



The push for local production, costs and benefits – A case study of Uganda’s Quality Chemicals



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Abstract

Many Africans lack access to essential medicines. There are myriad reasons for this: poverty, lack of awareness about the need for treatment, confusion over which drugs to take, technical and logistical challenges in procurement and distribution combined with a general lack of local healthcare staff and infrastructure, among other cultural and political factors.

One additional problem is the relatively high price of drugs, which the international community has prioritized by encouraging competition from various generic producers often through compulsory licensing. The latest cost-reduction strategy is the push for local drug production. But, as shown by the start-up problems of Quality Chemicals Industries Limited in Uganda, many burdens and barriers to access continue to seriously hinder the success of such enterprises. Indirect government subsidies to exporters selling into African markets, and pressure by donors and lobbyists on innovator producers to offer developing countries subsidized prices, actually undermine the competitiveness and viability of these nascent firms. Furthermore, the focus on drug pricing and local production can actually undermine the overall aim to increase access to medicines.

Introduction

“Essential medicines save lives and improve health when they are available, affordable, of assured quality and properly used.”⁴ Still, a lack of access to these life-saving medicines in developing countries remains one of the most pressing global public health concerns. Believing price was the primary barrier to accessing effective drugs in developing countries, the international health community has implemented a variety of strategies to lower prices for these countries in recent years. It has actively pushed for more competitive and efficient drug procurement practices, for instance, which encouraged more companies (especially in India) to produce copies of innovator products, increasing drug supply, and driving prices down.

The international community even altered World Trade Organization rules in its attempt to find a solution to access by allowing the breaking of patents on life-saving drugs through compulsory licensing, despite any long term effects this might have on innovation. The international community has also tried to increase the affordability of on-patent drugs in developing countries by encouraging innovator companies that it is in their own self-interest to tier their drug prices (whereby firms set prices based on the conditions in a particular market, effectively lowering drug prices for developing countries). Some companies were tiering prices for some drugs already but there was inertia within nearly all large multinational companies to make it a global practice. This was often because of other considerations, such as limited qualified staffing in poorer nations which meant selling fewer drugs at higher prices was easier for companies to manage, even if in principle not economically optimal. Despite these efforts, access to medicines remains limited for a variety of reasons, the most important, widespread poverty, having nothing to do with pharmaceuticals. Yet the international community continues to look for a quick solution.

⁴ “Equitable Access to Essential Medicines: A Framework for Collective Action, No. 8” *World Health Organization (WHO) Policy Perspectives on Medicines No. 08* (2004) Available at: <http://apps.who.int/medicinedocs/en/d/Js4962e/1.html>

Today, it is hoped that encouraging and promoting local production of pharmaceuticals in developing countries will also serve to bring the price of drugs down for these countries, and thereby increase access. Local production might serve this purpose in a variety of ways: it could lower transportation costs and hence overall costs; it could increase the number of producers in a local market, increasing both supply and competition, which over the long term should drive drug prices down and hence increase access.

Local production can also have significant industrial benefits for a developing country, such as increasing employment. It might also increase domestic expertise in the production of medicines for key local diseases and cut dependence on foreign suppliers, which although not an economic problem could be a political one. For these reasons, promoting local pharmaceutical production in developing countries is not only seen as a potential solution to the problem of public access to medicines, but is also seen as having other valuable socioeconomic benefits as well.

However, reviewing the underlying theoretical assumptions of local production should give one pause before assuming that local production is a viable, or beneficial, option for all developing countries to pursue, especially when it comes to the pharmaceutical industry.

If a country does not have capacity for competitive pharmaceutical production (the criteria for which will be discussed in a later section), then many of the theoretical benefits of local production are not likely to be realized. If production is driven by market forces over time then it is likely to become increasingly efficient. But production driven by aid agencies or through short-run government-backed contracts may actually lead to serious failure; both these entities tend toward simplistic short-term solutions, which ignore deeply rooted systemic dysfunctions and logistical challenges, and create artificial incentives while crowding out private sector responses.⁵

Such initiatives are often politically motivated, and may not be economically viable or socially responsible; after all, protecting a local producer against a more efficient and competent importer rigs the market to the detriment of the consumer's pocket, or the patient's health. Furthermore, government-backed entities are often treated more leniently than independent firms by enforcement agencies. In the case of government-backed locally-produced pharmaceuticals this is particularly dangerous as it could result in an increase in substandard drugs entering the market from local producers who are not technically competent or sufficiently regulated.⁶

The decision about whether pharmaceuticals should be imported (fully or partially finished) or supplied through local production is a difficult one, "and simultaneously involves health policy, industrial policy, and development; it is part of the debate about how best to provide needed medicines to those least likely to afford them."⁷ For wealthy nations, the importation of drugs is

⁵ Roger Bate, "Paging Dr. Ricardo," *Health Policy Outlook* no. 1 (February 2008) Available at: <http://www.aei.org/outlook/27447>

⁶ Roger Bate, "Thailand and the Drug Patent Wars," *Health Policy Outlook* no. 5 (April 2007) Available at: www.aei.org/publication25890/

⁷ Warren Kaplan and Richard Laing, "Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines." *Health Nutrition and Population Discussion Paper, The World Bank* (January 2005) p.2 Available at: <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/KaplanLocalProductionFinal.pdf>

largely driven by private sector demand, even if most of the drugs are procured through the public sector. But in many poorer nations there is limited effective private demand and therefore many decisions will rest with individual governments, and sometimes the international community.

It is important that the international community knows more about local production in practice, before promoting this ‘solution’, especially since many local governments may see worth in promoting local production for political reasons, even if it results in more expensive and lower quality drugs.

