The role of local manufacturers in improving access to essential medicines

Creating opportunities for the scale-up of local pharmaceutical production

The local manufacturing of pharmaceuticals is a hotly contested issue in many countries. It runs to the heart of key concerns such as quality, availability, and price of medicines (as well as the broader issues of economic development and trade). Within the Medicines Transparency Alliance (MeTA) – a multi-stakeholder initiative that has the active participation of government, the private sector and civil society working together to solve problems and improve transparency and accountability around access to medicines in seven countries – this debate is active. In this article, Nazeem Mohamed, co-Chair of the MeTA Uganda National Council and Chairman of the Uganda Pharmaceutical Manufacturers' Association (UPMA) sets out some of the arguments of the local manufacturers.

In Uganda, five large and six small-scale pharmaceutical manufacturing companies operate. This number, if functioning at full capacity, is capable of meeting the demand for supply of many of the essential drugs to the population of Uganda. However, in practice, this is not happening. The industry continues to face challenges that threaten its growth, and even, potentially, its existence.

The Uganda Pharmaceutical Manufacturers' Association (UPMA) is a registered association in Uganda of registered companies licensed by the National Drug Authority to operate a pharmaceutical manufacturing business in Uganda. The pharmaceutical industry in Uganda is made up of the local pharmaceutical manufactures, importers, wholesalers and retailers, and the Government through its regulatory arm. Civil society organisations also have a role to play to advocate for change in the medicines industry and to hold people to account. The multiple players involved make it a complex industry in which to initiate change. It is for this reason that UPMA are participating in the Medicines Transparency Alliance (MeTA) Uganda.

Challenges to local manufacturers

The challenges that local industry face are not small. Many difficult conditions have a multiplying effect resulting in stagnation and denying opportunities to contribute to the growth of the economy through job creation and investments. This article looks at a few of the challenges that are of significant importance to the pharmaceutical industry.

High cost of operations

The high cost of capital coupled with lack of incentives means that local companies are not borrowing money to carry out expansion and modernisation programmes.

High cost of energy

The high cost of energy has made it difficult for local companies to realise their full manufacturing potential. They are often forced to take tactical measures such as producing only at times when power is available from the national grid. The power interruptions also create wastage of reagents and other chemicals that are used in the quality control labs where the tests have been interrupted.

Unfair competition

Local industry faces unfair competition, particularly on price, from imported finished pharmaceutical products from counties such as India and China. In these countries, governments have instituted subsidy policies that enable manufacturers to lower export prices and still retain good margins. Because Uganda is predominantly supplied with generic finished pharmaceutical products, this has encouraged the registration of low-cost generic products at the expense of advancing pharmaceutical manufacturing in the country.

The biggest buyer in any country is the Government. Because price has become the most single important criterion for buying, local companies are often left out in tenders. UPMA have been advocating for price differential between international bidders and local industry, a practice that is carried out in many neighbouring countries such as Tanzania and Kenya.

India's story to counter competition

India succeeded in developing its pharmaceutical manufacturing sector because the Government under-

A quality control lab: at the mercy of power interruptions

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stood from the onset that the primary market for locally manufactured goods is at national level.

The biggest trading partner in pharmaceutical products with Uganda is India, which currently supplies around 60% of the country's pharmaceutical imports. A vibrant local pharmaceutical industry in India was built through industry-friendly laws:

- India has a stringent licensing system that acts as an entry barrier to foreign involvement. This has created a captive market for the local manufacturers.
- There are high tariffs for imported finished pharmaceutical products leading to high cost of importation and high market prices. Again, this minimises foreign participation in the market place.
- There are subsidies for export products resulting in lower export prices which motivate destination countries, predominantly Africa, to receive imported finished products from India.
- There is a Monopoly and Restrictive Trade Practices (MRTP) Act which restricts growth or domination by one company.

It is, therefore, encouraging to see that regulation controls have been used successfully in India and many developing and developed nations to provide the local industry with competitive advantage against unlimited foreign participation.

