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Malaria healthcare policy change in Kenya: Implications on sales and marketing of antimalarials

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ABSTRACT

Background & objectives: Malaria healthcare policy change in Kenya aimed at improving the control of malaria but faced a number of challenges in implementation related to marketing of the drugs. This research investigated the effect of the change of the national malaria policy on drug sales and strategic marketing responses of antimalarial pharmaceutical companies in Kenya.

Study design: A descriptive cross-sectional design was employed to describe the existing state of antimalarials market in Kenya after the change of the malaria healthcare policy.

Results & conclusion: Policy change did result in an increase in the sales of Coartem®. Novartis Pharma recorded a 97% growth in sales of Coartem® between 2003 and 2004. However, this increase was not experienced by all the companies. Further, SPs (which had been replaced as first-line therapy for malaria) registered good sales. In most cases, these sales were higher than the sales of Coartem®. Generally, the sales contribution of SPs and generic antimalarial medicines exceeded that of Coartem® for most distributors. The most common change made to marketing strategies by distributors (62.5%) was to increase imports of antimalarials. A total of 40% of the manufacturers preferred to increase their budgetary allocation for marketing activities. In view of the fact that continued sale of SP drugs and limited availability of AL poses the risk of increasing the incidence of malaria in Kenya, it is therefore, recommended that pharmacy surveillance systems be strengthened to ensure drugs that have been rendered non-viable or that prescription-only medicines are not sold contrary to the national guidelines.

Key words Artemether-lumefantrine; healthcare policy; malaria

INTRODUCTION

Malaria remains a leading cause of mortality and morbidity in Kenya especially in young children and pregnant women. The World Malaria Report (2012) states that there were an estimated 6 million malaria cases reported in Kenya in 2010 mostly caused by *Plasmodium falciparum* and 26,017 deaths were reported[1]. Malaria is endemic in the Coast Province and Lake Victoria Basin of Kenya. Highland malaria has been reported in Kisii and Kericho districts. In 1992, the Ministry of Health (MoH) in Kenya identified Uasin Gishu, Nandi and Kericho districts as epidemic-prone due to historical experiences with epidemics in 1988, 1989 and 1990[2].

The current national guidelines on malaria in Kenya make provisions for malaria treatment. These recommend artemether-lumefantrine (AL) for uncomplicated malaria. Quinine is recommended for severe malaria, treatment failure and for treatment of both uncomplicated and severe malaria in pregnancy. The guidelines recommend use of intermittent preventive treatment with sulphadoxine-pyrimethamine (SP) to prevent malaria in pregnancy.

One of the main considerations of the first-line drug of choice when policy change is to occur is its efficacy and affordability. Policy change occurs when a particular drug used to manage a disease records a treatment failure rate of over 25%[3]. Chloroquine was widely used to manage malaria in Kenya in the past[4]. However, due to the development of resistance to chloroquine, a new drug, sulphadoxine-pyrimethamine (SP) was adopted as the first-line treatment for malaria in 1998. Sulphadoxine-pyrimethamine going by the brand names—Fansidar® (Roche) and Metakelfin® (Pfizer Laboratories) had a record of treatment failure in Kenya above 25% by mid-June 2001[5].

Coartem® was developed in the early 1980s by Chinese researchers and was taken up by Novartis for further development and worldwide registration after 1992[6]. It has efficacy of 95% but Coartem® is significantly more costlier than the previous first-line choices for the treatment of malaria, namely chloroquine and SP[5].

In 2001, Novartis and WHO signed a Memorandum of Understanding making Coartem®/AL available at cost price through public health services[1]. Novartis provides AL at cost (no profit) to the Kenya government. AL is then distributed free of charge in government-run and mis-

sion hospitals.

The malaria policy change received mixed reactions from different stakeholders in the health sector. Kenya's Pharmacy and Poisons Board, a national drug registration and regulatory body, opposed the adoption of AL as the first line malaria therapy, especially as regards to its single sourcing from Novartis[5]. In addition, other pharmaceutical companies, those market antimalarial drugs in Kenya, have opposed this policy as they see it as a threat to their market share. Some of the multinational companies in Kenya include Novartis Pharma, Glaxo SmithKline, Sanofi Aventis, Astra Zeneca, Bayer and Boehringher Ingelheim[7].