As the major funder of drugs for developing countries, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) (of which the US Government is the largest donor) continues to increase the size of the global procurement market by encouraging more firms, international and African, to produce drugs. Other agencies, such as the German Agency for Technical Cooperation (GTZ), also encourage local production and even invest resources in local companies in helping them to meet international standards.⁸ Looking at experiences of developing countries in establishing local pharmaceutical industries, and at the underlying set of criteria generally needed for these industries’ success, this paper discusses whether local production is a viable strategy for many developing countries, particularly in Africa. A case study of local production in Uganda highlights the experience of one local producer in particular: Quality Chemical Industries Limited.

Background

Since independence from British rule in 1962, Uganda’s post-colonial history, like that of other African countries in the Great Lakes region, has been plagued by chronic political turmoil, regional instability, persistent civil wars and economic policies that have undermined trade, commerce and freely functioning markets, all of which have taken a heavy toll on the country’s development. Rampant and widespread infectious diseases have flourished in the politically uncertain environment, exacerbating already high poverty rates and stifling long-term economic growth by incapacitating a part of the labor force, lowering productivity, and decreasing outputs. Though the country has made significant progress over the past decades in combating HIV/AIDS—cutting infection rates in urban antenatal clinics from 31 percent in 1993 to 14 percent by 1998, and to just 6.4 percent in 2007^{9,10}—today, the biggest public health challenge facing Uganda is malaria.

With over 95 percent of its population living in areas at risk of contracting the disease year-round, malaria is highly endemic in Uganda.¹¹ Stable transmission rates nationwide, with relatively little seasonal variability, render malaria the leading cause of morbidity and mortality

⁸ “The Viability of Local Pharmaceutical Production in Tanzania,” *GTZ* (2007) Available at:

<http://www2.gtz.de/dokumente/bib/07-0300.pdf>

⁹ “Uganda Reverses the tide of HIV/AIDS,” *World Health Organization* Available at: <http://www.who.int/inf-new/aids2.htm>

¹⁰ “National HIV/AIDS Strategic Plan 2007/8-2011/12: Moving towards access,” *Uganda AIDS Commission (UAC), Republic of Uganda* (2007) Available at: <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1151090631807/2693180-1151090665111/2693181-1155742859198/UgandaNSP25Oct07.pdf>

¹¹ “Uganda: Progress and Challenges toward SUFI,” *Roll Back Malaria Report* Available at: www.rollbackmalaria.org/countryaction/uganda.html

in the country, killing an estimated 320 Ugandans each day, mostly pregnant women and children.^{12,13} In addition to these human costs, malaria also represents a significant burden on Uganda's national health system; not only does the disease account for an estimated 30-50 percent of outpatient visits at health facilities, but it is also responsible for 15-20 percent of all hospital admissions and as much as 14 percent of all hospital deaths.¹⁴ The economic costs of the disease are equally heavy, including diminished worker productivity, healthcare expenses, time away from work, and absenteeism from school.¹⁵ It is therefore obvious that Ugandans need high quality and affordable anti-malarial drugs year-round.

In the past, the mainstay of malaria control in Uganda has been treatment of clinical cases with anti-malarial drugs such as chloroquine (CQ) and sulfadoxine-pyrimethamine (SP). In 2004, however, growing parasite resistance to these common drug treatments nationwide prompted a policy shift. The Ugandan Ministry of Health adopted the newest generation of anti-malarials for its first-line treatment against uncomplicated malaria. Known as artemisinin-based combination therapies (ACTs), these dual therapy treatments are recommended over monotherapies as they reduce the risk of parasite resistance developing to each individual drug.^{16,17} Despite the proven efficacy of these drugs and the simplicity of their administration for patients, several systemic problems significantly hamper their uptake.

In 2004, GFATM (the biggest donor for anti-retroviral drugs (ARVs) and ACTs in Uganda) awarded a US\$137 million grant to Uganda to "support the introduction of highly effective artemisinin-based combination therapy malaria treatment" in the country.¹⁸ While these funds were earmarked for the procurement and distribution of ACTs through public health facilities and health centers, several obstacles have hindered their roll-out. First, the costs of these effective treatments were significant. There were both problems and delays associated with the procurement process itself, including uncertain forecasting of demand for anti-malarials which complicated manufacturers' production schedules. A variety of major logistical distribution bottlenecks also hampered public access to these donor funded ACTs, including coordination challenges between the Ugandan Government, the third party procurement agent, Crown Agents, and in-country parastatal distribution bodies responsible for the delivery of drugs. A general lack of adequate human and financial resources at both the district and individual health center levels compounded these barriers to access.

¹² "Uganda Malaria Operational Plan (MOP) FY 2008," *President's Malaria Initiative Report* (2008) p. 9 Available at: http://www.fightingmalaria.gov/countries/mops/uganda_mop-fy08.pdf

¹³ "Uganda mounts a major fight against malaria in northern districts," *UNICEF* (19 November 2008) Available at: http://www.unicef.org/health/uganda_46447.html

¹⁴ "Uganda Malaria Operational Plan (MOP) FY2008," *President's Malaria Initiative* (2008) p.10

¹⁵ Greenwood BM, K. Bojang, C.J. Whitty, and G.A. Targett, "Malaria," *The Lancet* 365(9469): 1487-98 (23 April 2005) doi:10.1016/S0140-6736(05)66420-3

¹⁶ Rogers et al, "Failure of artesunate-mefloquine combination therapy for uncomplicated Plasmodium falciparum malaria in southern Cambodia," *Malaria Journal* (January 12, 2009) Available at: <http://malariajournal.com/content/8/1/10>

¹⁷ Bill Brieger, "ACT Treatment Failure - reality today...or tomorrow," *Malaria Matters* (14 February 2009) Available at: <http://www.malariafreefuture.org/blog/?p=644>

¹⁸ This is the allocated amount. Of the total grant money for Round 4, disbursement details suggest that not all of the money allocated for Phase 1 (\$66 million) were disbursed--only \$59 million was. Additionally, the total amount was reduced from \$159 million to \$137 million. Though the grant report card is broadly favorable of Uganda's use of this grant, indicator 1.3 on page 9 of the Grant Performance Report indicates that the number of ACT doses procured during phase 1 was only 67% of what they anticipated. Phase 2 information for the grant is not available yet, but the amount disbursed in Phase 2 is dependent on a GFATM evaluation of their progress in Phase 1. Available at: <http://www.theglobalfund.org/en/commitmentsdisbursements/>

