that are consistent with national policy and recommendations, including those on packaging and on enclosing adequate information about drug use is recommended. Such fora are also opportunities to discuss other pertinent issues like drug stock management.

12.2 Implementation of Communication strategy

The intent of the Communication Strategy is to promote positive behavioural change on appropriate delivery of antimalarial drugs available for sale in duka la dawa baridi and their use by the rural community.

The Government recognizes that advocacy and information for behaviour change are fundamental to improvement of the health status of the people. It has committed itself to intensifying communication efforts through increased information for behaviour change, political support, and collaboration with other partners, to ensure that all Tanzanians have access to accurate malaria control information. Effective delivery of the communication strategy is important to get the desired outcome. Experience from other programmes show that apart from mass media using radio, television, posters, leaflets etc, face to face contact is critical for attainment of behaviour change. Persistent behaviour change also requires repeated actions from time to time especially at the community level. Concerted efforts that are sustainable will be required for effective implementation of the strategy from the National, district and community level to effect the required behaviour change. Experience on the subject matter of commercial /social marketing and community based organizations will be exploited for effective implementation of the strategy through contracting out.

12.3 Source of funding

12.3.1 Public funding

The Government of Tanzania and its partners are committed to malaria control. Also through the Sector Wide Approach, funding of Council Health plans has also increased significantly. The Strategy therefore should be integrated in the Medium Term Expenditure Framework at the National level. Council Health Management Teams would be encouraged to also include relevant activities, including supervision in their Comprehensive Council Health Plans.

12.3.2 Global Fund to fight AIDS, Tuberculosis and Malaria

The National Malaria Control Programme could use other available opportunities (such as the Global Fund) for effective implementation of the strategy, and particularly in conjunction with the introduction of Combination Therapy (CT) in Tanzania. The World Health Organization advocates for combination therapy because of high cure rate and delay in the development of resistance in either of the drugs involved in the combination. Unless the existing practices by both providers and communities change, the effectiveness of CT strategy will not last long. Adequate funds made available through the Global Fund could be used for effective implementation of a communication strategy as a prerequisite for effective introduction of CT in the country.

12.3.3 Bilateral funding

Based on comparative advantages, funds for implementation of the communication strategy at the National and District level could also be secured from other sources such as bilateral organizations, in addition to their contribution to the Basket fund or from those not participating in basket funding.

13 Work plan and cost estimates for the next two years

A draft work plan is shown in Figure 16. It is based on the following list of action points. It shows calendar time during which tasks should be completed. In some instances, for example task 11 “Test all batches”, the task is to set up a procedure that will then continue indefinitely.

The major task needed is to conduct a detailed communications assessment. This should be carried out by a specialist consultant and should result in detailed plans of how an integrated communications package could be introduced to enable the private sector to become more effective at supplying quality antimalarials to the population. That consultancy should include detailed cost estimates and a terms of reference so that contractors can be invited to bid for the task of carrying out the identified strategies.

ToRs of consultants are shown in Appendix 13.

There are many tasks in the work plan for which NMCP will inevitably be responsible. It was clear to the team that NMCP is seriously under-staffed and does not have the capacity or authority at the moment to meet these responsibilities. Unless there is significant investment in staff and resources at NMCP then progress on strengthening the private sector will be very limited.

The cost of a major investment in promoting the private sector will be substantial. PSI plans to spend in the order of two million dollars a year on promotional activities; a national communications package is likely to cost substantially more than this.

Unless there is a greater commitment by the MoH to strengthen the delivery mechanisms for malaria control in the private sector, malaria will remain a major cause of morbidity and mortality in the young children of Tanzania.

Work plan tasks (number in brackets refers to the ID number on the Gantt chart)

10) 3.1 Ensuring Quality of Registered Antimalarials at Factory Gate/ Point of Entry

11) As well as testing imported antimalarials, government capacity should be established to test all batches of locally manufactured antimalarials.

12) Expand the range of products tested at minilabs. The inclusion of amodiaquine and SMP tablets in routine quality control checks at ports of entry must be prioritised. The potential to add syrup and injectable antimalarial formulations to the products tested in mini-labs should also be investigated.

13) Antimalarials not tested by minilabs should be tested routinely at NDQCL. While waiting for appropriate methods to be developed for other antimalarials, these products should not go completely unchecked. Capacity exists at the NDQCL to test all of these drugs. While it may not be possible to test every batch produced or entering the country, batches should be sampled at the factory gate or port of entry, and the samples transferred to the NDQCL on a routine basis. In Dar es Salaam in particular this should be relatively easy to implement, as the port of entry testing for Dar es Salaam International Airport is currently done at the NDQCL.

14) 3.2 Preventing Distribution of Unregistered Antimalarials

15) Print registration number on inner and outer packaging. As drugs in blister packs often become separated from their outer packaging/box before use, it would be prudent to require that the registration number be printed on both the inner and outer packaging of the product.

