BUSINESS

Trip into the unknown

A plant in Uganda hopes to sell cut-price drugs by taking advantage of exemptions from rules that protect patents. But its operators face major obstacles, as **Tatum Anderson** reports.

On the outskirts of Kampala, and rather at odds with the dusty, low-rise buildings around it, stands a state-of-the-art, glass-fronted pharmaceutical plant.

Opened with great fanfare last month by Yoweri Museveni, the president of Uganda, the factory will manufacture drugs to treat HIV/AIDS and malaria for markedly less than the cost of imported drugs. The World Health Organization (WHO) estimates that in Uganda, fewer than 38% of the patients with HIV/AIDS that need antiretroviral drugs receive them. But although Africa carries the largest burden of HIV/AIDS and malaria in the world, it produces only 1% of the world's drugs, according to the World Bank.

"We want local solutions to local problems and this is the first step to say we can do it ourselves," says Fred Kitaka, finance director of Quality Chemicals, the Ugandan company that co-runs the plant.

Previously a drug importer, Quality Chemicals put up two-thirds of the US$30-million it cost to build facility, which can produce 6 million tablets per day. Cipla, a drug manufacturer based in Mumbai, India, has provided the remaining US$8.5 million, as well as consulting services. The Indian firm also holds 50% of the shares in Quality Chemical Industries, the company that runs the new plant.

The factory will start by producing some of Cipla's most widely used fixed-dose combination drugs, including an antiretroviral called Triomune, which contains lamivudine, stavudine and nevirapine. It will also produce Lumartem, an antimalarial combination therapy that is made by Novartis under the brand name of Coartem. The plant will start manufacturing early next year and will initially sell antiretroviral drugs at two-thirds of the cost of imported products. As production volumes rise, the factory claims that it will reduce prices further.

Kitaka says that the company can produce cheaper drugs by taking advantage of the staggered timetable for compliance with Trade-Related Aspects of Intellectual Property Rights (TRIPS), a global agreement under which companies can enforce patents on their products and prevent copycat producers from selling them.

At the moment, many of the drugs used by Ugandans are manufactured in India. But changes to India's patent law in 2005 to bring it in line with TRIPS mean that newer drugs are more likely to be patented, and therefore more expensive, says Kitaka. As one of the world's least-developed countries, Uganda does not need to pass TRIPS-compliant laws until 2016. It can therefore manufacture drugs that would be patented elsewhere until that time. (As it happens, Uganda is planning to revise its patents laws earlier than that.)

President Yoweri Museveni gives a thumbs up to Uganda's latest drug venture.

Figures from the WHO indicate that by 2005, 37 African countries had pharmaceutical industries, albeit on a small scale. There is strong political will in Africa to boost these facilities. But a 2005 World Bank study has shown that local manufacturing often does not make economic sense for poor countries. Production costs rise considerably because African countries often lack reliable supplies of electricity and water, as well as the engineers, chemists and other skilled staff needed to run drug factories. Raw materials for the drugs, as well and plastics and other packaging materials, may also have to be shipped in from elsewhere.

Viable markets

Sandeep Juneja, HIV project head at the Indian manufacturer Ranbaxy Laboratories says he doubts that many plants will be viable in Africa. An export market that consists purely of other low-income countries would be too small, he says. And under TRIPS, companies that set up factories that are exempt from licensing payments in low-income countries are extremely limited in the drugs they can export to slightly wealthier countries with tighter patent rules, such as Nigeria, Kenya or South Africa.

Additionally, plants in India and elsewhere that manufacture low-margin antiretrovirals often share overheads with lucrative, high-margin drugs. An African plant, however, "would have to recover all costs, including salaries, exclusively from the antiretrovirals, which may make it unviable", Juneja says.

The effect of TRIPS exemptions on countries such as Uganda are also limited by the fact that so many of the drugs imported from India are off-patent anyway, observers say. And even though Africa is home to some highly reputable manufacturers, such as South Africa's Aspen Pharmacare, which makes drugs licensed by GlaxoSmithKline, many health-care officials have doubts about the quality control of drugs produced in other African facilities.

Factories must reach international manufacturing standards before aid agencies will buy their drugs or other countries will import them. But the WHO, which certifies factories as having reached such standards, says that not many African manufacturers have even applied for inspections.

Industry observers say that with few inspectors to certify plants, factories wait perilously long for inspections. "We are finding high-quality local producers who are going out of business because the certification process is not resourced to do the job," says Philippa Saunders of Oxfam's Essential Drugs Project, based in London.

Despite the odds, Uganda's government, manufacturers and Cipla are determined to surmount these obstacles at the Kampala factory. The government — which helped to broker the deal between Cipla and Quality Chemicals — plans to expand Uganda's processing of active ingredients so that raw materials do not have to be imported. And in a technology-transfer arrangement, Cipla has overseen the design and building of the Quality Chemicals factory so that it meets international standards and can export to other African countries. It is also providing 40 staff to train Ugandan workers to run the factory over the next couple of years.

So Kitaka is confident of a return on investment in six or seven years, although he acknowledges that the firm's success will depend on a great many factors. And the stakes are more than financial. "We're not just making money," he says, "we are helping the communities we live in." ■