Today, ACTs purchased with GFATM money are distributed to public health facilities across Uganda and are meant to be given to patients free of charge. But corruption in health facilities, theft of stock for private sale, and general mismanagement exacerbate the potential for stock-outs, on top of the various supply and distribution problems previously mentioned.¹⁹ Recently, there have been allegations and reports about public health workers diverting ACTs away from the shelves of public health facilities, only to sell the donated drugs to private practitioners for personal profit.²⁰ There have also been allegations of health workers, including doctors, who knowingly withhold donated drugs from patients and refer them to purchase treatments from private practices for additional compensation.²¹ Leakages of donated ACTs from the public to the private sector limit public access to effective anti-malarials in Uganda as ACTs in the private sector are far too expensive for the majority of the population to afford. The average cost of ACTs ranges from US\$8-\$10²², which is thirty to sixty times more expensive than other, less effective anti-malarials, which can also have nasty side effects. Since these drugs are also available in private drug stores throughout the country patients often choose outdated but lower cost (approximately US\$0.20) treatments such as CQ, SP, or quinine, even despite the failure rates of these drugs. The Ugandan Government has banned the sale of most monotherapies due to their ineffectiveness but old stocks are still widely available.²³

The Government of Uganda has not always helped itself in its struggle against malaria either. In 2005, Uganda was temporarily suspended from receiving GFATM funding (\$367 million earmarked for ARVs, ACTs, and other resources) due to malfeasance that led to the misappropriation of millions of aid dollars.²⁴ Serious allegations of corruption and the mismanagement of funds involved the former Minister of Health, Maj. Gen. Jim Muhwezi, and several senior ministry officials including Cpt. Mike Mukula and Alex Kamugisha.²⁵ Still, only a few months after the suspension of these funds and before any public inquiry was conducted, GFATM grant money to Uganda began flowing again. In fact, GFATM admitted later in a press release that, “funding for life-preserving program activities in Uganda were maintained during the entire suspension period.”²⁶ Unfortunately such leniency on matters of corruption tacitly encourages further corruption (as has been seen in great detail in neighboring Kenya).²⁷ Therefore, though the international community has done much to assist Uganda in combating malaria and other diseases, its oversight of corruption and logistical problems leaves much to be desired.

¹⁹ Maureen Lewis, “Governance and Corruption in Public Health Care Sectors,” *Center for Global Development* (January 2006) Available at: www.cgdev.org/files/5967_file_WP_78.pdf

²⁰ John Njoroge and Molly Lister, “Hands on Minister gets shock in Clinic,” *The Independent* (21 July 2009) Available at <http://www.independent.co.ug/index.php/component/content/article/79-news-analysis/1292-hands-on-minister-gets-shock-in-clinic?format=pdf>

²¹ Ibid

²² “Understanding the Anti-malarials Market: Uganda 2007.” *Medicines for Malaria Venture, the Uganda Ministry of Health, HEPS, and WHO* (August 2008) Available at: http://www.mmv.org/IMG/pdf/Uganda_Antimalarials_Market_report_MMV_2007_FINAL_.pdf

²³ Peter A. Winstanley, Steven A. Ward and Robert W. Snow, “Clinical status and implications of anti-malarial drug resistance,” *Microbes and Infection, Volume 4, Issue 2* (February 2000) p.157-164.

²⁴ “Uganda Global Fund Declines Grant as questions linger over financial management,” *IRIN* (13 March 2007) Available at: <http://www.irinnews.org/Report.aspx?ReportId=70669>

²⁵ “Uganda Shaken by Fund Scandal,” *The Washington Times* (16 June 2006) Available at: <http://www.washingtontimes.com/news/2006/jun/15/20060615-111737-2004r/>

²⁶ “Global Fund Lifts Suspension of Uganda Grants,” *Global Fund Press release* (10 November 2005) Available at: http://www.theglobalfund.org/en/pressreleases/?pr=pr_051110

²⁷ Michaela Wrong. “It’s Our Turn to Eat: The Story of a Kenyan Whistle Blower,” Harper Collins. New York (2009)

It is within this broadly successful, but rather chaotic system of malaria control, that the Government of Uganda has recently pushed for local pharmaceutical production as a solution for many of these problems and that one Ugandan business (backed by the Ugandan Government) has responded to the challenge of improving access to drugs: Quality Chemical Industries Limited.

Local Production - A solution to local access?

The local production of pharmaceuticals refers to the production of drugs or other treatments by firms located in (and or owned by) a country, that are specifically tailored to meet the demands of the market in that country (i.e. Ugandan pharmaceutical firms that produce anti-malarials specifically for the Ugandan market). The term “local,” however, can take on several meanings depending on whether a strict ownership or economic perspective is adopted in considering production, so that local producers may include national firms, with sale activities strictly within the country, or multinational firms, which carry out only part of the production process within the country.²⁸ As each of the three levels of pharmaceutical production (primary, secondary, and tertiary) can be undertaken locally, local production includes a variety of products: primary production includes the manufacture of active pharmaceutical ingredients (APIs) and intermediates; secondary production includes finished dosage forms; and tertiary includes the packaging and labeling of products.²⁹

There are many reasons that a government might want its own companies to make essential medicines rather than have to buy from abroad, including: unreliable suppliers; questionable drug quality (from other developing country producers); avoidable costs (i.e. transportation costs) and difficulties involved in forecasting demand when preordering supplies.³⁰ In theory, local production seems like an attractive solution to many of these problems. Secondary, more industrial, reasons for a developing country wanting to promote local production might also include the desire to create a new employment base, increase transfers of technology and knowledge, enter a new export market, cut dependency on foreign suppliers, and better manage otherwise negative foreign exchange flows.³¹ Though local pharmaceutical production can have industrial benefits for developing countries, the extent to which it can provide increased access to medicines varies considerably from country to country.