16) Checklist of registered products. A clear checklist of all currently registered general sale products should be prepared by the Pharmacy Board. The list should be clearly presented, and ordered alphabetically by brand name, so that any product found in a Part II Drug Shop or general store can quickly be checked against the list. The list should be distributed to all drug inspectors, wholesalers, and retailers. It would be particularly beneficial for health assistants, who are the only inspectors of general stores, but do not have expertise in pharmaceuticals and are often unable to judge whether the drugs they encounter are permitted. It could also be produced in the form of a poster for display in Part II outlets to enable consumers to check the registration of products before they buy. The list must be reprinted and redistributed regularly to ensure that it is up-to-date.

17) Education campaign on registration. The message that you cannot be sure of the quality of any unregistered product must be clearly conveyed to retailers and consumers. This should form an important component of the communication package, in tandem with information on how to find out which products are registered.

18) 3.3 Ensuring the Maintenance of Drug Quality during Distribution and Sale

19) Working with wholesalers to improve their practices. The Pharmacy Board is working with local manufacturers to assist them in implementing internal quality assurance. A similar relationship should be established with the main drugs wholesalers, perhaps through one of the professional associations (Pharmaceutical Society of Tanzania (PST) or Tanzanian Association of Pharmaceutical Industries (TAPI)). The interaction should focus on the importance of good stock management and storage, packing for distribution, knowledge about regulations and drug registration in particular. As with the manufacturers, a timetable for improved practice should be established, with strict sanctions if these targets are not met.

20) Eliminating tins of antimalarials from Part II drug shops and general stores. The regulations banning the sale of drugs from tins should be strictly enforced for antimalarials. The issue should be highlighted with retail drugs inspectors, and wholesalers and retailers should be alerted to the intended clampdown and its rationale. The Pharmacy Board could also work with local manufacturers to encourage them to produce all their antimalarial tablets in blister packs. A concern is that this may increase the cost of antimalarials to consumers if the cost per tablet is lower in bulk packs, although tablets in tins and blisters are frequently sold for the same price in retail outlets.

21) 3.4 Post Marketing Surveillance

22) Abandon post marketing surveillance role for minilabs. We recommend that random routine testing of drugs in retail outlets in the regions be abandoned. The activities of minilabs should be focused on checking the quality of drugs at the top of the distribution chain (factory gate or point of entry). The energy of inspectors at national and regional level should be invested in ensuring that the distribution chain meets the operational standards for appropriate transportation and storage. Such a quality assurance system should then guarantee that only good quality drugs enter the distribution chain, and that their quality is maintained until the point of retail sale.

In some cases, there was no dosing information available on the tubs/tins, hence the retailers are likely to underdose or over-dose the patient. Besides, some outlets kept loose tablets in tins of drugs other than those of antimalarials with different dosage regimens. This scenario further aggravates the matter.

23) 4 Appropriate and understandable labelling and instructions

24) Ensure that the products sold in Part II shops are sold in their original packs as closed by the manufacturers, as required by the PB guidelines for Part II poisons, to avoid use of wrong labels for the right drug.

25) By next registration i.e. 2004, only amodiaquine, SMP and SP products conforming with the following regulations will be registered:

Inclusion of dosing information in Kiswahili as a requirement for registration at least for antimalarials. This will enable all Tanzanians to follow dosage instructions easily, communicate without message distortion, be motivated and encouraged to read the instructions on the label.

26) All dosing information to conform to National Malaria Treatment Guidelines. This will eliminate confusion over SMP and amodiaquine dosage regimens.

Manufacturers should include measuring devices in all syrups/mixture packages.

Generic names must be in large clear letters (larger than brand name).

Extra cards must be inserted in packs with user-friendly dosing instructions.

27) 5 Increasing the Availability of General Sales Antimalarials

28) Effective communication of drug regulations. It is essential that all those involved in the retail drugs market are clear about which types of drug can be stocked in general stores, and which brands are registered (or licensed for distribution) in Tanzania. This information should form a key part of the communication package for consumers, retailers, wholesalers, national distributors and local manufacturers (see section 8). Particular emphasis should be placed on reassuring general retailers in remote areas with few or no drug stores, and encouraging them to stock SP and amodiaquine.

29) Encouraging national distributors to stock and promote SP and amodiaquine. Individual retailers and sub-wholesalers have very little control over the products they stock because the product range is effectively determined by a small number of national distributors. Discussions should be held with the national distributors to clarify the regulations and encourage them to include SP and amodiaquine. Distributors should be encouraged to stock only SP and amodiaquine products appropriate for general retailers (i.e. blister packed with clear labelling and dosing instructions in Swahili). An alternative (or complementary) approach would be to work through the PSI distribution network, which bypasses the national distributors by delivering products such as Ngao (insecticide re-treatment kit for mosquito nets) and Salama condoms direct to large wholesalers.

