



# Enhancing local medicine production in east and southern Africa

*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. It highlights, from case study work in selected countries in East and Southern Africa the potential opportunities for strengthening local medicine production. In the brief we propose that African countries strengthen domestic capacities, co-operation between domestic private and public sectors within ESA countries, and regional co-operation across ESA countries to address bottlenecks. Some areas such as infrastructure development and training may be important groundwork for others, such as technology transfer and research and development. South-south cooperation in medicines production can play a role in this but it cannot be assumed. Negotiations on south-south arrangements should 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.*

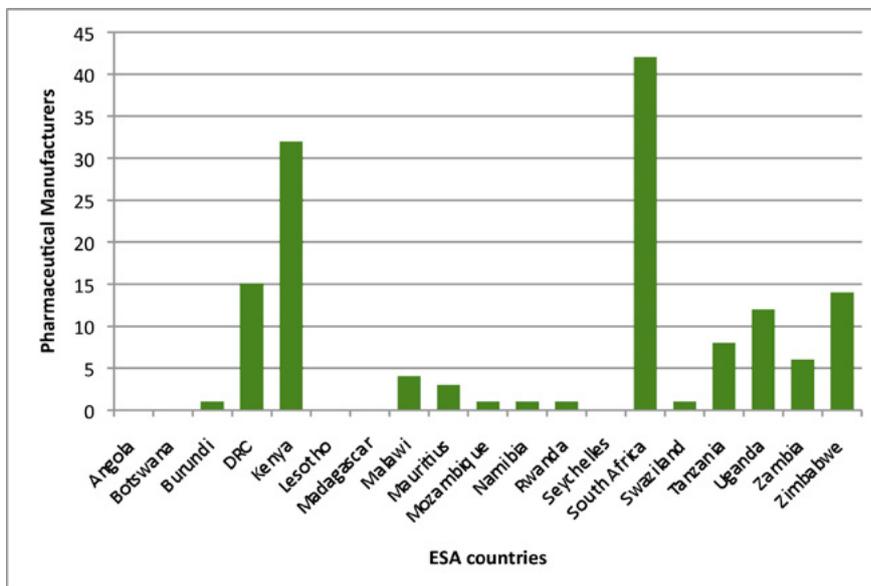
## Medicines production in east and southern Africa

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 domestic manufacturing plants. Kenya exports between 35 and 45 percent of its

pharmaceuticals, particularly to other east, central and southern Africa countries.

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.

Number of domestic pharmaceutical manufacturers in the ESA region



Sources: WHO (2011), EAC (2011)





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. As a result, Africa has 14 percent of the world's population but produces only 3 percent of the world's medicines and its pharmaceutical manufacturing sector contributes only 25-30 percent of the continent's needs (IFC 2008).

### Barriers to local production

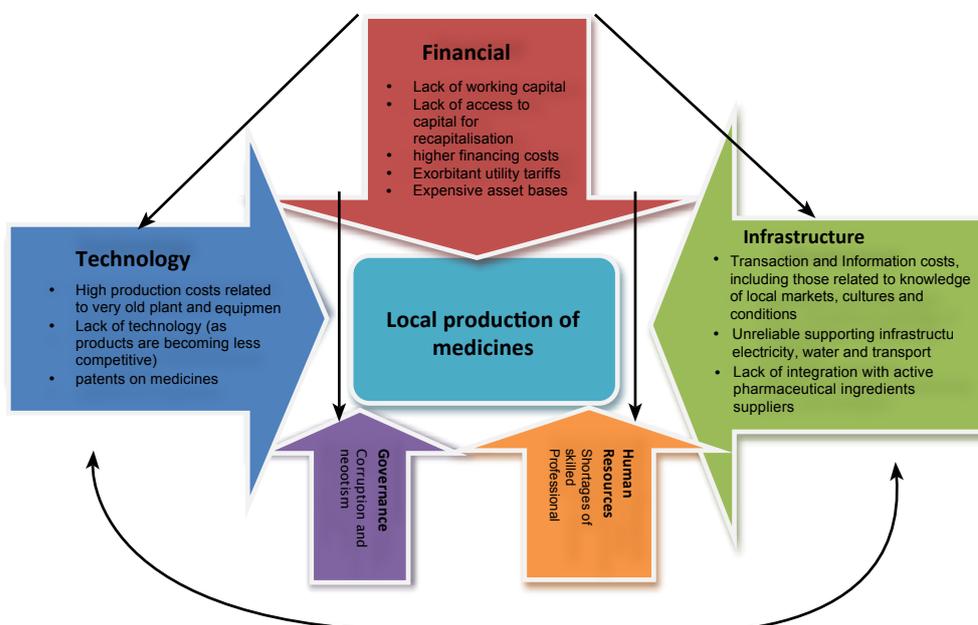
This gap in domestic manufacturing has been identified as a concern in the continent. The African Union (AU) Summit adopted a Pharmaceutical Manufacturing Plan for Africa in 2007. The plan calls for a mapping of productive capacities on the continent to inform a manufacturing agenda. It identifies the 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. From these plans and our own work we identify the barriers to expanding medicine production in the region as:

- Weak policy implementation and limited government support in the initial stages to encourage domestic investment in the industry;

- Small national markets, making it difficult for local manufacturers to achieve economies of scale in production;
- Importation of most active pharmaceutical ingredients and medicines, offering little value addition in local production, weakening technology transfer and making the supply chain vulnerable to corruption;
- High tariffs on imported inputs, high interests rates on credit, together with ageing and unreliable energy, water and transport infrastructure;
- Shortfalls in capital and technology, and dependence on external funding;
- Shortfalls in skills, 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;
- A prohibitive intellectual property regime;
- Gaps in the regulatory framework and in enforcement capacities to ensure quality assured, safe and efficacious medicines; and
- Weak or non-existent capacities for research and development.