In the light of the relatively recent and rapid change of national malaria healthcare policy, there was a need to examine the effects and responses to these changes elicited in strategies developed and implemented as well as drug sales in the privately-owned pharmaceutical companies to sustain their profitability and survival. The objectives of the study were to investigate the effect of policy change on the sales of Coartem®/AL in Kenya and to identify the marketing strategies employed by antimalarial pharmaceutical companies in Kenya after the change of malaria policy. The study will contribute to the understanding of challenges and opportunities faced by the pharmaceutical firms when healthcare policies change and their implications to the control of infectious diseases such as malaria.

MATERIAL & METHODS

The research undertaken was descriptive in design. The researchers intended to describe the existing state of the antimalarial drug market in Kenya after the change of malaria healthcare policy with a view to examine the effect of policy change on companies sales and strategies.

Population

There are 700 registered wholesale and 1300 retail pharmaceutical dealers in Kenya[8]. For this research, the sampling frame was the East African Pharmaceutical Loci/Drugs Index[7]. This index lists all registered pharmaceutical manufacturers and distributors in Kenya. The researchers identified the pharmaceutical companies that marketed or sold antimalarial medicines as the population of the study. The researcher initially listed all the malaria drugs registered in the country and then traced them to the companies that manufacture or distribute them in Kenya. The population consisted of 52 pharmaceutical manufacturers and their distributors.

Sampling

The sample was selected by purposively sampling distributors who represented more than one antimalarial pharmaceutical company. These were Surgipharm Limited and Harleys Limited (which distributed the product of five companies each), Laborex (K) Limited (which distributed the four companies), Ray Pharmaceuticals (distributed the product of three companies) and C. Mehta, Globe Pharmacy, Medisel (K) Limited, Omaera Pharmaceuticals and Europa Healthcare which distributed the product of two companies each. The rest of the wholesalers distributed the product of one company each. This resulted in a sample of nine wholesalers.

Manufacturing companies of foreign origin that marketed and sold antimalarial drugs were selected from the same list of wholesalers and manufacturers. This was to enable comparison of data on sales and strategies between Novartis Pharma and other companies. This gave a sample of eight manufacturing firms. The total sample of distributors and manufacturers was therefore 17 companies (Table 1). Questionnaires were sent to the sales or marketing managers or their equivalents in various companies sampled. A total of 17 questionnaires were sent out to a selected sample of 17 companies. Out of the 17 questionnaires sent out, a total of 13 were filled and returned. These included eight from distributors and five from manufacturers with a response rate 76.5%. A response rate of 50% is adequate for analysis and reporting, while one of 70% is very good[9].

The research had targeted sales and/or marketing managers as primary respondents. From the data analysis, it was found that the respondents held various positions. For distributors, respondents included sales manager, marketing manager, director, head of the department (sales and marketing), sales team leader, operations manager and pharmacist. The respondents among manufacturers included marketing managers and directors.

Data analysis

The data collected were coded, entered and analysed

Table 1. Sample of distributors and manufacturers

Distributors	Manufacturers
C. Mehta and Company Limited	Dafra Pharmaceuticals
Europa Healthcare Limited	Glaxo SmithKline
Globe Pharmacy Limited	Holley-Cotec Limited
Harley's Limited	Mepha Limited
Laborex (K) Limited	Novartis Pharma Incorporated
Medisel (K) Limited	Pfizer Laboratories
Omaera Pharmaceuticals Limited	Sanofi-Aventis
Ray Pharmaceuticals	Roche
Surgipharm Limited	

using SPSS version 11.5 software (SPSS, Chicago Inc.). From the data obtained, frequency tables, graphs and charts were generated to enable the interpretation and presentation of the findings. Information received from respondents was handled confidentially. The respondents' consent to give information through questionnaires was sought prior to data collection.

RESULTS

Number and formulation of antimalarial medicines were sold

It was found that mostly distributors sold both brand and generic antimalarial medicines. These data were missing for one of the distributors. Among the distributors sampled, 37.5% sold an almost equal number of antimalarial brands and generics 25% indicated that they only sold brand antimalarial medicines while 12.5% sold one brand antimalarial and one generic. This is illustrated in the Fig. 1. The specific names of distributors were withheld (replaced by letters A – H) to observe confidentiality.

Sales contribution of antimalarial brands and generics to total sales of distributors

It was found that Coartem® and its generic variant made the highest contribution to antimalarial medicine sales (56% for Coartem® and 10% for its generic) for one distributor. This was followed by Fansidar® (7%) then Metakelfin® (5%). Fansidar® and Metakelfin® are the brand names for the sulphadoxine-pyrimethamine and sulphamethoxypyridazine-pyrimethamine (SPs) respectively.