For local production to be successful and competitive it requires a constant supply of inputs, such as organic chemicals and biological agents like enzymes, as well as constant energy, clean water, skilled expertise, and advanced technology; without consistent supplies, the manufacturing of local drugs can be unreliable and in some cases, dangerous. Even if drug production is of acceptable quality, local producers must still be as efficient as foreign suppliers in order to succeed or they will fail in the face of competitors offering lower prices for the same product. Often, when nascent pharmaceutical companies lack the capacity needed to compete in the international market on their own, their respective governments will protect them from more

²⁸ Kaplan & Laing (2005) p.6

²⁹ “An intermediate is a material produced during steps of the processing of an API that must undergo further molecular change or purification before it becomes an API.” Kaplan & Laing (2005) p.4

³⁰ Ibid, 1

³¹ Ibid

efficient foreign producers. Such action can result in higher drug prices and lower access because there are fewer cheap foreign drug supplies.

A recent World Bank study compiled a series of indices helpful for “predicting the circumstances under which local pharmaceutical production in a country will be able to compete in the international marketplace” or, in other words, for predicting the pharmaceutical production capability of a given country.³² Using statistical analysis and data from a variety of countries, the Bank report assesses the strength of the association between local production and several independent variables such as population size, gross domestic product, total healthcare expenditure, and level of human resources; all were factors which had strong positive associations with high pharmaceutical production capacity. The report concluded that the ability for developing countries to be successful in local production varied greatly because,

“...to be globally competitive as a producer of pharmaceuticals requires a combination of factors that only a few developing countries can approach. There is a critical mass of industrial and socioeconomic development in human and technical resources that must be reached before any indigenous pharmaceutical industry can survive.”³³

Looking at some of the indicators mentioned above, it is easy to see why some developing countries have been successful, notably India. India has a good variety of raw materials for pharmaceutical production and export.³⁴ India’s vast population also provides significant demand for locally-produced pharmaceuticals and the location of the country facilitates access to markets around the world. Furthermore, as a significant proportion of its total population is enrolled in secondary and tertiary education, India has a large pool of highly skilled and qualified workers necessary for a viable pharmaceutical industry, which most other developing countries do not have.³⁵ All things considered, India has the industrial capacity and resources necessary to make local production efficient, competitive, and beneficial in practice.

Most developing countries, however, lack the combination of factors that make local pharmaceutical production viable. This is particularly true for many countries in sub-Saharan Africa. In Africa, a variety of these barriers are already well known, including a general shortage of skilled labor, lack of advanced technologies, weak flows of foreign direct investment, dependency on foreign aid, weak legal and regulatory systems, poor educational systems, poor infrastructure, unreliable energy supply and concerns over a lack of domestic tax base, inflation, and corruption, among other things.^{36,37}

If local production is inefficient, there is the temptation for governments to enact legislation to protect local firms from more efficient, foreign producers. In Tanzania, the government implemented a 10 percent tax levy on imported medicines to keep local producers competitive,

³² Kaplan & Laing (2005) p.18

³³ These factors might include: “GDP greater than about \$100 billion, population greater than about 100 million, sufficient numbers of the population enrolled in secondary and tertiary education, a net positive pharmaceutical balance of trade, and a competitiveness index greater than about .15” Kaplan & Laing (2005) p.26

³⁴ Ibid, 15

³⁵ Ibid, 25

³⁶ Kaplan & Laing (2005) p.12

³⁷ “The Business of Health in Africa: Partnering with the Private Sector to Improve People’s Lives,” *International Finance Corporation (IFC) Report, World Bank Group* (2007) p. 77

and in Nigeria the government banned the importation of many drugs manufactured locally, so much so that local industry now supplies more than 30 percent of medicines in the country.^{38,39} As a recent report from the International Finance Corporation (IFC), the World Bank's private lending arm, noted, while "in general these protectionist policies aid the domestic competitive position of sub-Saharan African pharmaceutical manufacturers... whether these policies will improve access to more affordable drugs or create the right incentives to improve drug quality is debatable," and results thus far have been mixed.⁴⁰

As the South African coordinator for the World Health Organisation's (WHO) Drug Action Programme, Martin Auton, has explained, "every little country wants to manufacture ARVs [and] a lot of it's about national pride - but you have to make sure it's economically viable, and not just producing for the sake of producing."⁴¹

Generally, drugs produced by smaller companies are more expensive than those produced by larger companies since they cannot benefit from economies of scale (whereby a producer's average cost per unit falls as scale is increased). Consequently, African manufacturers generally produce at a cost disadvantage to bigger generic manufacturers, particularly in India. "Although conversion cost scale efficiencies generally plateau around 1.0-1.5 billion tablets in blister packaging per year, production at most sub-Saharan African formulation sites is far below that level."⁴² Local African manufacturers in places like Ghana are estimated to bear a 30-40 percent cost disadvantage compared with larger Indian manufacturers, and almost a third of this is attributed to scale.⁴³

Not only do small African producers struggle to compete in price against larger foreign companies, but often their drugs cannot compete in quality. As the IFC notes in a recent report,

"While several manufacturers in the region are seeking [WHO] prequalification, it is a difficult process for most of them—it requires renovation of production facilities, familiarity with qualification requirements and processes, and a dossier of product efficacy and safety tests that meets with regulatory bodies' requirements. Given the prevalence of small manufacturers in the region, the above requirements represent too high an economic burden, and, at the same time, often exceed the limited technical capability of the management teams..."⁴⁴

Consequently, firms not meeting international quality standards miss out on a significant part of the pharmaceutical market in developing countries, namely the donor market, estimated at up to \$1 billion annually.⁴⁵ Currently, local manufacturers only capture a small segment of the donor