30) Encouraging manufacturers to produce smaller bulk packs. Blister packed SP and amodiaquine are generally sold wholesale in boxes of 75 tablets (25 packs of three tablets) for Tsh 1700-3000 for amodiaquine, and Tsh 3500-4500 for SP. The introduction of smaller bulk packs (e.g. 30 tablets per pack) should encourage more small retailers with limited capital to stock antimalarials.

Link with communication package for consumers. These interventions on the supply side will be complemented by the communication package for consumers to encourage early treatment of febrile illness with appropriate antimalarials and to raise awareness about local sources of antimalarials.

31) 6. Controlling availability of restricted products

32) Clear alphabetical list of Part II registered brands should be made available to all Part II and general outlets, pharmaceutical and general wholesalers and those involved in their

inspections (Regional Pharmacists, District Pharmacists, CHMTs and Health Assistants, so that they can quickly check and ascertain if the products in stock are registered.

Information to consumers and inspectors should highlight that quality of unregistered drugs is not guaranteed and that checking to ensure that the drugs are registered is in the interest of the consumers.

Major efforts should not be put into removing antimalarials like artemisinin derivatives and quinine from Part II outlets. This would require regulatory effort and undermine the fact that government patients are often sent to buy these drugs from Part II outlets, and in any event ADDOs are to be allowed to stock both quinine tablets and injections. Moreover their use is unlikely to be highly damaging to public health, so putting regulatory effort to remove them is unlikely to be cost effective use of resources.

33) Review the magnitude of the problem with regard to disposal of syringes and needles.

34) 7. Safety of Private Diagnostic Laboratories

35) Close laboratories which are in the same buildings as pharmacy outlets.

36) Educate the inspectors to recognise unsafe practices.

37) Introduce stringent inspection of private laboratories.

38) The owners of Part II outlets should not own laboratories.

33) Conduct a safe parenteral procedure survey of laboratories and Part II pharmacies.

39) 8. Ensuring that Consumers have adequate knowledge

40) Use commercial marketing strategic approaches described herein to be run by outside agencies or PSI.

41) Use road shows to be conducted in each area on an annual basis (not one-off push).

42) Integrate these shows with other media in a co-ordinated and sustained campaign.

43) Both Part II pharmacy workers and general shopkeepers must be involved in the road shows. They can be brought in before the road show is presented to the public to be given specific training and then involved in the road show, so that the public see them as being knowledgeable and a part of the health care system.

44) Redesign NMCP IEC materials to include Amodiaquine tablets and syrup as well as SP. A brochure and price list of activities and materials should be sent to the Districts. They can then order the materials through NMCP and pay for them out of the basket fund.

45) Laminate IEC posters for Part II and general shops (paper posters are counter productive because they are easily destroyed),

46) Develop and produce “top pocket” size laminated dosing cards and promotional material like T-shirts, kangas, caps etc. for consumers.

47) Work closely with manufacturers and encourage them to step up their poster and appropriate dosing campaigns.

48) Work with CEEMI to cultivate and sustain media relationship with the aim of creating an avenue for sustained publicity and editorials as well as damage control.

49) 9 Making General Sale Antimalarials Affordable to the Majority

50) Strategies should be adopted to push down mark-ups where they are excessive by providing information to consumers and increasing competition in the market:

51) Publicity campaign to push down SP prices. A key component of the communication package should be increased awareness of appropriate prices to pay for the first line drug, e.g. “don’t pay more than 200/= for 3 tablets of SP”. This must be combined with IEC materials and packaging that indicates clearly which brands fall under which generic category. The publicity campaign should include posters giving **recommended retail prices** for general sale antimalarials. This is already done for cigarettes. Although most manufacturers or importers provide distributors with schedules of recommended wholesale and retail prices, these are treated as suggestions only, and are not enforced. Retailers are

generally totally unaware of the recommendations. This could be addressed by printing recommended prices on product packaging (as PSI do with their socially marketed products), but commercial manufacturers are unwilling to take this step unilaterally, in case it made their products less attractive to retailers. An alternative would be to produce generic advertising materials listing recommended prices for SP. The main East African manufacturers may be willing to include their brand names on the poster in return for the additional publicity they would receive, especially as such price maintenance is likely to increase their profitability by increasing sales at a constant factory gate price.

52) Encourage more general shops to stock SP and amodiaquine. Expanding the range of shops stocking these antimalarials should increase competition and drive down prices where mark-ups are high (see section 9.1).