For a second distributor, Coartem® made a sales contribution of 0.02% to the total sales, which was lower than the 0.2% contribution from its generic variant. However, the overall highest contributor for antimalarial drug sales for this company was generic Fansidar® (SP) at 0.28%.

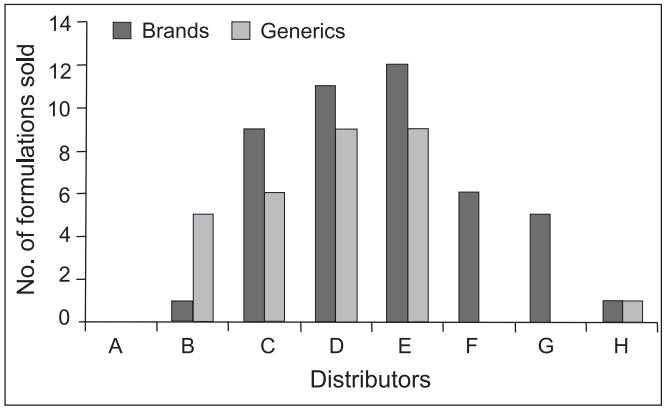

Fig. 1: Graph showing number of antimalarial brands and generics sold by individual distributors (Data missing for Distributor A). Names of distributors were withheld for anonymity.

For this distributor there was generally a greater sales contribution from generic variants rather than the brands. A third distributor had an equal contribution from the various antimalarials medicines towards its total antimalarial medicine sales (33% for each brand). This distributor did not report selling generic variants of antimalarial medicines. It had an equal spread of market demand across the three antimalarial medicines it sold.

A fourth distributor, who specialised in the sale of generics, recorded the highest contribution towards its overall sales from generic Cotecxin® (8%) followed by generic Coartem® at 7%. There was an almost similar contribution to total sales by the two generic variants. The highest sales contribution for a fifth distributor was from the brand Metakelfin® (17.6%) followed closely by Coartem® brand (16%). Another brand SP (Fansidar®) contributed 15% to the total sales of this company. Thus, total sales for SP outperformed sales for AL for this distributor. It was found that a sixth distributor recorded <1% contribution of sales from the Coartem® brand to its overall sales.

In Kenya, the policy change that made Coartem® a first-line treatment for malaria was announced in 2004. Between 2003 and 2004, Coartem® sales grew 97%. A negative growth of –15.5% was recorded for the total Novartis sales over the same period. The growth registered for the sales of Coartem® contrasted sharply with the total sales for Novartis during this period. Between 2004 and 2005, Coartem® sales grew by 5.7% while the total Novartis sales grew 26.7%. Thus, there was a significant dip in the growth curve for Coartem® sales during this period. The total Novartis sales in 2005 represented a growth of 7% over the total 2003 sales. The sales performance of Coartem® for the period 2004 and 2005 dropped significantly as compared to the sales registered during the previous period.

During the period 2005 to 2006, sales of Coartem® grew by 13% and overall Novartis sales grew by 10.9%. Finally, between 2006 and 2007, Coartem® sales grew by 49.5% while the total Novartis sales grew by 10.8%. There was a decline in total Novartis sales between 2004 and 2005 after which these sales appeared to have stabilized. Coartem® sales experienced a steady growth, increasing sharply between the period 2006 and 2007.

In summary, between 2005 and 2007, sales of Coartem® showed a steady increase, while total Novartis sales, initially recorded negative growth and then grew and stabilized at about 10% in the subsequent years. The sales of Coartem® grew 97% between 2003 and 2004, yet the change in policy was made in 2004. A decline in its sales was recorded between 2004 and 2005, when it would be anticipated that sales would grow.

Overall sales performance since change of policy

Among manufacturers sampled, 80% recorded growth in their overall medicines sales since the announcement of Coartem® as first-line therapy for malaria. A larger proportion (75%) of the distributors sampled opined that the announcement of Coartem® as the first-line treatment affected the sales performance of their overall medicines portfolio either positively or negatively while 25% disagreed.

For 20% of manufacturers sampled, there was an increase in overall sales of 5 to 10% since 2004 when policy change was announced. A further 20% of manufacturers reported growth of sales between 10 and 20% since the announcement of Coartem® as the first-line therapy for malaria. Therefore, there was a modest growth in overall sales for the manufacturers since the change in policy was made. The trend in the sales of Coartem® for Norvartis is presented in Fig. 2.

