MAKING IT LOCAL

Will African ambitions to build a strong domestic pharmaceutical sector improve desperately needed local access to drugs? **Karen McColl** weighs the evidence

Africans need better access to medicines. Despite recent advances, up to half of the population still lacks access to essential medicines in some countries.[1] During the World Health Assembly in Geneva next week (17-22 May), African health ministers will meet to discuss how they can work together to facilitate drug development, production, and access on the continent.

The key to the continent's future is economic and social development. It's not surprising, therefore, that the idea of building a strong domestic pharmaceutical sector is appealing to African leaders. It is also easy to understand why they may look with some envy towards countries like India—which, in just a few years, has built up a reputation as the "pharmacy to the developing world."[2]

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Rather than focus on local production, would African countries be better focusing on improved ways of delivering drugs to people?

A new study has identified more than 120 initiatives and institutions involved in researching and developing cures for neglected diseases, producing and delivering medicines in Africa, or otherwise improving access to medicines in the continent.[3] Most of these initiatives are being driven by international players. "In Africa, the agenda for drug development, production, procurement, and access to medicines is being largely defined by international programmes—a situation that would be unthinkable in other parts of the world," explains Carel IJsselmuiden, director of the Council on Health Research for Development (COHRED), which produced the study jointly with the New Partnership for Africa's Development (NEPAD). "While these international programmes have helped a lot, African countries are now saying we want to take charge of our own situation."

Local action

Although the contribution of these global health initiatives is recognised, there is increasing political momentum behind the idea of Africans themselves driving forward the agenda. The global strategy and plan of action on public health, innovation, and intellectual property, adopted at the 2008 World Health Assembly, and the African Union's Pharmaceutical Manufacturing Plan for Africa, adopted by African health ministers in 2007, are key elements of that new policy drive.[4 5] A new initiative led by NEPAD, in partnership with COHRED and the African Union, aims to translate these policy instruments into practice. This initiative, which builds on the joint study, proposes tools and a practical process for countries to put the global strategy into action.

From his perspective as a local manufacturer trying to make headway in Africa, Frederick Mutebi Kitaka speaks passionately about the need to build a strong pharmaceutical sector. "Over 80% of all malaria sufferers and more than 60% of people living with HIV/AIDS are in Africa, but we manufacture less than 1% of the drugs. This is a huge contradiction. Unless we can have our people participating in creation of African solutions to problems that are predominantly African, we will never get out of poverty. And unless we tackle poverty, we can't combat these diseases," argues Mr Kitaka, chief finance officer of Quality Chemical Industries in Uganda. He points to the benefits that companies such as his—a joint venture with the Indian generic drug manufacturer, Cipla—bring to the local economy by employing people, generating taxes, and generating foreign exchange.

The rhetoric is seductive, but the company's story also illustrates why local production of drugs is no magic bullet to ensure better access to medicines. In practice, the company is currently struggling to compete with cheaper imported antiretroviral and antimalarial drugs that benefit from state support or export subsidies.

Although local production can improve local access to medical products, it is not always the case. "In both Brazil and Thailand, the production of generic antiretroviral medicines has contributed to the success of their national HIV/AIDS programmes. Most other countries have scaled up treatment successfully without local production, relying on generics from India in particular," says Tido von Schoen Angerer, director of Médecins Sans Frontières' access to medicines campaign. "What is really important is that there is competitive production in the world and it is less important where that actually happens."

That is why some experts argue that, rather than encouraging local production, countries would be better focusing on

improving ways of delivering drugs to the people that need them.[6] Health systems need to be strengthened to ensure that medicines and vaccines can be transported, stored, prescribed, dispensed, and used appropriately. This means having the necessary physical infrastructure—such as roads, power supply, and refrigeration—as well as health professionals in functioning health services. When you consider that Benin, for example, has only 11 pharmacists for its 9 million population, the scale of the challenge in some countries becomes clear.

Fledgling industry

The NEPAD-COHRED study, which provides the first overview of who is doing what in terms of pharmaceutical innovation in Africa, found cause for optimism. Thirty seven countries in Africa now have some local manufacturing capacity for drugs. Egypt and Tunisia produce between 60% and 95% of their own national requirements for essential medicines. There is much more to innovation, however, than local manufacturing—and there are examples of innovation at different stages along the drug development pipeline. At the research end of the spectrum, collaboration between researchers and traditional healers in Nigeria, for example, led to the discovery and development of a drug for managing sickle cell anaemia. At the delivery end of the pipeline, a retail franchise model is being used in Kenya to set up a network of Child and Family Wellness shops to dispense essential medicines.[7]

Despite these encouraging signs, the challenges remain huge. The majority of local production involves preparation of finished products from imported ingredients. Only South Africa and Ghana have the capacity to manufacture active ingredients. In fact, 70% of sub-Saharan Africa's $1bn estimated annual drug production takes place in South Africa and a further 20% takes place in Nigeria, Ghana, and Kenya.

