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Overcoming barriers to medicines production through South-South co-operation in Africa

Access to essential medicines is one of the key requirements for achieving equitable health systems and better population health. The number of people with regular access to essential medicines increased from 2.1 billion to about 4 billion between 1997 and 2002. However, access to medicines in sub-Saharan Africa remains low. One reason for this is the low level of domestic production on the continent. This brief outlines the factors that affect medicines production in East and Southern Africa, drawing on the African Union, Southern Africa Development Community (SADC) and East African Community (EAC) pharmaceutical plans. It identifies the barriers to local production as: lack of supportive policies, capital and skills constraints, gaps in regulatory framework, small market size and weak research and development capacities. There are potential opportunities available through south-south cooperation in medicines production. Negotiations on such south-south arrangements would need to look not only at the immediate production investment, but at strengthening capacities for research and development, for regulation, medicines price and quality monitoring, prequalification, infrastructure and human resource development.

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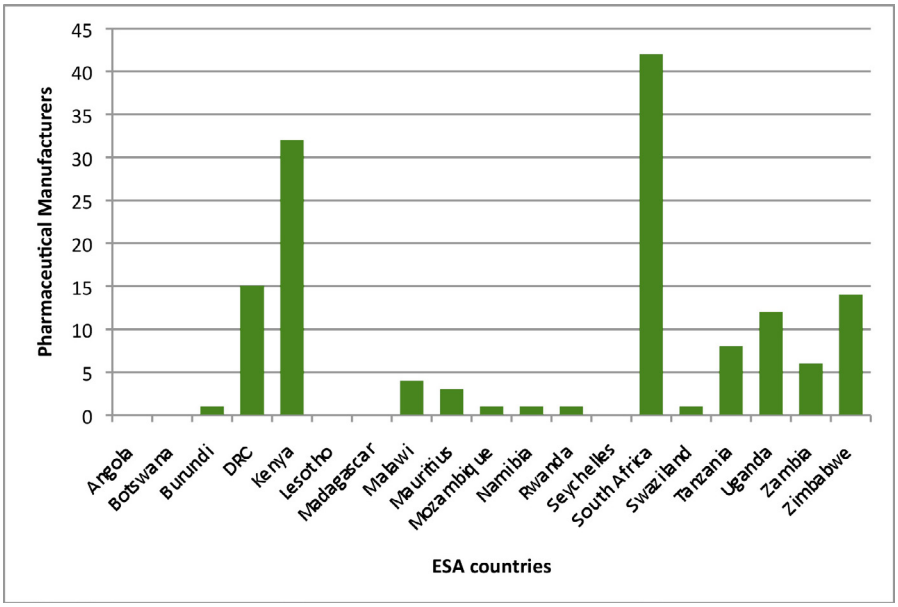
Medicines production in east and southern Africa

Few countries in east and southern Africa have a domestic pharmaceutical industry. As shown in the chart below, only South Africa and Kenya have a larger number of local manufacturing plants. Kenya exports between 35 and 45 percent of its pharmaceuticals, particularly to other east, central and southern Africa countries.

Number of domestic pharmaceutical manufacturers in the ESA region



Sources: WHO (2011), EAC (2011)

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Thirty seven sub-Saharan African countries have some pharmaceutical production, mainly for formulation of finished dosage forms, although in twenty five countries this is limited to packaging or labeling. Only South Africa has a limited degree of Active Pharmaceutical Ingredient (API) production. Most production outside South Africa consists of non-complex, high volume essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs and vitamins (IFC, 2008). This relatively low level of domestic manufacture makes the region highly dependent on outside sources for its medicine supply. The 2007 Southern Africa Development Community (SADC) Pharmaceutical Business Plan noted that only 15% of generic antiretrovirals (ARVs) used in the region were produced within the region and 85% were imported from India.

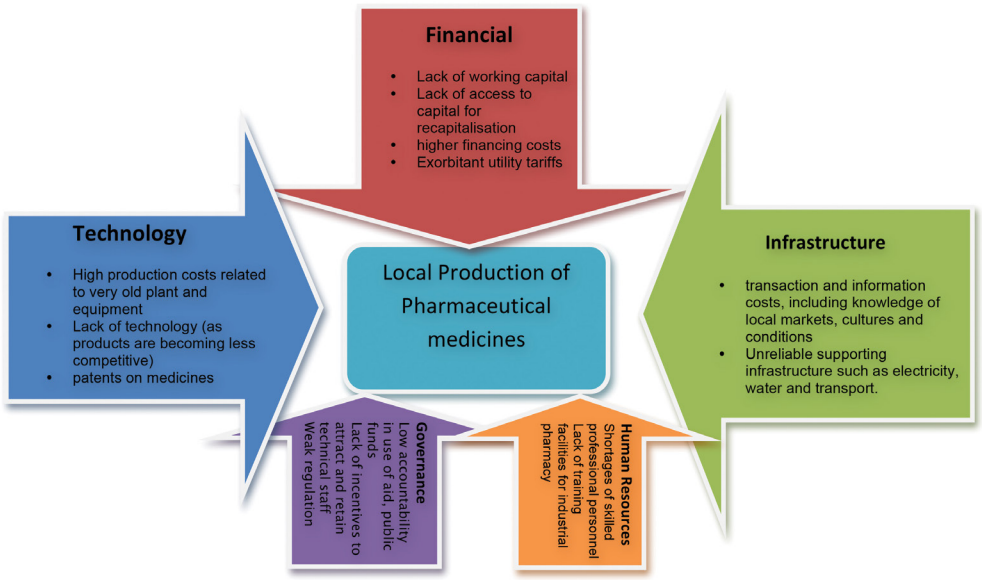
Barriers to local production

This gap in domestic manufacturing has been identified as a concern in the continent. The African Union (AU) Summit adopted in 2007 a Pharmaceutical Manufacturing Plan for Africa. It calls for a mapping of productive capacities on the continent to inform a manufacturing agenda. The plan identifies the barriers and bottlenecks to domestic medicine production, as do the subsequent 2007-2016 SADC and 2012-2016 East African Community (EAC) plans. All the plans have noted the over reliance on imports of medicines from developed countries. They identify the barriers to expanding medicine production in the region as:

- A weak policy environment and limited governmental support to encourage domestic investment in the pharmaceutical industry;
- High tariffs on imported inputs, high interests rates on credit, ageing and unreliable energy, water and transport infrastructure;
- Shortfalls in capital and skills, including in scientists and industrial pharmacists and in laboratories;
- Limited international linkages and mechanisms for and intellectual property constraints in technology transfer and in the sourcing of active pharmaceutical ingredients;
- Gaps in the regulatory framework and in enforcement capacities to ensure quality assured, safe and efficacious medicines;
- Small markets within individual countries, and
- Weak or non-existent capacities for research and development.

The flow chart below summarises these constraints:

Flow chart of constraints to local medicine production



Overcoming barriers to local production

A range of measures are needed to overcome these identified bottlenecks, including:

- **Government to set an enabling environment, including in policy** to facilitate investments in and support domestic production, such as through tax exemptions, interest and utility subsidies, low tariffs on imported inputs and guarantees on credit.
- **Investment in skills and capacities** for regulatory functions, technical, business and management aspects of manufacturing, and for strategic policy leadership, including through negotiating partnerships with international firms and governments;
- **Setting laws and strengthening enforcement capacities** within national medicines regulatory authorities including investing in laboratories, enforcement personnel and technical capacities in laboratories.
- **Negotiating regional and international agreements on markets** to widen the market size to improve viability of the industry and to access technology, enhanced product portfolios and investment capital;
- **Investing in Research and Development capacities** by developing science capacities, investing in local biodiversity and indigenous knowledge and in local R&D infrastructure.

Can south–south co-operation overcome barriers?

There is evidence of new interest in medicines markets and production in east and southern Africa, with India, Brazil, Thailand, China and other emergent economies involved in medicines production and trade. These countries are setting up plants with varying degrees of collaboration and joint ownership with African producers. Examples of this are shown in the box below:

Mozambican Medications Company (SMM) (Brazil-Mozambique ARV Plant)

The government of Mozambique in partnership with the government of Brazil, is building a plant to produce generic drugs for treatment of AIDS and other diseases. This is Brazil's largest single development cooperation project, with an investment of about US$23 million. A regional office of the Oswaldo Cruz Foundation (FIOCRUZ, Fundação Oswaldo Cruz) was installed in Maputo in 2008 to facilitate coordination on the ground. According to FIOCRUZ, during the first phase, equipment and drugs will be brought from Brazil, and packing will be done in Mozambique, with the medicines distributed in the country free of charge. This phase will develop local expertise and labour capacity to run the factory.

Quality Chemical Industries (Uganda) and CIPLA (India) ARV Plant

On Government of Uganda request, Cipla Ltd, a leading Indian pharmaceutical manufacturer, extended technical assistance to Uganda through a joint venture with a local partner Quality Chemicals Ltd (QCL), to locally manufacture antiretroviral and anti-malarial drugs under licence from Cipla Ltd. In October 2007 a $38m pharmaceutical plant was set up in Kampala. Cipla (India) and Quality Chemical Industries (Uganda) both hold 42 per cent stake each in the joint venture. In November 2009, TLG Capital of UK acquired a 8.2 per cent stake in the plant, as did Capitalworks Investment of South Africa. Cipla provided the technology and expertise to set up the plant which now provides an outlet for Cipla to produce medicines locally for the African market.

The two examples reflect rather different approaches to south-south co-operation. The first, largely through government to government development aid, supports Mozambican manufacture and local access to medicines. The second, through the private sector, supports distribution and sale. Both reflect growing capacities in emergent economies such as Brazil and India to develop and produce medicines, the expansion of pharmaceutical markets in Africa, and the increasing level of joint ventures in the industry across national boundaries.

How to align south–south co-operation to addressing barriers?

Emerging economies have the knowledge, skills and capital to overcome the bottlenecks ESA countries face in local production of medicines, and to lever global support for local production. For example, in 2007/8, Brazil, India, China and South Africa contributed nearly $200 million to global health initiatives such as Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

New south-south co-operation arrangements and joint ventures in medicine production present an opportunity for ESA countries to overcome bottlenecks in local medicine production, if measures for this are included in the joint agreements.

ESA countries need to negotiate and secure their own short and longer term interests in these investments processes, including in relation to their own biodiversity. Recent controversies around stockpiling of drugs and vaccines for pandemic flu from the H5N1 and H1N1 viruses have highlighted this.

Negotiations on such south-south arrangements would need to look not only at the immediate production investment, but at strengthening capacities for research and development, for regulation, for drug price and quality monitoring, for prequalification, infrastructure development and human resource development and other priority obstacles to local production. Regulators need strengthening to better spot when to say no to bad medicines and manufacturers.

South-south co-operation also needs to be complemented by, and not to displace regional processes. Regional level production and distribution agreements provide wider markets for medicines produced, generating economies of scale, better use of installed capacities, and greater possibilities of local supply of active ingredients and other raw materials.

Regional co-operation has also been important to harmonise medicine regulation and support skills development. It will continue to play a role in strengthening the negotiating position of countries in the region in ensuring that new partnerships in medicine production play a role in overcoming the bottlenecks identified in the AU, SADC and EAC plans to localise medicine production on the continent.

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