Adjustment of marketing strategy

A total of 87.5% of distributors sampled made changes to their marketing strategies since policy change on malaria while 12.5% did not. Some of these changes included increase in import quantities of the antimalarial medicines sold (50%), participation in malaria policy meetings (25%) and pursuit of partnerships with other companies (12.5%).

There was a variation in the response of manufacturing companies to the change in malaria policy and 40% increased their financial allocation for marketing antimalarial medicines while only 20% participated in health policy meetings.

Therefore, modification of strategies following change in policy differed for distributors and manufacturers. It may be suggested that manufacturers (being foreign owned and partially foreign-managed) needed to consult widely before modifying strategies. Distributors on the other hand, were largely locally owned and managed and were therefore more versatile and proactive in their decision-making.

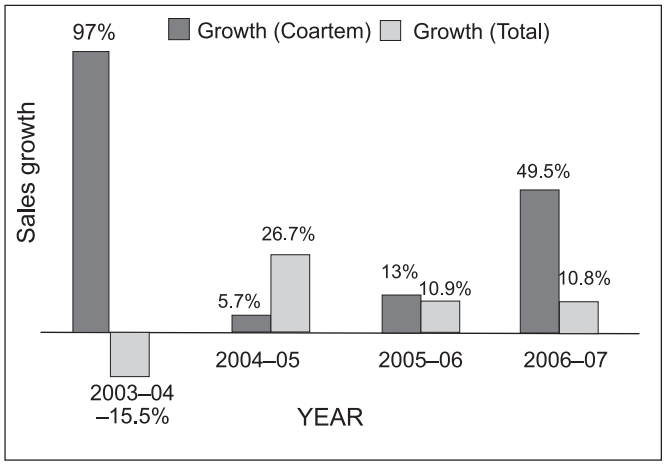

Fig. 2: Graph showing Coartem® sales growth and total Novartis sales growth for the period 2003 to 2007.

DISCUSSION

Policy change and its effect on Coartem® sales

Coartem®, an artemisinin-based combination therapy (ACT) was made first-line therapy for malaria in Kenya in 2004[10]. Despite the announcement of policy change in its favour there was poor translation into actual growth in its sales among distributors. Only one distributor out of the eight respondents had its highest contribution towards sales of antimalarial medicines from Coartem®/AL. This is indicative that policy change did not necessarily translate to high sales of Coartem® within Kenya although it was expected since the new drug had been given prominence by the healthcare policy. Secondly, the SP group of antimalarial medicines, which are officially non-viable and which have recorded high levels of resistance, still recorded good sales. Among some distributors, these sales exceed their sales of Coartem® or of its generic equivalents[5].

The research findings indicated that there were higher sales for generics and other antimalarial medicines than Coartem®. This may demonstrate a lack of awareness of policy change on the ground or poor marketing of the recommended drug. On the other hand, generics are relatively cheaper and readily available. Health policy is developed by the government and health stakeholders (WHO policy brief on malaria 2008). However, there may be a gap in the dissemination of the policy change and its implementation on the ground. In Nigeria, despite the recommendation of ACTs over chloroquine (CQ), <25% of pharmaceutical dispensers were aware of this and still maintained high stock levels of SP (92%) and CQ (72%) with only 9% of their stocks comprising of ACTs[11].

In Kenya, most antimalarial or febrile treatments are purchased over the counter (OTC) in small pharmacy shops often without prescription[12]. The findings of this research indicated that this contributed to high sales of SPs because Coartem® is a prescription-only medicine, hence, should not be dispensed over the counter. In addition, many patients prefer to walk to their nearest pharmacy outlet to purchase medicines at the more affordable cost and in more convenient dosages, so as to minimise costs, hence, contributing to higher sales of SPs[12].

A comparison of Novartis, Coartem® and total sales indicates that policy change in favour of this brand did not influence overall sales; each brand was sold on its own merit. The growth in total sales recorded by both the

manufacturers and distributors since the policy announcement cannot conclusively (or exclusively) be attributed to the policy change.

