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Medicines production and procurement in east and southern Africa and the role of south-south co-operation

Southern and Eastern African Trade, Information and
Negotiations Institute (SEATINI) and Centre for Human
Rights and Development (CEHURD)

with
Training and Research Support Centre and
Centre for Trade Policy and Law

In the Regional Network for Equity in Health in east and
southern Africa (EQUINET)

EQUINET DISCUSSION PAPER 104

August 2014

With support from IDRC (Canada)



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EXECUTIVE SUMMARY

• Medicines
• production and
• procurement
• in east and
• southern Africa
• and the role
• of south-south
• co-operation

Access to essential medicines is one of the requirements for achieving equitable health systems and better population health in the east and southern Africa (ESA) region. One constraint to sufficient access to essential medicines is the region's weak capacity to produce medicine. In May 2007, the African Heads of State and Government adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) to maintain a sustainable supply of quality essential medicines to improve public health and promote industrial and economic development. The plan assesses the barriers and bottlenecks to medicine production in the region. Equally, the plans of the Southern African Development Community (SADC) and the East African Community (EAC) for pharmaceuticals provide information on proposed policy measures to overcome barriers to access to medicines, including measures such as pooled procurement to make medicines more affordable. Thus, within the region an important policy goal is to create and sustain reliable, regional pharmaceutical industries whose operations are relevant to the local economies and responsive to the region's disease burdens.

This work forms part of the Regional Network for Equity in Health in East and Southern Africa (EQUINET) programme of work on 'Contributions of global health diplomacy to health systems in sub-Saharan Africa: Evidence and Information to support capabilities for health diplomacy in east and southern Africa'. This report compiles evidence from secondary and primary data collection on the role of south-south diplomacy, particularly the co-operation agreements with China, India and Brazil in overcoming bottlenecks to medicine production in ESA.

The methods used were: a literature review of published materials relevant to medicine production in the region; a policy dialogue forum involving senior officials within the health services from countries in the ESA region; three country case studies carried out in Kenya, Uganda, and Zimbabwe; and consultations carried out with senior officials from ministries of health in the ESA region. The study faced a number of challenges in original data collection noted in the report. They are acknowledged to weaken the analysis and conclusions and are noted as lessons learned on challenges facing data collection on emerging health co-operation that have significant economic implications.

The three case study countries, as for other countries in the region, face various bottlenecks to the production of medicines, despite existing pharmaceutical industries. Kenya has the most developed pharmaceutical industry in the EAC region and exports products to other countries in the region. Uganda's industry is smaller, but one of its plants has been granted Good Manufacturing Practices (GMP) accreditation by the World Health Organisation (WHO) and is engaged in the production of anti-retroviral (ARV) and anti-malarial pharmaceuticals. Zimbabwe's pharmaceutical industry is the second largest in the SADC region after South Africa. Although it has exported to other countries in the region and further afield, the industry has been performing poorly due to the economic context in the country.

The bottlenecks to local production in the countries in the region include:

- 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;
- External imports from large pharmaceutical corporations that are able to undercut the prices of local producers;
- Capital and skills shortfalls, including in scientists, industrial pharmacists and laboratories;
- Limited international linkages and mechanisms for technology transfer and sourcing of active pharmaceutical ingredients, and intellectual property constraints;
- 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 bottlenecks arise at national, regional and global levels. The underdevelopment of research and development is, for example, due in part to national factors such as a lack of funding, weak links between research institutes, industry and academia. It is also due to global factors such as limited technology transfer from more advanced pharmaceutical industries, restrictive intellectual property laws and lack of support from industry and governments in more industrialised countries, including the BRICS countries (Brazil, Russia, India, China and South Africa) to share their technology with the industry in ESA countries. Local production of pharmaceuticals in the ESA region faces bottlenecks related to market size and access, with the size, organisation and purchasing capacities of regional markets playing a role in this. At national level, local producers have difficulty securing financial investment, including from government funding and incentives.

ESA countries have made some progress in overcoming these bottlenecks, but gaps still exist, with evidence indicating measures that need strengthening at local, regional and global levels.

The study was not able to gather a comprehensive spectrum of data on south-south relations on the actual local production of medicines, as plans for this in Kenya and Mozambique had not matured to production. In practice, south-south co-operation on production was only available from the Uganda case study. In other countries, the evidence was derived more from policy commitments and plans and from the views of officials and policy makers. The case studies showed evidence of south-south co-operation in:

- Setting up of the only WHO Good Manufacturing Practice (GMP) compliant plant in east and central Africa;
- The establishment of a research and development (R&D) division at the Quality Chemicals International Limited (QCIL) plant with the help of Cipla Limited, with positive results for technology transfer;
- Potential for local production of active pharmaceutical ingredients (APIs) with partnership supporting manufacturing processes and capacity improvements;
- Development of personnel and skills through training and exchange programmes;
- Through government-to-government agreements, recruitment of pharmacists within the SADC region;
- Bilateral agreements in the SADC region that offer more preferential treatment and flexibility for medicines markets;
- Co-operation and specialist exchanges on specific health services and telemedicine;
- Co-operation on training of health personnel.

The evidence was too limited to support strong conclusions. It does suggest, however, that there is a policy commitment to south-south co-operation. For south-south co-operation to play a role in local production of medicines in the ESA region there would need to be greater national government intervention to direct such co-operation towards measures that overcome identified bottlenecks, particularly in capital investment, technology and skills transfer and in research and development.

As medicines production is a strategic economic area, it is argued that a convergence of interests with southern trade and investment partners cannot be assumed. Rather, national and regional economic and social interests need to be actively negotiated for. To tap the opportunity of south-south partnership agreements for local pharmaceutical production, ESA countries need to link negotiations to sustainable, medium- to long-term national plans for the local manufacture of medicines at lower cost than those imported into the country and that are co-ordinated on regulatory, trade and other measures at regional level. In part, this calls for more systematic implementation of existing policy measures at national and regional levels and for governments to play a role in incentivising local production and in ensuring a more conducive regional trade, investment and regulatory environment.

The report thus recommends measures to strengthen the enabling policy, legal, trade and investment environment, to strengthen oversight and regulation of medicines, and to enhance technical and strategic capacities in ESA needed for support of local production.

1. BACKGROUND

Access to essential medicines is one of the key requirements for achieving equitable health systems and better population health in the east and southern Africa (ESA) region, as well as globally. The United Nations Conference on Trade and Development (UNCTAD) notes that over the past 25 years developing countries have made significant strides to ensure greater access to medicines. The number of people with regular access to essential medicines increased from two to four billion between 1997 and 2002. However, nearly two billion people globally – many of whom live in least-developed countries – lack regular access to essential medicines (UNCTAD, 2011a). Thus, nearly two-thirds of the world's people are estimated to have access to full and effective treatments with the medicines they need, leaving one-third without regular access – mostly in Asia and Africa (DFID, 2004).

Although considerable progress has been made in access to medicines, the benefits of this progress have been unequally distributed globally. This problem may worsen as resistance develops to key medicines, such as those for malaria, TB and pneumonia. Where new medicines are developed to replace those no longer effective, they are frequently more expensive and may also require more stringent supervision to ensure they are properly used (DFID, 2004), potentially further worsening the problem of unequal distribution and subsequent health problems. UNAIDS has noted that although African countries are most affected by the AIDS epidemic, they are highly dependent on imported medicines and related products, with more than 80% of anti-retroviral medicines (ARVs) used imported from outside Africa (UNAIDS, 2014). The organisation reports that local production of ARVs is vital to secure continued access to life-saving treatment “for the 7.6 million people already accessing ARVs in Africa and the millions more, who still need access to treatment”. It further points out that local production is important not only for the AIDS response, but for other existing and future health challenges faced by the continent. The total pharmaceutical spending for the continent in 2012 is estimated at US\$18 billion and is expected to reach \$45 billion by 2020 (UNAIDS, 2014).

