

Willingness and Ability to Use TRIPs Flexibilities

Kenya case study

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2 Sources of supply and pricing/accessibility trends

The providers of health services in Kenya can generally be classified into three categories: public (government) hospitals, ranging from rural/up-country dispensaries to national referral hospitals; mission hospitals and NGOs offering health services⁷; and private hospitals. Each of these generally procure medicines from similar sources but follow different avenues, partly because of government policy in terms of procurement regulations, and partly because of individual institutional policies and needs.

The Ministry of Health regulates all government hospitals and procures medicines on their behalf. It does so by issuing tenders based on anticipated demand and in accordance with the Exchequer and Audit Act (Public Procurement Regulations). These regulations allow, *inter alia*, for a government ministry to employ the services of procurement agents and/or to directly tender for essential medicines under restricted conditions. The Ministry of Health utilizes these procurement procedures according to its particular needs, urgency and purpose. The procurement process employed by the Ministry of Health requires the winning bidders of a tender to deliver the essential medicines either directly to public hospitals or to the Kenya Medical Supplies Agency (KEMSA).⁸ KEMSA in turn supplies public hospitals based on a “push” system, although current initiatives aim at moving this to a more demand driven, “pull” system.

The sources of essential medicines for public hospitals are varied and depend on the type of drugs procured, but include proprietary drugs imported from developed countries, generic imports, and generics produced domestically. Over the years the bulk of drugs supplied to public hospitals were imported from pharmaceutical industries based in developed countries. These sources from developed countries consist of two sub-categories: supply in fulfilment of contractual agreements with the Ministry, and donations. Generic manufacturers in other developing countries, especially India, have also been an important source of supply of essential medicines for public hospitals, second only to quantities supplied by pharmaceutical manufacturers in developed countries. Domestic generic manufacturers are a third source of supply for the Ministry of Health, but this has been by far the smallest. However, the government, since mid-2002, seems to be moving slowly towards increasing the supply quota for domestic generic manufacturers as recent tender awards have shown⁹, especially with regard to

what the local manufacturers can produce. Thus local manufacturers are currently said to be supplying the Ministry of Health with over 60% of the non-injectable essential drugs while over 80% of injectable vaccines are being sourced from pharmaceutical manufacturers in developed countries.¹⁰

Since June 2002, mission hospitals and NGOs have been relying mainly on generic manufacturers, both local and foreign (including European generic manufacturers),¹¹ as their source of essential medicines, though they also source branded medicines, depending on availability and needs and on the patent and registration status of the particular medicine. These hospitals and NGOs are not bound by the government procurement regulations and instead rely on intermediaries to procure their requirements. Mission hospitals procure their essential drugs mainly through Mission for Essential Drugs and Supplies (MEDS)¹², while most NGOs procure from Centrale Humanitaire Medico-Pharmaceutique (CHMP), a non-profit organization affiliated to Pharmaciens San Frontières (PSF).

Unlike public and mission hospitals, private hospitals procure medicines on an individual institutional basis. One of them, Mater Hospital, has a policy of stocking a generic version for every branded drug and of using a 'just-on-time' supply system. This means that little drug stock is usually held. The sources are mainly pharmaceutical industries in developed countries, most of which have local marketing offices or distributors, and Indian and Chinese generic manufacturers through their local distribution agents. The level of supply from local generic manufacturers is low. Because private hospitals are profit-making entities, they do not generally engage in sourcing essential medicines directly from manufacturers, partly because of efficiency and human resource reasons and partly because of their policy of concentrating on their core business - treatment.

2.1 Domestic Supply

Kenya's generic manufacturing industry is characterized by an investment worth over US\$40 million by the three most active pharmaceutical manufacturers.¹³ These pharmaceutical manufacturers have been operating in an environment characterized by poor economic growth over the last decade.¹⁴ The last decade also witnessed an increased incidence of absolute poverty, especially between 1994 and 1997. It is estimated that over 50% of its population live below the poverty line.¹⁵ Its productive enterprise R&D investment per capita is less than 1 US cent and patents per 1,000 people falls below 0.0001.¹⁶ Aggregate R&D activity is therefore very low and this restrained environment in turn constrains domestic pharmaceutical manufacturers.