The spike in growth of Coartem® sales between 2006 and 2007 may have been as a result of implementation of policy change. It should be noted that though the policy change was announced in 2004, implementation of the policy occurred in July 2006[5]. This may explain the sales growth of 13% in the years 2004 to 2005 to 49.5% during the period 2006 to 2007. It is worthy of note that the sales recorded for Coartem® represent private market sales trends. The government procures Coartem®/AL at cost from Novartis and supplies it free at public health facilities. With policy implementation that came 32 months after its initial announcement, every medical practitioner and health worker should have had the new malaria guidelines for implementation. Thus, every malaria prescription ideally should have been for Coartem®/AL whether in the private or public sector. Further, patients are not restricted to procuring their medicines from public hospital pharmacies. Therefore, it is possible that some public sector Coartem®/AL prescriptions were dispensed at private pharmacies at market prices hence contributing to private market sales.

It can be suggested that sales of antimalarials are primarily a "pull" system, where demand is generated from the patients through to the retailer, then to the wholesaler (and back to the manufacturer). Thus, the relatively good sales enjoyed by SPs and generics in Kenya may continue due to high demand generated from the end-users (the patients) on an OTC basis. The findings on sales contributions by different brands agree with the findings of Murrah (as cited in Okoth)[13] that the implementation of the Kenya Industrial Property Act (which recommends parallel importation of medicines) has led to the proliferation of generic medicines, increased competition and reduced profitability. Further, it agrees with findings by Tobin and Pakham[14] that doctors, recognising the need for cost effective prescription and cost minimization prefer to prescribe generics hence lower sales of the brands.

Marketing strategies employed by antimalarial pharmaceutical companies in Kenya

Manufacturers, as compared to distributors, formulated product-specific rather than general strategies. This may be because they have a smaller portfolio than distributors and hence can afford to generate more specific strategies. The most common promotional strategies employed by pharmaceuticals were direct marketing, the giving of gifts and give aways and finally sponsorship of medical events for doctors. Distributors had strategies such as give aways followed by direct marketing and gifts. This illustrates the bargaining and decision-making lee-way enjoyed by manufactures for specific products or product lines. They have more control over the promotional activities and the budgets than do distributors who act as agents. It is note worthy that the strategies employed by both the manufacturers and distributors were similar.

The findings from distributors indicate they had an established presence in the market with strong local ownership. To their advantage, they can import and sell a variety of brands (even competing ones) and so build a strong portfolio. In addition, their knowledge of the local market and their relatively long market tenure makes them attractive to manufacturers looking for relatively easy entry and penetration into new markets, according to Turshen[15], multinational firms (from which developing countries import most of their pharmaceutical products) discourage the local manufacture of inexpensive medicines.

It has been recommended that firms should engage relevant authorities in persuasive factual arguments to take action in their favour[16]. Going by the current findings from the study where 12.5% distributors and none of the manufacturers engaged in lobbying, this remains an area to be exploited by local pharmaceutical companies. Participation in policy meetings and pursuit of partnerships may be viewed as long-term strategies to secure future market leadership. Pharmacy surveillance systems should be strengthened to ensure that medicines that have been rendered nonviable or that are prescription-only medicines are not sold contrary to the national guidelines. This will help protect the efficacy of the recommended drugs and reduce need for frequent changes in the policy.

Companies, especially multinational companies, should endeavour to pursue business partnerships with local manufacturers so that medicines that are relevant to this market are produced locally at reduced cost. This may be through the granting of licences to manufacture particular medicines. Such partnerships can help prevent actions suggested by organisations such as Oxfam and MSF who are encouraging developing countries to violate patents or to engage in parallel importation of medicines[17].

The malaria treatment policy in Kenya states that health policy is implemented in various stages including the training and supervision of health workers consistent with the new guidelines. However, provision should be made to train retail pharmacies and wholesalers as well. Much emphasis is laid on the health sector side; the training of medical personnel, nurses, clinical officers and so on while ignoring the commercial sector. There seems to be a gap between policy announcement and implementation at the point of dispensing medicines. Clearly, what is

being dispensed is largely not what is recommended. If the medical fraternity have the necessary guidelines and are implementing the policy change, sales of SPs (for example) should not be higher than sales of the recommended first-line medicine.

CONCLUSION

The malaria healthcare policy change in Kenya that recommended AL as a first-line drug was not supported by a change in the marketing of the antimalarial with continued marketing of SP drugs. This posed a tangible challenge to malaria control efforts in Kenya. The high cost of AL and the fact that it was a prescription only drug limited access to the new antimalarial. In future, the government should involve pharmaceutical companies in the implementation of the healthcare policy to ensure success.

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