Meeting standards

Most local manufacturing companies cannot access donor funds due to very stringent compliance conditions attached to ensure that the quality of medicines is good. To qualify for the funds, local industry must meet the World Health Organization's pre-qualification standards. No one company from the region has been able to attain such status. In the whole of Africa there are currently only two companies that have reached these standards. Local industry needs more support from government and other bodies to increase their capacity to meet these requirements if local industry is to flourish.

Inadequate research and development

As with many of the least developed countries, Uganda lacks funds, skills, and advanced technology to drive forward research and development. This leads to companies sticking to 'me-too' products.

The market

The pharmaceutical market in Uganda is worth around US$200 million, although no official data are available. It is estimated that between 80 and 90% of the products are imported from countries such as India, and increasingly from China. The vast majority of pharmaceutical wholesalers are also importers and this trend is on the increase. Because of very significant amount of donor funding to the public sector, the private market segment has declined over the years to approximately 30% of the total market.

In the areas of malaria, tuberculosis, and HIV/AIDS there is virtually no private market. Donor funding and funds from the G8 countries, through government

'Blistering'. The high cost of a machine like this puts it out of reach for most local companies

A raw material store: 80–90% of Uganda's pharmaceutical products are imported

procurement agencies, have been used to provide the necessary medicines to the public sector. This is a worthy achievement, but one which should not prevent efforts to produce medicines locally.

The market is essentially generic, with price being the major determinant factor for purchase and use. The choice of drug is mostly in the hands of the retail pharmacy, which is normally managed by a trader and not a professional pharmacist, who has to make the difficult balance between professionalism and commercial benefits. The latter is always more attractive, leading to the obvious choice of low-cost high-margin products. So local production faces competition challenges even at the consumer level.

The Government

The Government's policy is to promote local manufacturing of pharmaceutical products, but proper legislative framework within which the policy can be implemented is not yet in place. In 2006, and after many years of collaboration between the industry, Ministry of Health, National Drugs Agency, and Ministry of Finance, the East African Community imposed a 10% tax on all imports of finished pharmaceutical medicines to the East African states with the exception of anti-malarials, antiretrovirals (ARVs), and tuberculosis (TB) drugs which the countries have continued to receive through donor funding. Following intense lobbying from multi-national companies the law was repealed after only a few months. The reason advanced by the multi-nationals was that the tax would increase the price of medicines to the end consumer and thus reduce accessibility. However, retail margins in the region are so high that a 10% tax would have no significant effect on the consumer prices. This was demonstrated in Tanzania, where the Government had re-introduced the 10% tax in order to support local manufacturing. The prices of medicines in Tanzania did not increase after re-introducing the tax.

Many African countries find themselves in a similar situation. Some however, have implemented industry-supportive policies that have motivated local manufacturing. The results have been phenomenal with rapid growth in the industry.

For example, the Government of Nigeria banned importation of a long list of drugs that are manufactured locally, resulting in the local manufacturing industry supplying more than 30% of all medicines in the country. This has been a huge incentive to investors and there are now over 80 local pharmaceutical manufacturing companies in the country.

The Government of Ghana introduced a system whereby medicines are grouped in three categories:

- Category 1: medicines provided only through local production.
- Category 2: medicines that can be imported but attract tax.
- Category 3: medicines imported free of tax. In the case of Ghana there is a consistent attempt by the authorities to raise the price entry barrier in order to free market space for greater participation by local companies.

There are clear lessons to be learnt from other countries. The issues about the quality and price of medicines are critical to the development of local industry and to whether people in Uganda are able to access good quality medicines at the right price. At UPMA we would like to see a vibrant industry within Uganda itself. This requires support from the Government and other bodies. Participation in the Medicines Transparency Alliance Council is a key way for local companies to put forward their concerns, advocate for change, work with other stakeholders such as the Government, and ultimately increase the availability of essential medicines to the people of Uganda.

www.MedicinesTransparency.org
MeTA is a multi-stakeholder alliance working to improve access and affordability of medicines for the one-third of the world's population unable to access essential medicines due to high cost or local unavailability.

Africa HEALTH CPD Challenge

See page 78 to test yourself on this article