In east and southern Africa (ESA), the region's medicine production capacity remains weak. The continent has 14% of the world's population but produces only 3% of the world's medicines. While the overall pharmaceutical market in sub-Saharan Africa is worth \$3.8 billion annually, Africa's pharmaceutical manufacturing sector contributes only 25-30% of the continent's needs (IFC, 2008).

The African Heads of State and Government adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) at the African Union (AU) summit in May 2007 with the aim of contributing to a sustainable supply of quality essential medicines to improve public health and to promote industrial and economic development in Africa. The AU plan is the basis for a more co-ordinated approach to local production of medicines based on countries' needs. Developing a local manufacturing capacity has advantages in many areas, including for employment, skills retention, foreign currency savings and responsiveness to local health needs. The AU plan includes a research agenda in six priority areas: mapping of productive capacity, situation analysis and compilation of findings, manufacturing agenda, intellectual property issues, political, geographical, and economic considerations and financing. It provides an assessment of the barriers and bottlenecks to medicine production in the region that need to be addressed.

The Southern African Development Community (SADC) Pharmaceutical Business Plan and the East African Community (EAC) Pharmaceutical Manufacturing Plan also provide policy measures to overcome barriers to access to medicines, including for pooled procurement to make medicines more affordable (SADC, 2007; EAC, 2011). The regional dimension is necessary to foster the harmonised and co-ordinated production and trade policies needed for investment in essential medicine production and to create the capacities and markets to take advantage of existing or planned productive facilities within the region. The regional frameworks of the SADC and EAC to support regulation of medicines, information, procurement and quality control are important contributors to advancing local manufacturing. The region thus has a policy goal to create and sustain pharmaceutical industries whose operations are relevant to local economies and responsive to local disease burdens.

Multiple impediments slow policy application, however. For example, efforts to prequalify medicine production were reported to face hindrances in low levels of domestic public financing for health and competencies for manufacturing (AU, 2012). The global dialogue on research and development for neglected diseases at the World Health Organisation (WHO) points to lack of technology and skills transfer for local production.

While the region has traditionally been dependent on Western economies for bilateral and multilateral interventions in the health sector, including in medicines produced and purchased from the funding countries, new diplomatic collaborations and agreements have been pursued between countries in east and southern Africa and Brazil, India, and China around trade, joint manufacture, prequalification processes, and other areas of technical co-operation on medicines. These relations provide opportunities for overcoming bottlenecks in important aspects of pharmaceutical manufacturing such as technology transfer, particularly when linked to initiatives within the region such as the African Network on Drugs and Diagnostics Innovation (ANDI), which aims to promote and sustain African-led health product innovation to address African public health needs (SEATINI and CEHURD, 2013).

Within the EQUINET research programme on Global Health Diplomacy (GHD) for equitable health systems in ESA, co-ordinated by Training and Research Support Centre, in association with East, Central and Southern African Health Community (ECSA-HC), Centre for Trade Policy and Law (CTPL) Canada, this study sought to assess whether and how relationships and agreements with Brazil, India and China are addressing the bottlenecks identified in AU, SADC and EAC plans for pharmaceutical manufacturing and how far ESA countries are facilitating relevant inputs in these agreements, both at national and regional level.

The research was conducted through:

1. Compilation of existing literature (policies, official documents, published materials including peer review publication) and interaction with selected key informants;
2. Case studies of co-operation on production of essential medicines between Kenya and Uganda and India and China, respectively, and on Zimbabwe as a case that has built domestic production without a southern partner to explore how this differed;
3. Review with policy makers and officials on the findings to identify areas for policy dialogue.

This report compiles the evidence from the study.

- *Section 2* describes the methods used.
- *Section 3* presents the findings.
- *Section 4* discusses the findings and
- *Section 5* outlines the conclusions from the work.

2. METHODS

This report compiles evidence from secondary and primary data collection. The methods used were: a literature review of published materials relevant to medicine production in the region; a policy dialogue forum involving senior officials within the health services from a number of countries in the ESA region; three country case studies carried out in Kenya, Uganda, and Zimbabwe and consultations carried out with senior officials from ministries of health in the ESA region.

2.1 Literature review

The literature review was based on a desk study of published literature that included peer reviewed journal articles, policy documents, book chapters, media articles, academic reports, briefing papers and parliamentary reports. The documents included were those that referred to local production of pharmaceuticals, south–south co-operation, access to medicines, global health diplomacy and those that referred to the role of Brazil, India and China in access to medicines and local pharmaceutical production in ESA. The literature review included documents produced between 1992 and 2012, a period during which the debate on access to medicines gained momentum due to the global policy regime led by the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the quest for access to medicines in the era of HIV, given the minimal pharmaceutical production in ESA countries, despite its being the most affected by AIDS. The period also saw the emergence of Brazil, India, China, Russia and South Africa (BRICS). The literature review was conducted between 2012 and 2013. The reports were obtained from Medline, IDRC, Google Scholar and EQUINET databases and through Internet searches. Searches were also done on multilateral agency websites, e.g., those of the WHO, WTO, UNIDO, UNCTAD, World Bank; continental and regional organisation websites, e.g. those of the AU, SADC, EAC, UN Economic Commission for Africa; and mainstream international and regional media. The Internet and online library searches used the following search terms: access to medicines, local production, global health diplomacy, south–south co-operation + pharmaceutical production + east and southern Africa. Further searches were done for pharmaceutical production + east and southern Africa + Brazil or India or China. Where a relevant paper was found, the snowballing method was also employed, leading to other useful documents.

The search found 258 documents specific to medicines in ESA countries, including the role of Brazil, India and China in ESA countries. A final set of 58 documents met the inclusion criteria and terms noted above. Note that the documents included in the review are not exhaustive of all literature on access to medicines, local production and south–south co-operation.

The methods faced limitations in that much publication in Africa is in grey literature not accessible online that would usually be included in the review. This was addressed through fieldwork on the case studies. In some areas the review was able to triangulate information from official policy documents and peer reviewed scholarly papers to highlight debates around local production and access to medicines, and the potential role of south–south co-operation.

2.2 Policy dialogue forum

A policy dialogue forum was conducted at the 56th ECSA Health Minister's Conference in Arusha, Tanzania, in mid-December 2012. Its purpose was to interact with senior officials from the ECSA countries and share preliminary findings from the literature review with regards to bottlenecks to local production of pharmaceutical medicines in the ESA region and to get feedback from senior officials on the findings on bottlenecks to local production.

The policy dialogue forum was an event organised independent of the research project. It was a ministerial meeting of the East Central and Southern Africa (ECSA) Health Community, and the research team took advantage of the meeting because of its appropriateness to the issues being investigated. One senior official per country was interviewed. The interaction with senior officials was done through structured interviews where a summarised flow chart of the constraints/bottlenecks to local production was distributed to the

officials (at director level in the ministries of health, responsible for health, medical, nursing and technical services) of the countries available at the meeting. The interviewees (senior officials) were requested to rate how important they see each factor as a block to local medicine production in their country. Out of the nine countries available at the conference, the research team managed to interview seven senior officials from the following countries: Kenya, Lesotho, Malawi, Swaziland, Tanzania, Zambia and Zimbabwe. Officials from the other three countries were not interviewed due to time constraints.

2.3 Country case studies

In addition to the literature review and the policy dialogue forum, four case studies were intended and three country case studies finally carried out in Kenya, Uganda and Zimbabwe.

1. The Uganda case explored the role of Uganda-India co-operation in local medicines production and specifically the experience of the CIPLA-QCIL partnership, which has now been in existence since 2007.
2. The Kenya case explored the role of Kenya-China co-operation in local medicines production. As a limit to the methods, fieldwork found that the original plan remained at policy level and no plant had yet been established.
3. The Zimbabwe case explored the role of domestic producers using local private capital in local medicines production and, specifically, the experience of Varichem.
4. A fourth case study from Mozambique on Mozambique-Brazil co-operation could not be carried out due to access to a insufficient number of key informants to make the case viable and because production of medicines had not commenced. This loss of a full country case is an acknowledged limitation of the research that is taken into account in interpreting the findings.