³⁸ "The evolution of Drug Production in Nigeria," *National Agency for Food, Drug Administration and Control (NAFDAC)*

Available at: <http://www.nafdacnigeria.org/drugproduction.html>

³⁹ "A Case for Local Manufacturing of Pharmaceuticals," *Uganda Pharmaceuticals Manufacturers' Association (UPMA) Report* (2007) p. 5

⁴⁰ IFC Report, p.78

⁴¹ "AFRICA: Local manufacture - competition key to cheaper ARVs," *PlusNews* (September 2005) Available at:

<http://www.irinnews.org/InDepthMain.aspx?InDepthId=12&ReportId=56079>

⁴² IFC Report, p.77

⁴³ Ibid

⁴⁴ Ibid

⁴⁵ Ibid

market in sub-Saharan Africa, as “donor-funded contracts generally require product prequalification from stringent regulatory bodies such as the WHO or the USFDA.”⁴⁶ Therefore, the activity of these companies is largely restricted to the smaller, private sector in developing countries where, as mentioned in previous sections, products of local producers are up against the low drug prices of larger producers and the low prices of donated drugs leaked from the public market and sold into the private sector.

Unproven quality and cost disadvantages, as well as a general lack of other important factors, makes pharmaceutical manufacturing largely inefficient across much of Africa.

Local Production in Uganda

According to Uganda Pharmaceuticals Manufacturers’ Association the market for pharmaceuticals in the country is worth approximately US\$267 million, over 90 percent of products on the market are imported mainly from India and other Asian nations.⁴⁷

Currently there are five large and six small pharmaceutical manufacturers in Uganda. Challenges facing firms include operating at an estimated 50-60 percent of capacity,⁴⁸ no economies of scale, high costs of energy, competition from more efficient foreign suppliers (particularly India and China) and a lack of access to donor funding, largely due to stringent compliance conditions attached to these funds regarding quality assurance. A report from the Uganda Pharmaceuticals Manufacturers’ Association states that “all these factors render the locally manufactured medicines uncompetitive.”⁴⁹

Like Tanzania and Nigeria, Ugandan firms are pressing their government to subsidize and protect their companies in order to assist a local drug industry to develop. Companies claim the country will be able to move away from dependency on foreign products and increase access to affordable quality medicines.

By assessing one local pharmaceutical firm in Uganda, Quality Chemicals, it may be possible to ascertain the degree to which protecting local firms in the face of more efficient producers aligns with Uganda’s overall health goals of increasing affordability and public access to essential medicines.

Quality Chemicals - A viable solution?

Initially, the creation of Quality Chemicals (QC) in 2005 was viewed by top officials in the Ugandan Government, particularly Vice President Gilbert Bukenya, as a way to lower the country’s dependency on foreign suppliers, particularly on Indian generic drug imports. Believing that India’s “ratification of the TRIPS arrangement means that it will cease being a source for these generic drugs,”⁵⁰ the Ugandan Government supported the creation of QC in the face of what they believed to be a diminishing supply of generic medicines from major

⁴⁶ Ibid

⁴⁷ UMPA Report, p.6

⁴⁸ Ibid, 1

⁴⁹ Ibid, 3

⁵⁰ “About QCIL,” *Official Website of QCIL* (Accessed 20 August 2009) Available at: <http://www.qcil.co.ug/about.php>

producers.⁵¹ Furthermore, Ugandan officials believed that production and transportation costs could be lowered by producing drugs locally, that delays in supply would be cut, and, as a beneficial byproduct, local jobs would be created. In this sense, the government saw this local production project as not only moving the country toward greater self-sufficiency but also as falling in line with national efforts to industrialize. In light of this reasoning, the government proactively sought out potential partners for QC in the pharmaceutical industry. In 2005 QC entered into an agreement with the Indian company Cipla, creating Quality Chemicals Industries Limited (QCIL).

From 2006 to mid-2008 the QCIL plant was set up on an 11.7 acre property, with the expertise and technology for the venture provided by Cipla.⁵² The initial cost of the plant was US\$38 million, and capitalization for the project included 40 percent from Cipla, 40 percent QC, and 20 percent from the government (although this recently increased to 22 percent after it injected an additional 10 billion Ugandan Shillings into the project).⁵³ According to a well-placed source in the Ministry of Health and the Ministry of Finance, Planning and Economic Development, the government signed an agreement with QCIL's partners to provide the company with 420 billion Ugandan Shillings (US\$200 million) over 7 years. In the last quarter of 2008, about US\$28 million of these funds were disbursed to QCIL.^{54,55}

Initially, the company planned to produce two million tablets per day, and 600 million tablets per year but eventually a target of 1.2 billion tablets a year was thought feasible, given QCIL hoped to sell to retailers in the private, public, and regional markets (particularly to countries such as Rwanda, Burundi, Sudan, Democratic Republic of the Congo, and Swaziland).⁵⁶ The company also hoped to be able to access donor funds from GFATM and to provide drugs to regional programs supported by USAID's President's Malaria Initiative and other donors. At the very least, the Government of Uganda believed that they would be able to use GFATM grant monies earmarked for the purchasing of ACTs to buy drugs from Quality Chemicals.⁵⁷

Progress and Problems: Quality Chemicals Industries Limited (or local production) in practice

Though QCIL was supposed to be ready to produce ARVs and anti-malarials for the local market as of January 2008, according to the company's website, production did not begin until February 2009 with the plant only producing the ARV, DUOVIR-N (Uganda's first-line treatment of AIDS) supposedly at a commercial level.⁵⁸ These claims, however, are confusing since QCIL's drugs have not been approved by a recognized international body, and apparently no domestic

⁵¹ "About QCIL," *Official Website of QCIL* (Accessed 12 August 2009) Available at: <http://www.qcil.co.ug/about.php>

⁵² JD Mallet, "Audit Report on Good Manufacturing practice according to WHO recommendations: Quality Chemicals industries Limited" *International Committee of the Red Cross (ICRC)* Confidential report conducted March 12-13 2009 (Published 19 May 2009) p.3

⁵³ Yasiin Mugerwa, "ARV investors ask government for 22 billion Shillings," *The Monitor* (May 9, 2009) Available at: http://www.monitor.co.ug/artman/publish/news/ARV_investors_ask_govt_for_Shs22b_84569.shtml

⁵⁴ Personal interview by James Taylor with source at Ministry of Finance, Planning, and Economic Development in Kampala, Uganda (23 April 2009). All personal interviews in this paper were conducted by James Taylor.

