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RECONCILING NATIONAL TREATMENT POLICIES AND DRUG REGULATION IN KENYA

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OPINION/COMMENTARY

Malaria is the second largest public health challenge (after HIV/AIDS) in Kenya, with an estimated 34,000 children dying from the direct effects of infection each year. It accounts for over a third of all consultations in government clinics (DOMC 2001). The typical Kenyan child will use antimalarial drugs at least four times in a year (Spencer et al. 1987). Economic losses due to malaria are also large (Gallup and Sachs 2001). As matters of public policy to reduce morbidity and mortality due to malaria, the medicines to which communities resort must be safe and effective, and efforts to control malaria must complement and not contradict each other. But currently, neither of these areas is successfully addressed, due to a clear disconnect between antimalarial drug registration in Kenya and the National antimalarial drug policy. Three examples illustrate this problem. The first example, albeit now an historical one, is the registration of sulfamethoxypyridazine products for human use in the late 1990s, at a time when the national antimalarial policy stated that only sulfadoxine-pyrimethamine or sulmethoxypyrazine-pyrimethamine (SP) drugs should be used as first line antimalarial policy (DOMC 1998).

Sulfamethoxypyridazine has been considered unsuitable for human use for some years (WHO 1991) and is now generally restricted to veterinary use only. There were at least seven sulfamethoxypyridazine-pyrimethamine products in the Kenyan market in 1998 though these were later withdrawn following a report from the National Quality Control Laboratory (Amin 2005). The second example is the presence of ineffective antimalarial drugs in the Kenyan market. Following the precipitous decline in their efficacy, chloroquine and sulfadoxine/ sulmethoxypyrazine-pyrimethamine were replaced as first-line antimalarial drugs in 1998 and 2004 respectively, (Shretta et al. 2000; MoH 2004), yet these are still being registered today (Table 1) and are widely available (Amin et al. 2005). These two examples point to poor post.-marketing surveillance and recall systems (regulatory failure). Regulation will need to be strengthened not only to protect the market from banned

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substances and inefficacious products, but from the threat posed by counterfeit and substandard products.

A third pointer to a registration-policy disconnect is the licensing of artemisinin-based monotherapies. In recent years, there has been a shift towards combination therapy in malaria to reduce the rate at which resistance develops (Hastings 2001). The WHO now strongly discourages the use of monotherapy for first-line antimalarial drug therapy, and instead advocates 'Artemisinin-based Combination Therapy' (ACT) to try to stem the spread of drug-resistance. Accordingly, Kenya recently changed its policy from sulfadoxine/sulfamethoxypyrazine-pyrimethamine (which, in this context, is a 'monotherapy') to artemether-lumefantrine, an ACT (MoH 2004). But there is concern that the continued availability and use of artemisinin monotherapies may encourage parasite resistance and undermine the effectiveness of ACT in Kenya. In January 2006 the World Health Organization called on local and international manufacturers of artemisinin monotherapies to withdraw such products from African markets voluntarily. Some manufacturers such as Cipla of India have responded positively, but others have not (<http://www.un.org/apps/news/story.asp?NewsID=18437&Cr=malaria&Cr1=>, accessed 17/05/06). In Kenya, as in other countries, drugs are registered on the basis of safety, quality, and efficacy and not on the basis of 'need'. This means that artemisinin monotherapies currently on the market are there legally even though they are deemed to be a threat to the new first-line antimalarial drug policy. In the short term, the Kenyan regulator, the Pharmacy and Poisons Board (PPB), could encourage manufacturers to 1) phase out their products voluntarily and give a grace period over which this can be achieved, and 2) not submit new artemisinin or any other antimalarial monotherapy for registration. If this does not work, in the medium-long term, a change in legislation will be needed to give the PPB the mandate to withdraw these products from the market.

A number of other strategies could bridge the gap between registration and antimalarial drug policy in Kenya. The most obvious is the inclusion of malaria experts in the evaluation of antimalarial product dossiers submitted for drug registration. A complementary approach to this is greater participation of PPB, and professional pharmacy bodies such as the Pharmaceutical Society of Kenya in the Working Groups where policy options for malaria are debated. Greater participation in policy discussion on malaria will extend the PPB's role in antimalarial drug policy changes from only registering products for the market, as if this were an end in itself, to looking at the wider public health impact of deciding whether to register a given product or not.

The consequences of ineffective drug regulation for malaria are many. Antimalarial drugs are consumed by millions of very poor people each year (Snow et al. 2003), and inadequate treatment can rapidly lead to death in those who have yet to develop any clinical immunity (Greenwood et al. 1987). Protecting the future of new medicines, like artemisinin derivatives, from the threat posed by widespread inappropriate use is a global responsibility (IOM 2004). We believe that monitoring the effectiveness of drug regulation regionally and globally is just as important as the monitoring of drug efficacy or parasite resistance. Countries will need help in improving each step of drug regulation, legislation and operations. An international call to ban medicines will only be effective to the extent that countries have the political will and the means to implement it.

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Ineffective (SP and Chloroquine) and counterproductive (artemisinin monotherapies) antimalarial drugs registered in Kenya by the Pharmacy and Poisons Board (PPB) since April 2004 (when policy change to ACT was announced) till June 30 2005

Table 1

	Product	Dosage form	Active ingredient(s)	Manufacturer (Local/International)	Registration date
Sulfadoxine/Sulfamethoxypyrazine-Pyrimethamine	A	Suspension	Sulfadoxine 250mg/ pyrimethamine 12.5mg	Local	19-May-04
	B	Tablets	Sulfalene 500mg/ pyrimethamine 25mg	Local	4-Jun-04
	C	Tablets	Sulfalene 500mg/ pyrimethamine 25mg	Local	8-Apr-04
	D	Tablets	Sulfadoxine 500mg/ pyrimethamine 25mg	International	22-Mar-05
	E	Suspension	Sulfadoxine 250mg/ pyrimethamine 12.5mg	Local	28-Jun-05
	F	Tablets	Sulfadoxine 500mg/ pyrimethamine 25mg	International	19-May-05
Chloroquine	A	Injection	Chloroquine 300mg	International	7-Oct-04
Artemisinin monotherapies	A	Tablet	Artemether 50mg	International	8-Apr-04
	B	Tablet	Artemether 50mg	International	8-Apr-04
	C	Injection	Artemether 40mg	International	3-Nov-04
	D	Tablet	Artesunate 100mg	Local	8-Apr-04