The Kenya country case study was conducted with a combination of two key methodologies. The study reviewed literature specifically on the Kenyan pharmaceutical industry, including policy documents, annual reports and technical documents produced by the government, research institutions and technical UN agencies like the United Nations Industrial Development Organisation (UNIDO). Thirty documents were reviewed, using search terms, strategy and sources including local grey literature sources as for the literature review but focused on Kenya and the East African Community (region) and China. Key informant interviews were carried out in June 2013, with stakeholders selected on the basis of a stakeholder analysis and for their knowledge on the issues and by virtue of their professions and occupations in the Kenyan health, trade and pharmaceutical industry. These were country government officials at the Ministry of Health and specialised government agencies such as the Kenya Medical Research Institute, Kenya Intellectual Property Institute, Pharmacy and Poisons Board and Kenya Medical Supplies Agency. There were also respondents who were directly working in the pharmaceutical industry (private sector and University of Nairobi School of Pharmacy). Finally, there were respondents from the civil society sector. *Table 1* compiles a list of stakeholders interviewed across all country case studies.

A similar methodology was adopted in the Uganda country case study. A review of literature specifically pertaining to the Ugandan pharmaceutical industry was conducted. Twenty documents, which are all included in the bibliography, were reviewed, with search terms and strategy as above but focused on Uganda and India. Key informant interviews and one focus group discussion were carried out between January and November 2013, involving a number of stakeholders in the pharmaceutical industry on the same basis as for Kenya using stakeholder analysis and a cross-section of key informants. Included were: officials from the ministries of health, trade, and justice; representatives of specialised agencies such as the Uganda Investment Authority and the National Drug Regulatory Authority; representatives from the private sector such as Quality Chemicals Industries and Abacus Pharmaceuticals; representatives from civil society and academic institutions (see *Table 1*). Three site visits were conducted at various manufacturing plants to witness the state of pharmaceutical production in the country. These were the plants of Quality Chemicals Industries Limited (as the only WHO Good Manufacturing Practices (GMP) compliant plant in east and central Africa), as well as Kampala Pharmaceutical Industries and Abacus Parenteral Drug Limited (as representative of other pharmaceutical manufacturers in Uganda). Representatives from Marvid Pharmaceuticals and GKO Pharmaceuticals were interviewed to include small, locally funded manufacturers.

Table 1: Stakeholders interviewed in country case studies

Category of stakeholder/key informant	Country	Number targeted for inclusion	Number interviewed	Number lost to interview (%)
Government officials	Kenya	4	2	50
	Uganda	5	4	20
Academic institutions	Kenya	1	1	0
	Uganda	1	1	0
Private sector	Kenya	2	1	50
	Uganda	6	6	0
	Zimbabwe	1	1	0
Research institutes	Kenya	1	1	0
	Uganda	0	0	0
Specialised government agencies	Kenya			
	Uganda			
	Zimbabwe			
Professional associations	Zimbabwe	1	1	0
Civil society	Kenya	1	1	0
	Uganda	2	2	0
Embassy	Kenya	1	0	100
	Uganda	1	0	100
Total number of interviews	Kenya	14	9	36
	Uganda	16	13	19
	Zimbabwe	3	3	0

The Zimbabwe case study reviewed literature specifically on the Zimbabwe pharmaceutical industry, including: policy documents; annual reports and technical documents produced by the government, research institutions and technical UN agencies like UNIDO. Twenty-five documents, which are all included in the bibliography, were reviewed, with search terms and strategy as above but focused on Zimbabwe and southern Africa. Three key informant interviews were included from government, a pharmaceutical producer and a representative of non-state actors implemented between January and February 2014, selected on the basis of their knowledge of and/or experience with working in the health and pharmaceutical sector and the pharmaceutical industry (see *Table 1*). A smaller number of informants were used as they provided sufficient coverage of the main stakeholders for the focus areas, given that no south-south agreement was included and that this focused only on domestic production.

The loss to follow-up of interviews was not significant in Uganda or Zimbabwe but was a little higher in Kenya, although there was still a sufficient number in each category of Kenyan respondents to cover that category. Those not interviewed were unavailable at the time the study was conducted despite several efforts to set up interviews with them. It was not possible to interview a specialised government institution, as one does not exist in Uganda. As for the site visits due to financial and time constraints, only informants in the Kampala Metropolitan Area were interviewed and only plants located in the metropolitan Kampala area were visited.

In relation to ethics, the key informant (KI) respondents received introductory letters in advance of the interviews detailing the background and purpose of the research, structure of the interview and information pertaining to data storage of the interview transcripts. The respondents signed consent forms agreeing to be interviewed. Anonymity is preserved on quotes unless respondents indicated that they were willing to be quoted. In Kenya, the Ministry of Health gave authority to implement the work. In Uganda clearance was obtained as part of the Center for Health, Human Rights and Development's research clearance from the National Council for Science and Technology. In Zimbabwe individual interviewees gave consent for the interviews.

2.4. 'Fast-talk' consultations with policy actors

Consultations were carried out at the the 2nd East, Central and Southern Africa Health Community (ECSA-HC) pre-World Health Assembly (WHA) preparatory meeting for senior officials from ministries of health held in Harare, Zimbabwe, from the 29-30 April 2014. Using a 'fast-talk' format, a set of common questions were identified from the work to date for discussion with senior officials, exploring information gathered to date and their responses to the key issues arising. The questions particularly explored the policies, incentives, regulatory, licensing requirements, institutional reforms, tax incentives, funding, training of personnel needed to support local production and lever benefits from south-south co-operation; the changes needed to domestic law and policy; and areas for regional trade agreements and protocols in the ESA region (EAC, SADC). The interaction with senior officials was done through structured interviews. Of the eight countries available at the meeting, four officials were interviewed (Swaziland, Uganda, Zambia and Zimbabwe). The other four were not available for interview.

2.5. Limitations

The study faced a number of challenges in original data collection that are acknowledged to weaken the analysis and conclusions, viz:

- In only one country (Uganda) was comprehensive information accessed on the nature of co-operation in existence, its scope and extent. The Kenya/Sino pharmaceutical plant did not finally advance and the factors affecting this outcome were not always forthcoming or in the public domain. The planned assessment of the Mozambique-Brazil case could not be carried out due to barriers to access to sufficient KIs and because the envisaged plant had not yet initiated production at the time of the study;
- In all countries there were difficulties in accessing all key informants;
- Much of the grey literature on the pharmaceutical industry is not in the public domain, particularly on current negotiations and agreements.

These limitations have affected the strength of findings from fieldwork and meant that we were more reliant on desk review; they are taken into account and noted in any discussion of findings. The research team mitigated this shortfall to some extent through two rounds of dialogue with senior officials in the region to assist in interpreting evidence from desk review or in addressing gaps in evidence. The gap in functioning examples of good practice in case study countries has meant that the study has been more focused on the bottlenecks than the learning from promising practice. These challenges face data collection on emerging areas of health co-operation that have significant economic implications and may be important for considering design of future studies in this area.

3. FINDINGS

3.1 Contexts for pharmaceutical production in ESA

The three countries included have similarities in their contexts in terms of disease burdens, but different economic conditions.

Kenya faces health burdens that include HIV/AIDS, malaria, and tuberculosis (MoMS and MoPHS 2010; 2012). For tuberculosis (TB), for example, Kenya is ranked tenth in the world, and the caseload continues to increase (MoMS and MoPHS 2010). Underfunding of the health sector means that medicines, medical devices and diagnostics become out of reach for many people, particularly the poor and vulnerable (MoMS and MoPHS 2010; WHO, 2010). The East African Community (EAC) Pharmaceutical Manufacturing Plan 2012-2016 (EAC, 2011) noted that the majority of the region's population (Burundi, Kenya, Rwanda, Tanzania and Uganda) have low purchasing power and can hardly afford to buy medications, with women particularly affected. The Plan further notes that the public healthcare system in the EAC region is constrained by budgets and, to a large extent, unable to fulfil population healthcare needs (EAC, 2011).