⁵⁵ "Quality Chemicals Industries Limited" *Pharmaceutical Technology.com* Available at: <http://www.pharmaceutical-technology.com/projects/qualitychem/>

⁵⁶ Ibid

⁵⁷ "About QCIL," *QCIL Official Website* (Accessed 16 August 2009) Available at: <http://www.qcil.co.ug/about.php>

⁵⁸ Ibid

orders have been received either. QCIL claims its anti-malarials have passed “internal tests” by the National Drug Authority (NDA) in Uganda, the national organization charged with “ensur[ing] that only high quality, efficacious and cost effective medicine (both human and veterinary) are availed to the population of Uganda.”⁵⁹ George Baguma, QCIL’s Director of Marketing, said that the initial reason QCIL was interested in applying for WHO prequalification was “to give the plant an international touch” and because “the NDA is not so strict on the source of API.”⁶⁰ Having acknowledged that NDA’s regulations are more relaxed than internationally recognized bodies, if QCIL is producing and delivering ARVs, the quality of drugs remains in question.



Image 1: QCIL Production Line

In general, there is a lack of information regarding QCIL’s current and future business plans and production schedules, and there is no “sharing” of information, says Peter Ogwal from the Danish International Development Authority (DANIDA).⁶¹ Though QCIL continues to publicize that it has the capacity to produce enough drugs for Uganda and for the entire Great Lakes region, anti-malarial production has not yet occurred on a commercial level.⁶² Instead, QCIL continues to import Cipla’s ACT Lumartem (artemether-lumefantrine) to fulfill its contracts. According to a USAID contractor in Kampala, Uganda, QCIL has reportedly received two shipments of Lumartem this year: one in early 2009 and another in mid-April (3.3 million doses at a cost of \$7.7million) from Cipla. A third far-cheaper shipment of ACTs was delivered by the WHO to the country in May (a \$1.2m shipment equivalent to 1.15m doses) containing drugs from the Swiss company Novartis.⁶³ Though both QCIL executives and Cipla representatives continue to advertise forthcoming production of seven Cipla

versions of brand name drugs at a commercial level, in addition to a version of Lumartem, this seems unlikely considering that as of February 2009 the plant had only one production line (See Image 1), and a Good Manufacturing Practice audit of the Quality Chemicals plant conducted by the International Committee of the Red Cross in March 2009 noted, “There was a ‘handling of product complaints’ procedure not yet in use because no product was yet distributed by QCIL.”^{64,65}

QCIL continues to struggle with a variety of production challenges. In February, the CEO of QCIL told the Vice President of Uganda that the company was still experiencing “intermittent

⁵⁹ *Official Website of National Drug Authority (NDA)* Available at: <http://www.nda.or.ug/>

⁶⁰ Personal interview with George Baguma, Luzira, Uganda

⁶¹ Personal Interview with Peter Ogwal, Kampala, Uganda

⁶² ICRC report (2009) p.8

⁶³ Personal interview with USAID contractor, Kampala, Uganda

⁶⁴ ICRC report (2009) p.8

⁶⁵ James Taylor, a co-author, visited the plant in February 2009 and observed this.

power supply,” and asked the government for a dedicated power line to QCIL and availing the company power at concessional rates, admitting that the “the cost of running this plant on a generator is prohibitive.”⁶⁶ Additionally, QCIL is having trouble sourcing artemesia, the raw material for ACT production. Given the size of the company, QCIL’s demand for artemesia will be low by comparison with other larger producers and, considering the plant has yet to produce ACTs on a commercial scale and has no track record in its production, it is unlikely that QCIL will be high on the list of artemesia producers’ sales targets. Furthermore, since most of the artemesia is produced in China, and East African production is limited or already pledged to other manufacturers, QCIL faces real problems in sourcing this crucial raw material. Consequently, QCIL has been forced to outsource API procurement (from India), increasing its production costs further.⁶⁷

QCIL continues to heavily rely on subsidies from the Ugandan Government in order to avoid major losses and remain in business. Production issues aside, since its drugs are not approved by a stringent drug regulatory agency like USFDA nor are they WHO prequalified, it cannot access the majority of donor funds, which drive the public market, 70 percent of total sales in Uganda by volume.

Quality issues undermine QCIL’s regional appeal as well and, though sources at the Ministry of Finance and the Ministry of Health continue to claim that several countries in the region have expressed interest in procuring from QCIL—the company has yet to receive any orders from these countries and seems to also be excluded from the regional market.^{68,69}

QCIL is therefore restricted to competing in the private market (only 30 percent of the total market) where their potential share is marginal considering their products are up against cheaper drugs from foreign suppliers and against donated drugs leaked into the private market for small profits. QCIL currently claims that, eventually, they want to sell their ACT at US\$2.40 per dose.⁷⁰ This price however could be undercut by many of the other suppliers in the market, some of which may be able to sell at under US\$1. The public sector tender price charged by Swiss and Indian sellers has fallen every year and is now about US\$0.80.⁷¹

QCIL’s prospective share in the private market could potentially become even smaller due to a new GFATM initiative that will increase the number of subsidized drugs in the private market, called the Affordable Medicines Facility-malaria (AMFm).⁷² AMFm aims to subsidize the cost of ACTs in the private sector with the ultimate goal of increasing access.⁷³ If it works as planned, the introduction of AMFm will drop the current purchase price of ACTs from US\$6-10 per