These barriers interact as shown in the flow chart below.

Flow chart of constraints to local medicine production





Addressing these interacting barriers thus needs a multifaceted approach. For example, even where there is willingness to transfer know-how or technology, recipients must also have the capacities to effectively appropriate the technology transferred, in a policy and political environment that is conducive to pharmaceutical innovation.

### **Overcoming barriers to local production**

Exploring the experience of countries like Uganda that have strengthened a local producer through a south–south partnership; and of countries like Zimbabwe and Kenya that have strong domestic production capacities points to measures that have already been taken in the region to strengthen domestic production of medicines, including:

- **Governments setting an enabling regulatory environment**, with sound laws governing the pharmaceutical sector, with a capacity for their enforcement, including laboratories and personnel;
- **Local training and research and development institutions** that develop capacities for science and technology to sustain a domestic industry;
- **Regional trade agreements** to widen the market size to improve the returns to producers, and to access skills, technology and investment capital;

While many countries have national pharmaceutical policies, there is a gap between policy and implementation in a number of areas. For example governments could introduce stronger measures to exempt duty and value added tax (VAT) on imported pharmaceutical raw materials and packaging materials to stimulate local production, together with reduced corporate tax rates, investment tax credits and other incentives for companies to set up production. Where countries have done the opposite, exempting imported drugs from duties and taxes, while raising them on raw materials and packaging, this makes imports cheaper than locally produced medicines.

These contradictory measures arise if there is a gap in the dialogue between governments, pharmaceutical companies and training institutions on what capacities and measures are needed to support the local pharmaceutical industry.

### **The role of regional and south–south co-operation**

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 becoming involved. In Uganda, for example, on request by the government, Cipla Ltd, a leading Indian pharmaceutical manufacturer entered a joint venture with local partner Quality Chemicals Ltd (QCL). This enabled local production of antiretroviral medicines and anti-malarials under licence from Cipla Ltd. Evidence of south-south co-operation was also found in the ESA region in the establishment of a research and development division at the QCIL plant with the help of Cipla Limited, in training and exchange programmes; and in co-operation around human resources for health with China, Cuba, Brazil and India.

However south-south co-operation cannot be assumed to imply equality in partnership. Emergent economies outside the region have interests in consolidating their own trade position and African countries would need to negotiate for their specific interests in south-south co-operation. It may be that co-operation on building capacities and infrastructure in the region facilitates future investment in manufacture in the longer term more than direct partnerships in pharmaceutical manufacturing.

ESA countries could, as a more primary goal, strengthen domestic strategies, capacities and co-operation between domestic private and public sectors within ESA countries, and regional co-operation across ESA countries to address bottlenecks. Regional co-operation is also important to harmonise medicine regulation and for medicine procurement.



In the Southern African Development Community (SADC) region, there are government-to-government agreements on recruitment of pharmacists; bilateral agreements offering preferential treatment and flexibility for medicines markets; co-operation and specialist exchanges on specific health services and telemedicine; and co-operation on areas of training of health personnel. ESA country membership of the Common Market for Eastern and Southern (COMESA), SADC and the East African Community (EAC) offers opportunities to negotiate for a tripartite Free Trade Area between the three blocs to widen markets for medicines and to strengthen regional interactions on the technology, infrastructure, capacities, research and development and capital needed for pharmaceutical production.

### Areas of action for enhancing local production

Our research suggests a need for immediate and medium term actions to

1. Strengthen awareness, oversight and reporting on implementation of laws, policies and co-operation agreements on pharmaceutical production, including to ensure transparency and quality of practice;
2. Establish dialogue among governments, pharmaceutical companies and training institutions on human resource requirements projected for the industry at national and regional level; on measures for legal recognition of pharmaceutical specialties (clinical, industrial pharmacists, laboratory technicians, scientist and engineers) and designing and implementing schemes to train, attract and retain personnel;
3. Implement agreed infrastructure projects in water, energy and transport corridors under regional integration programmes in the EAC and SADC regions;
4. Stimulate and support local pharmaceutical industries through fiscal incentives and through tax and duty exemptions on imported inputs to local production;

5. Develop through ministries of trade and health a database on essential medicines, and their local production or imported source and cost, to inform procurement and investment; and to
6. Negotiate for a share of external funds to be used for local procurement from companies prequalified by the World Health Organisation.



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Produced September 2014  
with support from IDRC Canada  
Cite as: SEATINI, CEHURD, TARSC,  
CPTL (2014) Enhancing local medicine  
production in east and Southern Africa,  
EQUINET Policy brief 39,  
EQUINET Harare

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