Kenya's development strategy is defined by *Kenya Vision 2030* (Government of Kenya, 2007). Kenya's National Pharmaceutical Policy (NPP) of 2012 succeeded the Kenya National Drug Policy (NDP) of 1994 and is premised on the principles of human rights, good governance, partnerships, effective regulation and international collaboration (MoMS and MoPHS 2012). The policy encourages a multisectoral and integrated approach that recognises the role of the government, private sector, non-governmental organisations, civil society and other regional and international bodies. This makes the pharmaceutical industry dependent on the economic and political climate as these shape trade at local and global scale.

The Kenya health sector is governed by the Public Health Act 1957 and pharmaceuticals, by the Pharmacy and Poisons Act, Cap 244 (1957, revised 2009). Other laws pertinent to the pharmaceutical industry include:

- **Industrial Property Act (2001)** governs the promotion of inventive and innovative activities (regulating patents, industrial designs etc.);
- **Anti-Counterfeit Act (2008)** prohibits trade in counterfeit goods, including pharmaceuticals;
- **Kenya Public Procurement and Disposal Act (2005)** establishes procedures for public procurement and disposal of obsolete or surplus assets and equipment;
- **The Industrial Registration Act (CAP 118, 1988)** governs the registration of industrial activities (pharmaceutical manufacturers are to be registered under this Act);
- **The Food, Drug and Chemical Substances Act (CAP 254);**
- **The Environmental Management and Co-ordination Act (1999)**
- **The Narcotic Drugs and Psychotropic Substances (Control) Act (1994);**
- **The Employment Act (2007)** governs the right of employees and basic conditions of employment;
- **The Industrial Training Act 1979 and Revised Edition 1983** governs the training of persons engaged in industry

In **Uganda**, life expectancy increased from 45 years in 2003 to 52 years in 2008. But as for Kenya, the country faces a high burden of tuberculosis, HIV and AIDS, other communicable and maternal and child health burdens (WHO, 2012b; Zakumumpa, 2013). The per capita total expenditure on health in Uganda has steadily increased in recent years and in 2010 was estimated at over \$40, up from roughly over \$20 in 2005. There are significant differences between rural and urban areas in health and health care. For example, 80% of the births in urban areas are attended by skilled health personnel compared to only 38% in rural areas.

The demand for essential medicines has continuously exceeded supply. There has been significant increase in per capita expenditure on medicines from \$0.5 in 2010/11 to \$0.9 in 2012/13 but this still falls far short of

the annual needs of the population (MoH, 2008b). Medicines in public health facilities are relatively more affordable than those in the private health facilities, where medicines are 3-5% more costly (MoH, 2008b; 2010). Therefore, government is the primary provider of essential medicines in Uganda. Only 45.7% of public health facilities have essential medical supplies (medicines, diagnostics, bandages etc) compared to 57.5% in mission facilities and 56.3% in private facilities. Because of these shortfalls in access to medicines, up to 70% of government facilities suffer monthly stockouts of an indicator medicine. The length of stockouts in public health facilities has been estimated at 72.9 days per year compared to 7.6 days per year in mission facilities while the mean availability of originator and generic medicines on the Essential Medicines List (EML) is at 3.5% and 45.7% respectively (MoH, 2008b; 2010).

Most medicines provided by the government are not locally funded, but through global initiatives that influence both the source and destination of their funded medicines (MoH, 2008b). Only 30% of the EMHS are provided for in the national budget with the rest of the resources being obtained from donor funds and out-of-pocket funding (MoH, 2009). In 2006/7, for example, global initiatives financed \$2.39 per capita out of the total of \$4.06 per capita spent on EMHS (MoH, 2009). External financing of pharmaceutical products often ends in external procurement. With most medicines externally sourced, the country is unable to guarantee that the public will have sustainable access to medicines. Any cutbacks in external funding could have a catastrophic effect on the health sector. To address these issues, Uganda has developed an extensive policy framework to outline how the government intends to support pharmaceutical production in the country.

- The **National Health Policy (2009)** guides implementation of health service delivery in Uganda;
- The **Uganda Health Sector Strategic Plan III (2010/11-2014/15)** addresses the issue of human resource constraints (including stipulating the opening of a modern school of pharmacy at Makerere University) and undertakes to strengthen the policy and legal environment governing the production, procurement and distribution of pharmaceuticals in Uganda;
- The **National Drug Policy (NDP) (2002)** was created to ensure the availability, accessibility and affordability at all times of essential drugs of appropriate quality, safety and efficacy, and by promoting their rational use (MoH, 2002);
- The **National Pharmaceutical Sector Strategic Plan (NPSSP) II 2009/10-2013/14** aims to prioritise and streamline the pharmaceutical sector to ensure availability and rational use of essential, efficacious, safe, good quality and affordable medicines (MoH, 2008a);
- The **National Development Plan (2010/11-2014/15)** undertakes to ensure that local production follows recommended procedures and to strengthen the existing regulation and its enforcement in the pharmaceutical sector.

In addition to the policy frameworks above, Uganda's laws provide for the rights and obligations of stakeholders involved in the local pharmaceutical industry and standard procedures of how licenses, approvals and incentives can be applied for, among others:

- **The Uganda Investment Code Act (1991)** regulates local and foreign investments in Uganda, and includes benefits for priority investment areas, of which the pharmaceutical industry is one (GoU, 2000);
- **The National Drug Authority and Policy Act (1993)** establishes the national drug policy and a national drug authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs;
- **The Food and Drugs Act (1959)** provides for the prevention of adulteration of food and drugs;
- **The Public Procurement and Disposal of Public Assets Act (2003)** provides for the regulation of practices in respect to public procurement and disposal of assets, including of pharmaceuticals.

In **Zimbabwe** a decade of economic contraction from 1998 to 2008 resulted in a deep economic and social crisis characterised by a hyperinflationary environment, industrial capacity utilisation of below 10% and an overall cumulative gross domestic product (GDP) decline of 50% by 2008 (GoZ, 2013). The formation of a government of national unity in February 2009 and the subsequent introduction of a multicurrency system led to a stabilisation of the economy, although it is still in need of capital injection to kick start all

sectors, especially manufacturing, whose base was seriously eroded during the years of economic turmoil. Zimbabwe held its eighth presidential and parliamentary elections on the 31 July 2013, and the incoming ZANU PF government faces a myriad of challenges. The manufacturing sector remains in crisis with capacity utilisation declining from an average of 57% in 2011 to 44% in 2012 and 39% in the third quarter of 2013 (GoZ, 2013).

The economic decline in Zimbabwe was associated with a sharp decrease in real funding for social services, including the health sector, a decline in health infrastructure, loss of experienced health professionals, drug shortages and a drastic decline in the quality of health services. Based on household survey data, Zimbabwe's National Health Strategy (2009-2013) notes that Zimbabweans are dying from easily preventable and treatable conditions, e.g. HIV and AIDS, TB, diarrhoea, acute respiratory infections, malaria, malnutrition, injuries, hypertension, pregnancy-related and perinatal complications, mental health disorders, among others. Cholera epidemics, exacerbated by a countrywide breakdown of sewage and water supply and treatment systems, claimed 4,269 lives out of a total of 97,469 cases by the end of April 2009. Life expectancy at birth has fallen from 63 in 1988 to 43 years in 2005/6 (MoHCW, Ministry of Health and Child Welfare, 2009). Zimbabwe's health sector is principally governed by the Ministry of Health and Child Care (formerly Ministry of Health and Child Welfare) guided by the National Health Strategy for Zimbabwe: "Equity and Quality in Health: A People's Right", covering the period 2009 to 2013 (MoHCW, 2009).