⁶⁶ “Visit by the Vice President,” *QCIL Official Website* Available at: <http://www.qcil.co.ug/newsDetails.php>

⁶⁷ ICRC report (2009) p. 9

⁶⁸ “Burundi to purchase ARVs, anti malarials from Uganda,” *Uganda Business News* (31 May 2009) Available at: <http://www.ugpulse.com/articles/daily/news.asp?about=Burundi+to+purchase+ARVs,+anti+malarials+from+Ugnada&ID=10523>

⁶⁹ Personal interview with Dr. Rwakimari, (former director of National Malaria Control Program at MoH), Kampala, Uganda

⁷⁰ Personal interview with George Baguma, Luzira, Uganda

⁷¹ “MMV and Novartis Launch Coartem Dispersible,” *Medicines for Malaria Venture* (20 February 2009) Available at: http://www.mmv.org/article.php3?id_article=580

⁷² “Report of the Affordable Medicines Facility—Malaria Ad Hoc Committee,” *The Global Fund* (7/8 November 2008) Available at: http://www.theglobalfund.org/documents/board/18/GF-B18-07_ReportAMFmAdHocCommittee.pdf

⁷³ “Affordable Medicines Facility—Malaria,” *The Global Fund* Available at: <http://www.theglobalfund.org/en/amfm/>

treatment to US\$0.20-0.50.⁷⁴ Backed by the international community, it is the hope of GFATM and others that by making ACTs so cheap, they will not only expand access but will also drive the older, ineffective monotherapy drugs out of the market.⁷⁵

Obviously AMFm has significant implications on the viability of local pharmaceutical producers like QCIL, as participating pharmaceutical manufacturers must comply with GFATM's Quality Assurance Policy in order to be eligible for AMFm funding.⁷⁶ QCIL and other smaller producers will be left out of the AMFm donor market if their products do not meet quality standards, including WHO prequalification and/or approval by a stringent regulatory authority. Local industry would be potentially crippled, further demonstrating the risky nature of local production ventures in donor driven markets.

QCIL is obviously concerned about its lack of access to donor markets and has described WHO's prequalification process as "too long, though we are otherwise ready for prequalification."⁷⁷ To bypass prequalification, QCIL might endeavor to be granted a site variation of a Cipla pharmaceutical plant from WHO. QCIL would essentially function as another Cipla plant, but in Uganda.

Discussion

The future of QCIL looks uncertain as the Ugandan Government is pressed to provide more protection. In May, Emmanuel Katongole, the CEO of QCIL, asked the Government of Uganda to grant the company a ten year tax holiday in order for it to remain competitive.⁷⁸ That same month, the company's Chief Marketing Officer, George Baguma, testified in front of the Social Services Committee of Parliament that the company needed 120 billion Ugandan Shillings (US\$54 million) for the next financial year just to stay operational.⁷⁹ QCIL is arguing for more subsidies, using funds which could probably be spent in more productive ways such as improving health system infrastructure or addressing existing supply chain problems, both of which are primary causes of stock-outs and limited access. But QCIL and local industry are also demanding protection from the government too—a 15 percent tariff against all foreign made ACTs.⁸⁰

The opportunity cost of protecting QCIL has serious implications and the government has already demonstrated questionable judgment in regards to protecting QCIL. "In its 2008/09 national budget, the government set aside \$38 million to buy ARVs from QCIL – which would have been the first ever domestic contribution to the country's donor-driven ARV program.

⁷⁴ "\$225 Million Partnership to bring effective malaria drugs to all who need them," *The Global Fund Press release* (17 April 2009) Available at: http://www.theglobalfund.org/en/pressreleases/?pr=pr_090417

⁷⁵ Ibid

⁷⁶ Affordable Medicines Facility—Malaria Ad Hoc Committee Report, *The Global Fund* (2008)

⁷⁷ "Report on the Approval Process for the Affordable Medicines for Malaria (AMFm) in Uganda" *Response from QCIL during meeting regarding AMFm in Uganda* (2 April 2009) p. 6

⁷⁸ "Pharmaceutical firm wants 10-year tax holiday" *Uganda Business News* (24 May 2009) Available at: <http://www.ugpulse.com/articles/daily/news.asp?about=Pharmaceutical+firm+wants+10+%96year+tax+holiday&ID=10402>

⁷⁹ Yasiin Mugerwa, "ARV investors ask government for Shs22b," *The Daily Monitor* (9 May 2009) Available at: http://www.monitor.co.ug/artman/publish/news/ARV_investors_ask_govt_for_Shs22b_84569.shtml

⁸⁰ Anthony Bugeme, "Uganda produces ARVs, Malaria Drugs," *The New Vision* (February 20 2009) Available at: <http://www.newvision.co.ug/D/8/13/672152>

However, less than half the allocated funds were actually used to purchase ARVs.”⁸¹ In fact, in early August 2009, during a stock-out of ARVs, it was revealed that the Ministry of Health diverted “an estimated US\$15 million earmarked for purchasing antiretroviral (ARV) drugs, which was instead used to buy shares in a local drug factory and pay health workers.”⁸² As a result of these questionable and unauthorized decisions on behalf of the Ministry of Health, Peter Ogwal of DANIDA has said that “the Auditor General will audit the Ministry of Health as it is the institution from which the UGX 60 billion (approximately US\$30 million) to fund QCIL came from, and probably also carry out some sort of audit of QCIL. In this way, we hope to get some inference on what the money actually did.”⁸³

QCIL’s problems and demands deflect attention from the other problems affecting access to drugs, which existed prior to QCIL’s grand plans and still exist today. For example, a key cause of poor access to high-quality drugs in the country is the inefficient delivery and poor forecasting by the parastatal National Medical Stores (NMS) and by district health offices.

