

Tide turns for drug manufacturing in Africa

Original Text

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With several efforts underway to increase the local production of drugs in developing countries, Tatum Anderson assesses the pros and cons of manufacturing medicines in Africa.

A drugs producer in Uganda has become the first in a least developed country (LDC)—a category reserved for the world's poorest nations—to achieve a world-class seal of quality for its manufacturing standards.

The Quality Chemicals plant, in the Ugandan capital Kampala, is the first to get this far along the so-called WHO pre-qualification process; a stringent quality check imposed on manufacturers of drugs. There are around 37 manufacturers in sub-Saharan Africa. “There has been excitement”, says George Baguma chief marketing officer at Quality Chemicals. “We are the first in sub-Saharan Africa to get pre-qualification of a plant outside South Africa.”

The next step is to gain approval, or pre-qualification, for each malaria and HIV/AIDS drug the firm produces, before international agencies, such as UNICEF, are allowed to buy from the company.

It is an important milestone because of scepticism over domestic, or local manufacturing, in such countries, says Suerie Moon, an expert on local production at the Kennedy School of Government, Harvard University, MA, USA. “There is a lot of doubt in the global health community as to whether a firm in an LDC is capable of producing at WHO pre-qualification standards”, she says. “It sends a clear signal that it's possible and is an important part of changing the way people think about local production.”

A World Bank report set the tone in 2005, concluding that in many parts of the developing world, producing medicines domestically made little economic sense and could even end up reducing access to medicines. The thinking was that few developing world producers could compete with those from India and China. And, crucially, from a public health point of view it does not matter where the drug comes from as long as it is safe, affordable, and of good quality.

Manufacturers, especially in poor nations, face a multitude of expenses that push up the cost of medicines beyond those from India and China said the report's authors, Richard Laing from WHO and Warren Kaplan, assistant professor of international health at Boston University, MA, USA. Difficulties include unreliable water and electricity supplies. Companies are also often forced to import machinery, packaging, and active pharmaceutical ingredients (APIs) because there is little production of starting materials at home. Technical specialists are scarce too.

By contrast, India and China are pharmaceutical powerhouses with plentiful supplies of skilled professionals and decades of government support. The countries' enormous populations have helped support industries too.

Andreas Seiter, a senior health specialist at the World Bank says that few factors have changed dramatically since 2005, particularly in Africa. “There is still a cost disadvantage for local manufacturing in Africa”, he says. “In Ghana, for instance, with energy costs and importing raw materials and no large volumes produced, they are not competitive with Indian and Chinese manufacturers.”

And it is not just about cost. Some say that the quality of drugs produced can be much lower than international standards and that countries are putting industrial agendas ahead of public health if they buy from inefficient local facilities rather than better-quality medicines abroad.

Others attribute Quality Chemicals' success to one of India's leading pharmaceutical companies, Cipla, which designed the plant (it is a carbon copy of Cipla's facility in Goa, India, say insiders). Cipla sent its experts to train Ugandan staff and even applied for WHO pre-qualification certification on behalf of Quality Chemicals.

Why then, is there currently a flurry of global activity aimed at increasing local production in developing countries? WHO, several UN agencies, the European Union and non-governmental organisations, are looking at local production strategies; Michel Sidibé, executive director of UNAIDS, last year called for local production of antiretrovirals to be ramped up; and importantly, the African Union (AU) grouping of African Governments, is currently devising a fully costed business plan for the production of drugs for HIV/AIDS, tuberculosis, and malaria on the continent.

Pharmaceutical companies from Democratic Republic of the Congo to Ethiopia are being helped to reach international standards too. German development agency GTZ is even sending individual inspectors from the German regulator to Africa to do personal plant assessments. Although no substitute for a full WHO pre-qualification, the process helps identify improvements necessary to reach international standards.



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Drug manufacturers in Africa face problems that can push up the price of medicines

Other African manufacturers have also applied for pre-qualification says Lembit Rāgo, coordinator of WHO's medicine quality assurance and safety unit, who set up WHO's pre-qualification process. Local production is gaining in popularity because, despite imports, a third of the world's population is still without access to medicines, more than half in parts of Africa and Asia. The view is that local production, with other strategies, must be ramped up to fill the gap.

Many developing countries are keen because they fear supply insecurity since their citizens' health is dependent on supplies from abroad and they want the economic benefits of local industry. LDCs are also exempt from some world patent rules which, in theory, enables them to legally produce more affordable copies of drugs that would be subject to patents elsewhere, including India.

There is disagreement as to whether employment increases substantially or how insecure foreign supplies really are. Dilip Shah, head of the Indian Pharmaceutical Association, argues that there are so many Indian suppliers, insecurity is highly unlikely.

For its part, Quality Chemicals told *The Lancet* that Indian manufacturers are able to sell at artificially low prices, because of financial help from their government, and this damages the African industry. “Our government does not subsidise us, so our products look more expensive”, says Baguma. “The environment is hostile.”

Additionally, attaining pre-qualification in a poor country is a costly business, he says. Salaries for Indian experts engaged in technology transfer has been paid for by Quality Chemicals at five-times the cost of local staff, and Cipla applied for pre-qualification because it can help surmount a myriad of obstacles including important laboratory studies that would delay pre-qualification by a lone African firm for years.

A few other changes have also altered the case for local production since the World Bank report. For a start, the substantial rise in global health donor funding means there is a greater demand for drugs, and a greater potential market for local manufacturers. And because donors require international manufacturing standards, many local manufacturers are now investing in improvements to compete for the funds.

There has also been a shift towards a more pragmatic approach to local production. Agencies are working on establishing evidence for specific cases where local manufacturing makes sense, says Precious Malebona Matsoso, director of public health, innovation and intellectual property at WHO. “We want to show countries that it might be feasible for them to import but in some instances to manufacture”, she says. “We can make the tools available to help countries make those decisions.”

Manufacturing in some countries might be more viable than others, for instance. Daniel Ayele, of GTZ Ethiopia says that Ethiopia might be able to sustain local producers because it is Africa's second most populous nation.

Some products, and not others, might make more sense to manufacture locally. Not every API import is prohibitively expensive for instance and intravenous drips, which are mostly water, are tricky to import.

That is also why the AU wants to promote regional rather than local production. The populations of several neighbouring countries might support one manufacturing plant located in one of them. “If the countries that are producing can work together we could, as a continent, have more access to the medicines”, says Jane Byaruhanga, health officer at the AU Commission in Addis Ababa.

Here too, alternatives might also be more appropriate says Byaruhanga; several African countries might choose instead to club together and buy drugs from abroad at a cheaper price or use flexibilities in world trade rules to access more imports.

Improving access to good, affordable drugs, after all, is not just about local production. More research into drugs and vaccines for diseases that disproportionately hurt the poor is needed. Regulators need strengthening to better spot bad drugs and manufacturers—local or foreign. So are improved drug distribution systems to prevent drug stock outs and hefty price mark-ups levied by the supply chain.

But for local manufacturing to work, say proponents, governments must be prepared to coordinate, harmonise legislation of drugs within regions and if manufacturing does not make sense from a public health viewpoint, to step away. That might be easier said than done says WHO's Rago. “Local production is not a panacea. The tragedy is that it is sometimes promoted blindly”, he warns. “Of course countries want to create industries to provide medicines for their people but the cost should not be higher prices and lower quality. That is the irony we have seen in many parts of the world.”

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