Zimbabwe has a sound legal framework for quality management and biotechnology development in the pharmaceutical sector. The pharmaceutical sector in Zimbabwe is largely governed through the Medicines Control Authority of Zimbabwe (MCAZ), considered to be one of the strongest regulatory bodies in SADC and the Common Market for Eastern and Southern Africa (COMESA) region and an active participant in all regional regulatory bodies' activities (Zimtrade, 2009). Policies governing pharmaceutical products include:

- The **Zimbabwe National Medicines Policy (ZNMP) (2011)** implemented by MCAZ, aims at, among other things: regulation, procurement, production, distribution, sale, and import/export of medicines; training and development of human resources; effecting licensing and enforcement; pharmacovigilance and clinical trials; and laboratory trials.
- The **Zimbabwe Agenda for Sustainable Socio-Economic Transformation (2013)** is the most recent 5-year development plan, which, among other things, recognises the need to produce vital pharmaceutical products locally (GoZ, 2013).
- The **Industrial Development Policy (IDP) (2012-2016)** has as its objective to restore Zimbabwe's manufacturing sector. It also specifically targets the pharmaceutical sector as a pillar to reviving the manufacturing sector (Ministry of Industry and Commerce, 2012).

The Patents Act 1971 (Chapter 26:03 as amended up to Act No. 14/2002) allows any department of the State or any person authorised by the Minister of Justice to make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State.

3.2 Current pattern of pharmaceutical production

Kenya, Uganda, and Zimbabwe are experiencing a number of challenges in health infrastructure, population poverty, a huge disease burden, the lack of availability and the poor quality of drugs, inordinately high prices of medicines, and the trade rules and intellectual property protection inherent in them – all contributing to the lack of access to medicines that are safe, effective and affordable (UNDP, 2011). There is an increasing realisation that in order to deal with the gap of access to adequate basic medicines in the region, promoting local manufacturing in key countries like those in ESA is crucial. As such, UNAIDS, the WHO and UNDP have stressed the need to invest in regional and national production capacity in the pharmaceutical sector and in the development of local expertise (UNAIDS, UNDP and WHO, 2012a). The current patterns of pharmaceutical production in each of the case study countries are expounded below.

Kenya occupies a strategic position within the regional and global economy, and pharmaceutical sector issues are also at the centre of its regional and global engagements within the EAC, COMESA, WHO and WTO and in its bilateral relations with a number of countries. Kenya has the most developed and advanced

pharmaceutical manufacturing sector in the EAC region with a total market size estimated at \$240 million in 2008 (EAC, 2011; UNIDO, 2011). Of this market, generic medicines dominate with a market share of 56% compared to branded medicines at 44%. Locally produced medicines enjoy a 28% market share of the total pharmaceuticals consumed in the country. About 35-45% of local production of medicines is exported in the region, mainly to Tanzania and Uganda. This has been attributed to the relative proximity of these markets and the understanding of the local regional conditions of trade as compared to overseas competitors.

The Kenyan pharmaceutical industry has 42 companies listed as local pharmaceutical manufacturers including one multinational company, GlaxoSmithKline (MoMS and MoPHS 2010). Nevertheless, Kenya still imports about 72% of its medicines mainly from India and China. This has presented the country with both opportunities and challenges. The opportunities include the ability of the country's population to access medicines at affordable prices as they are relatively cheap compared to some locally produced medicines. But there are also challenges, which include shortages of some essential medicines, a huge import bill for medicines and the growing challenge of counterfeit and substandard medicines.

It emerged in the interviews especially from the civil society informant that the market for compromised (counterfeit) medicines is created by high prices of quality medicines, which the majority of the population cannot afford (Kenya KI1). A high prevalence of compromised medicines reflects failures in investing in drug regulation, a prerequisite if countries rely on imported medicines. Other contributing factors include lapses in the pharmaceutical supply chain management systems, corruption and lack of transparency in procurement practices, unregulated Internet purchases and weak mechanisms for national and international collaboration.

The growth of the Kenyan pharmaceutical sector has been phenomenal according to an interviewed pharmaceutical consultant, with an increasing number of companies that have upgraded their facilities, and the export of medicines to the EAC, Great Lakes region and West African countries, and local production being aimed at domestic markets (KI 2). Bigger companies have operated in Kenya for a long time and because of this have developed knowledge of markets and international linkages vital for unlocking resources and technology for expansion (Kenya KI2). Some companies have achieved international standards. For example, Universal Corporation received WHO prequalification for anti-retroviral (ARV) production in November 2011, allowing it to manufacture the combination ARV drug, Lamizido. Prequalification is a service provided by the global health body to test the safety, quality and efficacy of medicinal products before they are released to the public (IRIN, 2011).

In 2004, Kenya became the continent's second country after South Africa to start producing generic ARV drugs. A local company, Cosmos Ltd, was licensed by GlaxoSmithKline PLC (GSK) to produce generic versions of Zidovudine and Larnivudine and a combination of the two, for sale in Burundi, Kenya, Rwanda, Tanzania and Uganda. In the 1980s, the building of a pharmaceutical plant in Eldoret with the help of the Chinese government was mooted. This was a government-to-government partnership with each party owning 50% of the equity in the proposed investment. The Kenyan government, then led by President Daniel Arap Moi, agreed to provide the land while China would supply the equipment, technology and financial resources in the establishment of the plant. However, the project stalled, resulting in significant loss of time to continue with the investment (Kenya KI10). The government tried to revive the project in 2004 only to discover that the equipment brought by the Chinese had by then become obsolete. The policy orientation had also shifted from state controlled, state-owned companies to a more liberalised paradigm. As a result, establishment of the pharmaceutical plant was abandoned. There are no current plans to revive the project as the government has adopted a policy of maintaining a regulatory stance while allowing the private sector to do business (Kenya KI6).

Had the establishment of the pharmaceutical plant succeeded, it would have been one of the first in the African region and set the pace for government-to-government co-operation in local medicines production. Despite its advanced pharmaceutical sector, Kenya still imports a large quantity of medicines for a variety of reasons, as highlighted in *Box 1*. Currently, most of the investments in the pharmaceutical industry in Kenya are in distribution. For example, one of China's largest pharmaceutical companies, Beijing Holley-Cotec

Pharmaceuticals, opened a drug distribution centre and an East Africa Logistics Centre in Nairobi in 2006 to serve the east and central African region. The centre is reported to be distributing anti-malarial medicines to the private and public sectors at less than current market prices (Onjala, 2008).

Box 1: Imported pharmaceuticals into Kenya

A number of factors have contributed to the flood of imported pharmaceuticals, many of them substandard, into Kenya. These include:

- Foreign drugs are easy to register with the Pharmacy and Poisons Board;
- Registration costs for imported drugs are low and GMP and bioequivalence enforcement is lax;
- Kenya was one of the first countries in the region to reduce its pharmaceutical import tariffs to zero; other countries in the EAC followed in 2007;
- The PPB has little capacity to monitor the GMP status of foreign pharmaceutical factories producing drugs for import into Kenya. Its inspectors are supposed to visit foreign plants before drug registration, but cases have been reported of inspectors being shown one plant during the registration process and drugs then being produced under contract at a different facility;
- Quality testing of incoming imported drugs is patchy and irregular. The PPB introduced new guidelines requiring batch testing of imported drugs at the Ports of Entry (PoE) from March 2010 but it is unclear if personnel and equipment are in place to implement this;
- Penalties on importers for importing substandard drugs are weak and the strengthening Kenyan shilling is making imports even cheaper;
- Many international pharmaceutical companies have offices for their regional marketing agencies based in Nairobi and their products are imported into Kenya first, for subsequent distribution to other countries in the region.

At the same time, local pharmaceutical producers are disadvantaged on a number of fronts:

- Since they lack WHO pre-qualification, they are excluded from procurement by international NGOs and purchases funded by entities such as the Global Fund;
- Since many producers are small, they do not have the capacity to participate in larger volume tenders;
- They are facing severe price competition from imports;
- They are financially strained by delayed reimbursements from the government of duties and VAT already paid.

Source: UNIDO, 2010a.