Further development

How will the new NEPAD-led initiative help African countries strengthen pharmaceutical innovation in a way that brings real benefits for their people? For starters, the initiative aims to ensure that the process is African-led and reflects countries' needs. The key to that will be to help African countries develop a better understanding of their own needs. In practical

DISTRIBUTION OF AFRICA'S DRUG INDUSTRY[3]

Countries accounting for 90% of Africa's drug production

No drug production

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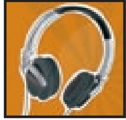
Ugandan president Yoweri Museveni tours a new anti-retroviral therapy factory just outside of Kampala, Uganda, a joint venture between the Ugandan company Quality Chemicals and the Indian generic drug manufacturer, Cipla

A woman working on a production unit at Sandal Dar El Beida pharmaceutical factory, Algiers



bmj.com podcast bmj.com editor David Payne talks to Emily Friedman, a health policy and ethics analyst, about Cambodia—a country with a difficult past that is now rebuilding its healthcare system to try to meet some of the particular needs of its population. Listen to this podcast and others at http://podcasts.bmj.com/bmj

terms, the initiative will do this by offering a new tool to help policy makers assess their situation and by running a series of regional workshops over the coming three to five years. Countries will then be able to draw up strategies and to seek donor funding specifically to help them reach those longer term goals.

This process will also help policy makers understand the difference between investing in pharmaceutical innovation for long term economic gain and trying to improve access to medicines. Crucially, it should help countries avoid the pitfall of mixing the two. "In the end, decision makers must be clear on the balance they want to achieve and craft a strategy that meets their short and longer term goals—economic development, improved access, or both," says Professor IJsselmuiden.

> **"Over 80% of all malaria sufferers and more than 60% of people living with HIV/AIDS are in Africa, but we manufacture less than one percent of the drugs"**

The hope is that a better understanding of what can realistically be achieved will foster a new type of innovation. Most importantly, the initiative hopes to encourage countries to work together and develop regional strategies. Countries could pool resources, with individual countries developing particular skills and areas of expertise. One country might specialise in clinical trials, for example, while another could specialise in quality control, or in professional training for pharmacists. "We can progress more rapidly by pooling resources across regions. This cooperation will reduce investment costs and create economies of scale in innovation and production," explains NEPAD's chief executive Ibrahim Assane Mayaki. NEPAD is already working with African countries to try and harmonise drug registration procedures.

African institutions involved in pharmaceutical innovation have tended to collaborate mainly with US or European counterparts—this is hardly surprising, given the funding arrangements. "Up until now, most of the collaboration has been external, which is not a bad thing in itself," explains Rob Ridley, director of the special programme for research and training in tropical diseases based at the World Health Organization. "But the continent has now progressed to a level where there can be more internal collaboration and self-generation of innovation, as happens elsewhere in the world," he says. To this end, a new network, the African Network for Drugs and Diagnostics Innovation, is being set up to link research and development institutions across Africa.[8] Dr Ridley is optimistic that we are entering a new phase of collaboration within Africa—he believes that the desire for collaboration is strong, but that funding and mechanisms are needed to make sure it happens.

Can the new initiative convince countries to work together rather than to go it alone? High level political support will be essential. African science and technology ministers endorsed the initiative in March, and the briefing session for health ministers in Geneva next week is the next step towards securing that support. As well as showcasing examples of African-led innovation, the meeting aims to kick start the discussion on how countries can best work together to generate real, lasting benefits from pharmaceutical innovation in Africa.

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Tackling organ shortages

"Organ donation has become a vital way to save lives around the world, but a vast shortage of donors means people are continuing to die while on waiting lists," writes csm@csm. New York State assemblyman Richard Brodsky's proposed new bill in Albany provides for an opt-out solution for all New Yorkers. Tom Koch counters that the New York proposal occurs within a system that has disadvantaged poor people who cannot afford health insurance or, if they are insured, have policies that will not support transplantation: "To assert as a good the policy of presumed consent in a context of systematic inequality is to make of the poor donor fields for more wealthy people. That is horrendous." Czech doctor Radkin Honzak says that his country's opt-out donor system has so far not caused any problems. Reikidoc favours an opt-in system: "An opt-out system would interfere with people's personal preferences and violate their right of privacy." Finally, Pakistan's president, Asif Ali Zardari, has donated all his body organs after signing a bill to regulate the transplantation of human organs in the country.

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US abortion law and harm reduction

US health policy blogger Vidhya Alakeson blogs about anti-abortion legislation in the USA. "In much of Europe, abortion is not even an election issue, let alone a healthcare issue. In the US, healthcare reform can easily get tangled up with abortion," she writes, before explaining how increasing numbers of states are becoming more restrictive in giving women access to services to help them terminate unwanted pregnancies. She concludes: "Among all this bad news, there is a silver lining for the majority of Americans who support choice for women. With nominations to the Supreme Court now in the hands of the Obama administration, the threat of overturning the decision in Roe vs Wade that legalised abortion has receded."

Richard Hurley, assistant magazine editor with the *BMJ*, attended the 21st conference of the International Harm Reduction Association in Liverpool and learnt that harm reduction globally is hampered by criminalisation of drug taking and hypocrisy. His conclusion: "Clearly prohibitionist ideology, politicking, and pandering to a reactionary popular media still carry at least as much weight as scientific evidence."

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