With a reputation for inefficiency and corruption, the NMS is generally not looked fondly upon by district officials or many individuals and groups involved in Uganda’s public health issues.⁸⁴ Making matters worse, Uganda’s own regulatory agency, the National Drug Authority (NDA), continues to be understaffed and underfunded, with limited capacity for regulation, especially since DANIDA stopped funding the drug oversight body in 2002, exacerbating an already insufficient budget.⁸⁵

With the capacity of Uganda’s own drug oversight body severely limited, the failure of the NMS has not gone unnoticed by international development organizations on the ground. For instance, after repeated complaints from USAID staff working on health projects requiring collaboration from the Government of Uganda and the NMS, a confidential internal document was produced at the behest of the director of the USAID mission in Kampala which provides vast and clear evidence of mismanagement, abuses of power, and of opportunism in emergency situations, among other disappointments. Leaving aside its failures in the procurement and distribution of drugs and of medical supplies for other infectious diseases, it seems as though the NMS is not currently in a position to even provide the services necessary to cope with the country’s malaria problem.

It is important to recognize these deficiencies of NMS and NDA because it highlights the failure of health systems throughout Uganda. As long as the national procurement and distribution system in Uganda remains inadequate and inefficient, the number of pills produced by Quality Chemicals or the number of ACTs donated from abroad, will be irrelevant if they cannot reach the shelves of rural health centers where over 87 percent of the population lives.⁸⁶ In June 2009,

⁸¹ “Uganda Health Ministry diverts ARV money,” *PlusNews* (10 August 2009) Available at: <http://www.plusnews.org/Report.aspx?ReportId=85658>

⁸² Ibid

⁸³ Personal Interview with Peter Ogwal, Kampala, Uganda

⁸⁴ Dr. Sam Okuonzi, “Drug Shortage is Due to Inefficiency in NMS,” *The New Vision* (24 February 2009) Available at: <http://www.newvision.co.ug/D/8/459/672503>

⁸⁵ Charles Wendo, “Uganda’s drug regulatory agency faces financial crisis,” *The Lancet* Volume 358, Issue 9280, P. 482 (11 August 2001) doi:10.1016/S0140-6736(01)05684-7

⁸⁶ “13% of total population in Uganda estimated to be urban, 87% estimated to be rural,” *CIA World Factbook* (2009) Available at: <https://www.cia.gov/library/publications/the-world-factbook/geos/ug.html>

the World Bank's country director in Uganda, Kundhavi Kadiresan, underscored this persistent problem noting that "in the Health Sector, the recent Public Expenditure Review identified that 93 percent of drugs procured by the National Medical Stores (NMS) did not reach their intended recipients."⁸⁷

Donors must share some of the blame as well. James Tibenderana, the director of Case Management at the Malaria Consortium in Uganda, believes that the main problem is that "donors have not addressed problems with the entire procurement and delivery system of health commodities. They have focused on bits and pieces of the system rather than the entire supply chain management system."⁸⁸ For example, warning systems in the supply chain have not been working effectively throughout the country, which have led to many stock-outs, particularly within the last year. Yet there is still little idea about minimum and maximum stocks until it is too late. Ambrose Talisuna, Country Representative of Medicines for Malaria Venture in Uganda echoed this sentiment, "the National Medical Stores has had many challenges, and supply chain failures are still a big issue."⁸⁹

Even one senior officer working on malaria control and treatment with USAID in Uganda believes that there is "limited capacity" in the Ministry of Health's National Malaria Control Program (NMCP) for procurement and that power is concentrated in the hands of a few individuals at the Ministry of Health, specifically in those of senior management, including the Permanent Secretary.⁹⁰ Dr. Tibenderana of Malaria Consortium put it even more succinctly, "The National Malaria Control Programme has absolutely no power."⁹¹

Conclusions

Medicines must be produced, and it is as tempting for any government to promote local production as it is for local and foreign businessmen to take advantage of taxpayer largesse. But where production is driven by aid agencies, local governments, and rent-seeking businessmen, the outcomes are rarely beneficial to the general population – especially if numerous factors (educated work force, significant domestic market size, economies of scale in production, constant energy, potable water and other raw material inputs) are not available. Few developing countries have the conditions required to be able to sustainably produce high-quality pharmaceuticals; India is a rare exception. Most of Africa's efforts, including those in Uganda, are not economic.

The provision of essential medicines by a developing country government to its citizens is vital, and should be the overriding consideration of the international community when it decides how to help those nations. Through its aid efforts, the international community should influence developing nations to not obstruct access to subsidized drugs from abroad. Donor funds should also not be used to procure medicines of uncertain quality in order to protect an infant

⁸⁷ Angelo Izama, "Wastage in Public expenditure must be addressed," *Daily Monitor* (30 June 2009) Available at: http://www.monitor.co.ug/artman/publish/business_power/Wastage_in_public_expenditure_must_be_addressed_-_World_Bank_87248.shtml

⁸⁸ Personal interview with James Tibenderana, Malaria Consortium, Kampala, Uganda

⁸⁹ Personal interview with Ambrose Talisuna, MMV, Kampala, Uganda

⁹⁰ Personal interview with senior USAID officer, Kampala, Uganda

⁹¹ Personal interview with James Tibenderana, Malaria Consortium, Kampala, Uganda

pharmaceutical industry. This is especially the case in a county like Uganda, where hundreds of people die every day from treatable diseases and misallocations of resources are lethal.

There is, however, reason to sympathize with businessmen in developing countries, including those behind QCIL. Although it is not intended, nearly every part of the aid system undermines their efforts. Furthermore, the erratic nature of aid, as compared with far more consistent market demand, means even when businesses can get on their feet, they might be undercut at any time by new, and often temporary or short-term, aid initiatives. Hearing these complaints it is understandable that the aid community wants to help local producers. But at the end of the day, protectionist approaches, or lowering drug standards, the only obvious quick 'fixes' to increase market share for local producers, is not beneficial for patients' pockets or health.