There are few pharmaceutical manufacturers operating in **Uganda** despite high levels of consumption of medicines in the country. The pharmaceutical industry is mainly comprised of mainstream manufacturers, supplemented by several other small-scale pharmaceutical manufactures mostly involved in pharmaceutical compounding. The National Drug Authority website lists 15 manufacturers but those registered under the Uganda Pharmaceutical Manufacturer's Association (UPMA) – according to the chairman of the association – number just five. Note that membership to the UPMA is voluntary and some small manufacturers have not joined the UPMA. The membership comprises companies registered with the registrar of companies and licensed by the National Drug Authority to operate small or large pharmaceutical manufacturing businesses in Uganda. According to the chairman of the UPMA, the aim of the society is to provide sustainable accessibility, quality and affordable pharmaceutical products through local manufacturing.

In terms of production, various sources note that between 90% (FEAPM, 2012) and 95% (EAC, 2011) of all medicines are imported, mainly from India and China, and about 60% are distributed by the private sector. Only 7% of the local drugs are branded medicines and the remaining 93-95% are generics (FEAPM, 2012).

According to the EAC, Uganda's pharmaceutical industry revenue was estimated at \$90 million compared to Kenya's \$208.6 million, but this is projected to rise to \$270 million in 2014 (EAC, 2011). The Federation of East African Pharmaceutical Manufacturers (FEAPM) placed Uganda's total pharmaceutical business in 2012 at \$317 million. Remarkably, the percentage of the drugs sourced from local producers is just 5% compared to Tanzania's 30%, even though the number of licensed pharmaceutical manufacturers totals up to 13, compared to 8 in Tanzania (EAC, 2011). Even then, a lot of the raw materials used in the manufacturing (more than 90%) are imported, mainly from India and China because these are not readily available in Uganda. In fact, the Uganda Investment Authority estimates that pharmaceutical and health products account for more than 10% of the country's total imports (EAC, 2011). The local pharmaceutical manufacturing industry lacks information – such as on the size of the market – to guide investment plans (FEAPM, 2012). The local manufacturing industry produces generic products and there is limited research and development. As a result no originator medicines are being made in the country (FEAPM, 2012). Uganda's situation mirrors current trends in generic pharmaceutical manufacturing in most less developed countries.

With the pharmaceutical industry dominated by 95% imports, local manufacturers have a limited role in the local pharmaceutical market. According to the FEAPM, there were more than 500 registered pharmacies, more than 4,500 chemist shops and 115 hospitals in Uganda that constituted an outlet for pharmaceutical products, with 80% of all private pharmacies located in Kampala (FEAPM, 2012). The National Medical Stores (NMS) is the government corporation mandated to procure, warehouse and distribute health commodities to public health facilities in Uganda. The Joint Medical stores distributes to faith-based organisations in Uganda. NMS accounts for 55% of the pharmaceutical supply in Uganda, JMS 35% and the private distributors account for 10% (FEAPM, 2012).

Quality Chemicals Industries Limited (QCIL), located in Kampala, was formed in 1998 and focused mainly on importation of generic medicines from India. In 2004, Quality Chemicals and CIPLA Limited, an Indian pharmaceutical manufacturer, entered into a joint venture to set up a pharmaceutical plant in Uganda. The factory was commissioned in 2007. QCIL is the only local manufacturer involved in the manufacturing of HIV/AIDS anti-retroviral drugs and anti-malarial drugs. These drugs are manufactured under licence from CIPLA. The plant is Good Manufacturing Practices (GMP) compliant and has been approved by the WHO for the manufacturing of pharmaceuticals. Senior officials at QCIL emphasised in interviews that the plan is to compete in new brands of pharmaceuticals. Due to the need for quality and affordable anti-retroviral and anti-malarial pharmaceuticals in Uganda at the time, the government threw its weight behind the joint venture and provided various subsidies, including land and tax waivers, to ensure that the plant was established.

The pharmaceutical sector in **Zimbabwe** is the second largest in the SADC region after South Africa in terms of size and development and produces more than 65% of the essential drugs list and about 15% of special essential drugs list of Zimbabwe (Zimtrade, 2009). However, the industry has performed poorly due to the prevailing economic situation, characterised by lack of trade finances, competition from imported drugs, drug donations, declining government spending on drugs, prolonged registration times (about 24 months), and electrical power shortages. The lack of credit lines hampered the industry's ability to participate significantly in the export market (WTO, 2011). In addition to being a source of employment, the pharmaceutical sector supports both downstream and upstream industries. The biggest upstream success has been the establishment and support of a relatively vibrant primary packaging manufacturing industry. On the downstream side, local manufacturers support a number of retail pharmacies and pharmaceutical wholesalers. It is estimated that the sector contributes about 15% to GDP (Zimtrade, 2009).

Despite its contribution to GDP, UNIDO (2010b) notes that the current status of the manufacturing sector is unknown given "a general lack of timely, sound and appropriate data for planning purposes in Zimbabwe, especially in the industry sector" (UNIDO, 2011:23). Further, "[t]he country is a net importer of pharmaceuticals *inter alia* because of the large import bill for raw materials used as inputs in the manufacture of local formulations" (UNIDO, 2011:23). Notwithstanding this, the government has identified the pharmaceutical sector as one of four key industries to be the driver and pillar of the manufacturing development policy for 2011-2015. The criteria for priority in implementation are: the expected contribution

to GDP; job creation and job retention; levels of export earnings; potential for value added; and forward plus backward linkages with other sectors of the national economy (WTO, 2011). According to the Medicines Control Authority of Zimbabwe (MCAZ), there are nine registered pharmaceutical companies in the country, four are generic manufacturers and the rest largely concentrate on trading and have a narrow range of products. According to UNIDO's assessment, the four generic manufacturers could easily account for 90% of the secondary pharmaceutical manufacturing (formulation) business in the country (UNIDO, 2011). CAPS (established 1952), Datlabs (1950s), Graniteside Chemicals (1957), Meditech, Plus Five Pharmaceuticals (Pvt) Ltd (1996), Pharmanova, Reckitt & Colman, Varichem Pharmaceuticals (1985), and Zimbabwe Pharmaceuticals (undated) make up the list of the pharmaceutical companies registered in Zimbabwe.

In 2011, the chairman of the Pharmaceutical Manufacturers' Association reported in a workshop on the state of the pharmaceutical industry in Zimbabwe that the industry was collapsing due to: viability problems and perennial losses; low capacity utilisation (0 to 40%); instability inherent in companies surviving through lines of credit from banks; outdated facilities requiring upgrades or replacement; no new product pipelines; and decline of players entering the industry (Mujuru, 2011). CAPS Pharmaceuticals collapsed in July 2013 after the company's assets were auctioned to settle debts, including \$4 million owed to the Commercial Bank of Zimbabwe (CBZ) (Ndelela, 2013). It was the country's largest pharmaceuticals manufacturing company before it plunged into a financial crisis. The situation has further deteriorated over 2013 with government noting that liquidity challenges have contributed to reduced manufacturing activity. The February 2014 monthly economic review by the Ministry of Finance notes that since the beginning of the year, imports declined by 15% to \$487.5 million from the \$576.6 million recorded in December 2013. "The decline in imports (especially raw materials) can be attributed to the low activity in the manufacturing sector" (Ministry of Finance, 2014:23). The fall in raw materials imports generally has affected the viability of the industry.

3.3 Key bottlenecks to local medicine production

The review and interviews offered insight into the main bottlenecks to local medicine production in ESA, supported by the analysis of the plans developed by the AU, EAC and SADC on the priorities, opportunities and challenges to be addressed to establish pharmaceutical capacity in Africa as a whole, east Africa, and southern Africa, respectively (AU, 2007; EAC, 2011; SADC, 2007).

The plans highlight that pharmaceutical manufacturers operating within the SADC and EAC regions generally produce at a higher cost compared to larger international generic manufacturers. Regional and domestic manufacturers are constrained by reduced scale, expensive asset bases coupled with older technology, higher costs of financing, a lack of integration with active pharmaceutical ingredients suppliers and unreliable supporting infrastructure such as electricity, water and transport (EAC, 2011; SADC, 2007). For example, a WTO (2011) trade policy review for Zimbabwe revealed that the country faces challenges to local production and international competitiveness due to: high production costs related to very old plants and equipment; power shortages; exorbitant utility tariffs; lack of working capital; lack of access to capital for recapitalisation; and lack of technology (as products are becoming less competitive).