The relatively small domestic pharmaceutical industry in Kenya is beset by a number of problems that make it difficult to grow and to become more competitive nationally and



regionally. Although the pharmaceutical industry is characterized by a large number of registered manufacturers, mostly based in Nairobi and its environs,¹⁷ only close to a third of these are actively engaged in the actual manufacture of drugs, particularly generics: Cosmos Limited, Laboratory & Allied Limited, Elys Chemical Industries Limited, Regal Pharmaceuticals Limited, Biodeal Laboratories Limited, Pharmaceutical Manufacturing Company, Beta Healthcare International Limited, Nairobi Enterprises Limited and Universal Pharmacy (K) Limited.¹⁸ Whereas the Kenya Essential Drug List heavily influences their product lines,¹⁹ local production capacities are hampered by a myriad of internal factors, such as ageing manufacturing facilities and use of obsolete or inefficient technologies.²⁰ Moreover, these local manufacturers have very limited production capacity and engage in minimal research and development. What R&D there is in the pharmaceutical sector is restricted to innovation in manufacturing processes rather than innovative pharmaceutical products.

The main external factor impeding expansion of local production capacities is non-availability of local primary, secondary and tertiary ingredients. Local manufacturers do not possess technology to refine pharmaceutical raw materials to acceptable pharmaceutical standards. Thus almost all active pharmaceutical ingredients (APIs) are imported from India, China and other developing countries. The cost of production is also generally high due to poor infrastructure and an antiquated communications system. Electricity, the only source of industrial energy, is also very costly.²¹

Inadequate market-size or “lack of a market”²² is also an oft-cited factor. In seeking efficient economies of scale for a number of products, Kenyan manufacturers often need to supply both Kenyan and non-Kenyan markets. Exacerbating the market-size problem is that none of the local generic manufacturers are WHO pre-qualified.²³ Thus, even with Kenya being a beneficiary of the Global Fund to Fight Tuberculosis, Malaria and AIDS (GFTAM) and World Bank (WB) health programmes, the Ministry of Health will not be able to source locally-produced drugs using funds from these programmes after December 2004. Instead, procurement from the local generic manufacturers will be limited to funds allocated in the national budget.

As a source of supply for essential medicines, increased local production could have favourable effects on availability, but unfavourable effects on affordability, given current cost disadvantages in the industry. With regard to availability, the fact that most of the essential medicines have to be imported means that in the event of shortages from the foreign sources, local industries cannot cover the shortage; this problem occurs frequently. The case for affordability of locally-produced medicines is largely negative - the lack of capacity to manufacture pharmaceutical ingredients and high production costs impact negatively on price, and ultimately on quantity. Both these factors will be exacerbated in the near future when the Protocol on the Establishment of the East Africa

Customs Union comes into force later in 2004²⁴. The Protocol proposes, under Article 11, to impose a 10% tax on goods imported into the Union, and also on goods from Kenya exported to Uganda and Tanzania. If importers of essential medicines and APIs will pass this tax burden to the consumers, then prices of these medicines will increase. This tax will, however, be phased out gradually over a period of five years from the date the Protocol will come into force.

2.2 International Supply

In general terms, international supply of pharmaceutical products into Kenya can be classified into two categories: as a source of supply of APIs for local generic manufacturers and as a source of finished pharmaceutical products (FPPs), whether branded or generics. As stated earlier, APIs are not locally manufactured and thus all pharmaceutical generic manufacturers in Kenya rely on foreign API sources, mostly from India and China. This has a cost and price effect on the generic FPPs manufactured locally.

FPPs sourced internationally, either proprietary or generic, can be further sub-classified as purchased or donated.

As stated earlier, international FPPs, both brand name and generic, are the main source of supply of essential medicines in Kenya. Brand name or proprietary FPPs are ordinarily considerably more expensive than their generic counterparts, but generic equivalents are ordinarily not available for on-patent medicines. The market price of imported FPPs is based on several factors including patent status, number of competitors, cost, insurance and freight (CIF) costs, tax and duties²⁵ paid at the point of entry, distribution and storage costs related to importation. This complex system of costs certainly affects the affordability of essential medicines.

Apart from cost issues, shortages of essential medicines, particularly anti-retrovirals (ARVs), occur frequently, particularly in government hospitals. For example, in early March 2004 most public and private hospitals experienced a shortage of efavirenz (brand name *Stocrin*), a drug manufactured by Merck and used in ARV treatment. For HIV/AIDS patients, constant availability of ARVs is essential for treatment efficacy. Shortages, which in turn affect adherence to treatment, can lead to serious potential consequences ranging from development of resistance to first line treatments to, ultimately, death of HIV/AIDS patients.

Donated FPPs cause market distortions that can affect choice of treatment regimes, the emergence of competitive markets, and the long-term costs of treatment. Accordingly, pharmaceutical donations are highly scrutinized and their long-term costs must be



weighted against any short-term gains. In this regard, it is particularly important to note that drug donations can deter expansion of the local pharmaceutical industry and/or the development of a foreign generic industry that can sustainably supply procurement needs on an affordable basis.²⁶