53) Reducing Government facility prices for SP and amodiaquine. In many government PHC facilities all services are provided free. However, some districts have begun to introduce "cost-sharing" for drugs including first and second line antimalarials. In a Kilombero dispensary patients were charged 300/= for an adult dose of SP (and in addition were required to pay a 200/= consultation fee). This represented a huge mark-up of 825% on the discounted price at which the drugs were purchased by MSD, apparently a deliberate strategy to allow cross-subsidisation of other more expensive drugs, such as Benzyl penicillin. This is an entirely inappropriate strategy for the first line antimalarial in government facilities, and eliminates the potential to exert downward pressure on prices in the retail market. In view of the additional travel and waiting costs incurred by patients visiting health facilities, Government price schedules should be revised to ensure that the total direct cost of treatment is at a minimum not more expensive than care from shops, and is preferably substantially cheaper.

54) 10 The role of training

55) NMCP should not be involved in training because there would not be adequate capacity to implement separate training programmes since training of drug retailers would also be done through ADDO training. It should however encourage any donor who wishes to implement pilot projects on a small scale in order to learn more about what works to do.

Communications would be a better way to change both consumer and retailer behaviour.

NMCP should be involved in the approval of all malaria training materials to avoid inconsistency in message delivery.

A seminar should be given whenever there is a change of policy.

56) 11 Planning the Introduction of Artemisinin-Based Combination Therapy

57) Decide how to make ACT available to the public *and* private sector.

58) Identify mechanisms to make it affordable.

59) Decide on a date for its introduction.

Figure 16 Outline Work Plan

ID	Task Name	Duration	Resource Names
1	**Report processing and discussion**	**0 days**	
2	Circulate report to stakeholders	21 days	NMCP
3	Meeting to discuss report	1 day	NMCP
4	Consultative meeting with Mfr, Importers etc	1 day	NMCP
5	Agree courses of action based on report	5 days	MoH/PB/NMCP
6	organise consultancy on comms strategy	60 days	NMCP
7	tender documents for comms work	10 days	NMCP
8	process and accept comms consultancy	36 days	NMCP
9	carry out comms consultancy	50 days	consultant
10	**3.1 Ensure Drug Quality**	0 days	
11	Test all batches	60 days	PB
12	Include amodiaquine test at Minilabs	140 days	PB
13	NDQCL testing	120 days	PB
14	**3.2 Unregistered Antimalarials**	0 days	
15	Print registration number	180 days	PB/Mfr.
16	Checklist of registered products	90 days	PB/NMCP
17	Education on unregistered drugs	180 days	NMCP/Districts
18	**3.3 Drug Quality during distribution**	0 days	
19	Work with wholesalers	180 days	NMCP
20	phase out bulk tins	365 days	PB/NMCP
21	**3.4 Post marketing surveillance**	0 days	
22	stop random testing	60 days	PB
23	**4 Appropriate labelling**	0 days	
24	Appropriate labelling	90 days	
25	keep in original packs	90 days	NMCP/Part I,II and shops
26	New requirements for registration	60 days	PB
27	**5. Increase availability through shops**	0 days	
28	Effective communication of regs	90 days	NMCP
29	Promote SP & Amodiaquine	120 days	PB/NMCP
30	Produce smaller bulk packs	180 days	manufacturers/NMCP
31	**6. Control of Part II drugs**	0 days	
32	Stocking Part I drugs at Part II pharmacies	120 days	PB/NMCP/Districts
33	Safety of Parenteral procedures	120 days	NMCP
34	**7. Safety of Private Laboratories**	0 days	
35	close labs in Part II pharmacies	180 days	Districts
36	Educate inspectors	90 days	NMCP/Districts
37	Improve inspection	180 days	Districts
38	Lab owners	365 days	PB/NMCP
39	**8 Consumer Knowledge**	0 days	
40	commercial marketing	365 days	Contractor/NMCP
41	Develop road shows	120 days	contractor
42	Road Shows	270 days	contractor
43	Involve PartII and general shops	90 days	contractor
44	Redesign IEC material	120 days	contractor
45	Laminated Posters	31 days	contractor
46	Promotional materials	90 days	contractor
47	Manufacturers posters	90 days	Mfrs/Contractor
48	Work with CEEMI	270 days	contrator/NMCP/CEEMI
49	**9 Make antimalarials affordable**	0 days	
50	Develop strategies to reduce prices	60 days	PB/NMCP
51	Promote the strategy	90 days	NMCP/Districts
52	Encourage shops to stock SP & AQ	90 days	NMCP/Districts
53	Reduce price of SP in Govt. facilities	90 days	Districts
54	**10 Role of training**	0 days	
55	NMCP start to approve all training for consistancy	0 days	NMCP
56	**11 Planning the Introduction of ACT**	0 days	
57	Strategy for introduction	120 days	NMCP/PB
58	Make ACT affordable	120 days	MoH/PB/NMCP
59	Decide date for introduction	30 days	NMCP/PB