The literature raises as constraints shortages of skilled professional personnel and points to infrastructure and skills as major determinants for technology transfer (COHRED and NEPAD, 2009; WHO, 2011; UNCTAD, 2011a; EAC, 2011; Loewenson, 2011). At the Seventh Joint African Union (AU) Conference of Ministers of Economy and Finance and the Economic Commission for Africa (ECA) Conference of African Ministers of Finance, Planning and Economic Development in Nigeria in March 2014, the AU, UNAIDS, UNECA and UNIDO held a high-level meeting on Local Manufacture of Pharmaceuticals: an Untapped Opportunity for Inclusive and Sustainable Industrial Development in Africa, with the African ministers. The high level meeting concluded that:

The challenges the pharmaceutical industry faces in upgrading facilities and production practices in Africa include the requirement for large capital investments and the need for experts, specially trained workers, increased regulatory oversight and regulatory harmonisation at the regional and continental levels in order to create bigger markets. However, there is growing consensus

that strengthening the local production of essential medicines is a priority, along with advancing industrial development and moving the continent towards sustainability of treatment programmes for HIV, tuberculosis and malaria, and improving access to safe and effective medicines to treat a broad range of communicable and non-communicable diseases (UNAIDS, 2014:1).

Willingness of the pharmaceutical industry to transfer its know-how and techniques is not sufficient for successful transfer of technology (COHRED and NEPAD, 2009; WHO, 2011; UNCTAD, 2011a; EAC, 2011; Loewenson, 2011). Recipients of transferred technology must also have minimum absorptive capacity to receive and effectively appropriate the technology transferred and work in a policy and political environment conducive to pharmaceutical innovation. This absorptive capacity is determined by the existence of a sustainable and efficient cadre of highly skilled scientists.

A senior lecturer at the School of Pharmacy at the University of Nairobi (identified with permission) pointed out that the university has the capacity to produce industrial scientists but there is no direct relationship with the pharmaceutical industry (Kenya KI3). She called for regular dialogue with pharmaceutical companies to understand their human resource needs and to offer internships and exchange programmes for the School of Pharmacy to remain abreast with developments in the pharmaceutical industry. The 2010 Sessional Paper by the Kenya Ministry of Medical Services also identifies the current training content and mechanisms for deployment of pharmaceutical personnel as major constraints to their utilisation. The Sessional Paper points out that:

Pharmacy training is largely oriented towards clinical practice and academic knowledge, with minimal emphasis on other skills required to handle pharmaceutical sector functions, like procurement and supply, manufacturing and trade. Also lacking are mechanisms for the provision of basic pharmaceutical services at the community and primary care levels (MoMS and MoPHS 2010:45).

Business intelligence is also crucial for dealing with trade, investment and industry challenges. A facilitative policy environment is thus essential to attract substantive investment, as well as adequate training resources and incentives to attract and retain the necessary skilled personnel (UNCTAD, 2007; UNCTAD, 2011a; UNCTAD, 2011b; AU, 2007; SADC, 2007; EAC, 2011; WTO, 2011). Chaudhuri (2008) notes that the business environment in the region is not always conducive to setting up pharmaceutical production. For example, in Tanzania market reforms were observed to lead to a loss of public sector and local private capacities necessary for medicine production. The two pharmaceutical public sector companies, Keko and TPI, were privatised; although government still holds 40% equity in both companies, it has stopped providing any funds to these companies – limiting their growth and capacity to attract and retain personnel.

Bate (2008) observes that governance issues are also a challenge in local production of pharmaceuticals. Local production supported by foreign aid to local public sector producers can distort the market by protecting a specific local producer against another more efficient and competent producer due to government's ability to direct aid to specific producers. Politicians may use aid resources to reward political allies with production contracts. They may use mark-ups on imported pharmaceuticals (designed to protect nascent local industries) for private use, especially where civil society is weak and unable to ensure accountability on public funding (Bate, 2008). Bate (2008) calls for legislative and regulatory frameworks and stronger governance policies as fundamental to the successful development and establishment of local pharmaceutical production.

In the consultations, senior officials noted that donations of essential medicines produced outside the country, while important for health services, also raised dependency on donated medicines, reducing the incentive to invest in local pharmaceutical production. This they suggested could be addressed by a share of external fund support for medicines being procured locally, or within the region, to support the operations of local plants, particularly for the firms already prequalified by WHO. External funds may also be used to subsidise the prices of these medicines, making them affordable to produce and for public institutions and

the population to purchase. This and other strategies should be used to ensure price regulation throughout the supply chain from manufacturer to patient. Where there are no WHO prequalified companies, international co-operation could assist to support this, including through the necessary skills and technology transfer.

At the international level, patents on medicines pose a barrier for firms based in non-least developed countries interested in producing newer medicines or setting up local production, such as those for HIV/AIDS, pandemic flu or type 1 diseases (Elbeshbishi, 2007; WHO, 2011; Loewenson, 2011; Klug, 2012). The 2001 WTO Declaration on TRIPS and the 2001 Doha Declaration extended the deadline for least-developed country WTO members to grant or enforce pharmaceutical patents until at least 2016. The Doha Declaration increased interest in exploring the possibilities for pharmaceutical production, particularly in least-developed countries due to the waiver they received up to 2016 to make their laws TRIPS compliant. Countries in east Africa are, for example, reported to be taking advantage of this to ensure the establishment of local production plants. At the same time the literature also documents reversals of TRIPS flexibilities due to free trade agreements and economic partnership agreements imposing TRIPS-plus obligations in their terms (Agnam, 2011).

Such issues are also noted at country level. For example Kenya's National Pharmaceutical Policy (NPP) has identified the following key issues in local pharmaceutical production that need attention:

- Conflicting policies and legislation and overregulation of the industry;
- Poor infrastructure and high costs of power and other production inputs;
- Negative publicity on generics and on locally manufactured products;
- Limited technology transfer for manufacture of generics;
- High costs of GMP compliance and of international accreditation for local drugs manufacturers;
- Lack of full implementation of TRIPS flexibilities;
- Weak regulatory environment for GMP compliance, hindering access by the local industry to regional markets and donor-funded programmes;
- Entry barriers (legal and administrative) to starting local manufacturing ventures;
- Limited pool of specialised pharmaceutical personnel to meet the needs of industry, such as research and development (R&D), industrial pharmacy, biotechnology, quality control and assurance (MoMS and MoPHS 2012).

The officials interviewed at the regional policy dialogue forum confirmed the issues identified from the literature review as those hindering local pharmaceutical production in the ESA region. Officials interviewed from five of the six countries viewed financing issues – especially the lack of working capital and higher financing costs – as the most important obstacles to establishing pharmaceutical plants in the region. Only the interviewee from Tanzania saw other factors such as governance and human resources and skills base as *more* of an obstacle than financial constraints, although other country respondents saw other factors as obstacles on an *equal* level to financing (see *Table 2*).

Table 2: Country responses to major obstacles to pharmaceutical production

Country	Obstacles				
	Financial	Infrastructure	Technology	Governance	Human resources / skills
Lesotho	5	1	3	2	4
Malawi	5	4	3	2	1
Tanzania	3	4	4	5	5
Swaziland	5	5	5	4	5
Zambia	5	5	5	1	4
Zimbabwe	5	3	2	5	3

Key: 1 signifies low importance, 5 signifies high importance of obstacle.

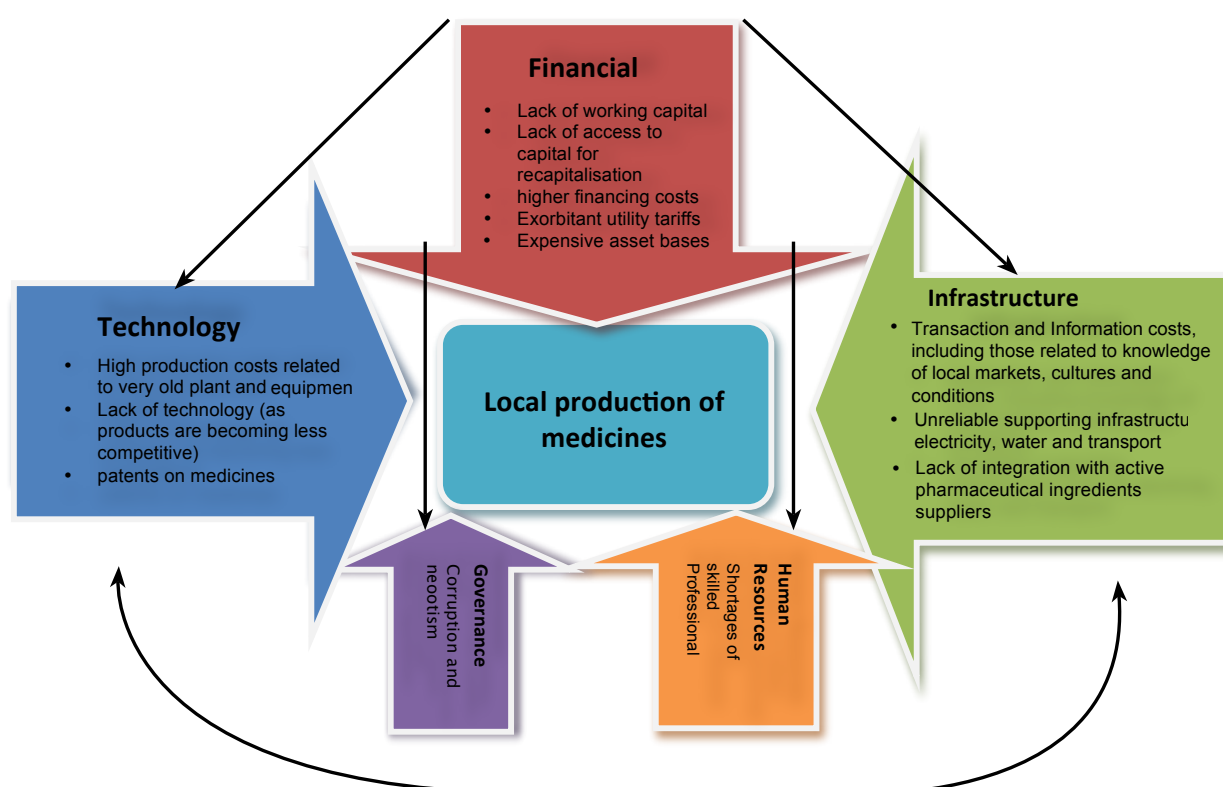
Respondents from Swaziland, Tanzania and Zimbabwe identified governance challenges such as lack of clear leadership in pushing for pharmaceutical local production and corruption (especially in procurement of medicines) as major obstacles. The respondent from Zimbabwe stressed the issue of tariffs on inputs/raw materials, the lack of markets to sell pharmaceutical products and skills shortages (particularly in terms of scientists). In addition to the issues identified in the literature review, the policy dialogue forum identified further blocks in a lack of strategic leadership in both government and private companies and inadequate specialised professionals, specifically industrial scientists and pharmacists

In short, in triangulating evidence across all the key processes there is a broad range of bottlenecks to local medicine production, including:

- 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.

Figure 1 summarises the barriers and how they are linked. For example, financial constraints have an impact on the requisite infrastructure, technology and skills for establishing local production. The availability of infrastructure attracts investment in and use of technology. The availability of human resources both affects the capacity to use resources and is affected by the availability of resources to train, attract and retain skilled personnel (pharmacists, scientists, engineers, technicians).

Figure 1: Flow chart of constraints to local production



Source: Author

Sections 3.4 to 3.8 group these various bottlenecks into five broad areas, namely: policy and legal issues; research and development and technology transfer issues; skills and capacity issues; issues related to production, markets and market access and financial investment and incentives issues. Sections 4.1 to 4.4 offer a discussion of these issues, organised according to: progress and gaps in overcoming bottlenecks; the role of government and leadership in addressing bottlenecks; the role of south-south co-operation in overcoming bottlenecks, in terms of potential and limitations; and, finally, implications for policies, agreements and negotiations on medicines and research and development.

3.4 Policy and legal measures and issues in overcoming bottlenecks

Across the three case studies it became apparent that the governments of Kenya, Uganda, and Zimbabwe have put in extensive policy and legal measures to deal with various aspects of the pharmaceutical sector, as highlighted in the individual country contexts in Section 3.1. However, one of the Kenyan government officials interviewed stated:

Every five years we put in place updated policies in the health sector, for example the national pharmaceutical policy, the health policy and others related to infrastructure development. But implementation is a challenge and this is what we need to work on. (Kenya KI 4)

The bottleneck to local medicines production does not appear to be a lack of policy and legal measures, but in their implementation. In Kenya, the Pharmacy and Poisons Board (PPB) regulates the pharmaceutical industry through the Pharmacy and Poisons Act. The regulation centres on drug registration, pharmacovigilance, pharmaceutical inspection, Good Manufacturing Practice (GMP) inspection and trade issues (UNIDO, 2010a). Although the law mandates PPB to carry out these activities, it is feared that the openness of the Kenyan market has outgrown the adequate levels of regulation required to monitor the trade in pharmaceuticals, especially with regards to the importation of counterfeit medicines. The high level of imported medicines in the local market was attributed by a civil society respondent to a high level of liberalisation of the Kenyan economy without an adequate corresponding level of regulation. In addition, the 2010 sessional paper on national pharmaceutical policy by the Ministry of Medical Services points out that there are statutory institutional mandates that overlap with PPB, especially those of Kenya Bureau of Standards (KEBS), Kenya Revenue Authority (KRA), National Campaign Against Drug Abuse (NACADA), the Anti-counterfeit Agency and the drug inspectorates of the ministries in health. This overlap means that there is a conflict of roles in drugs regulation, with a weak central authority incapable of effectively enforcing regulations (see *Box 2*).

In Uganda, the National Health Policy (2009) acknowledges that the public sector has been unable to fulfil its mandate to provide medicines to those who need it because of inadequate financial and human resources, capital investment and related management issues (MoH, 2010). It acknowledges the shortfalls in the regulatory framework and highlights laws that have been proposed for regulatory review, including: the Pharmacy Profession and Practice Bill; Uganda Medicines Control Authority Bill; National Health Insurance Bill and the Traditional and Complimentary Regulatory Bill. In Zimbabwe, with the opening up of the economy through trade liberalisation, there has been an influx of medicines from different parts of the world thereby putting a lot of pressure on the already constrained regulatory environment. The country's manufacturing sector performance remains weak in the face of an influx of imports, tight liquidity conditions, declining competitiveness pressures, low investment and tightening of credit conditions (Standard, 18 May 2014). The paper further reported that despite the inception of a multi-currency trading regime in 2009:

Zimbabwe's business environment remains uncompetitive owing to high operating costs, low foreign direct investment and an uncertain investment climate accentuated by lack of policy consistency (Standard, 18 May 2014).

In Uganda the review of official documents, particularly national development and pharmaceutical plans as well as health strategies, do not mention south-south co-operation as a strategy for developing the pharmaceutical industry. This is despite the government supporting Quality Chemical Industries in its partnership with the Indian pharmaceutical company, CIPLA.

Box 2: Challenges affecting regulation of the pharmaceutical sector in Kenya

- Conflict of roles of government offices, contrary to corporate governance principles;
- Weak central authority for pharmaceutical regulation and conflicting mandates and responsibilities between the PPB and other agencies and departments;
- Outdated management structures and inadequate legal framework, which places the medical profession as key regulator of the pharmaceutical sector and profession.;
- Increasing globalisation and sophistication of the pharmaceutical sector, including sophistication of crime such as counterfeiting and illegal trade;
- Inadequate financial resources to cater for the full scope of pharmaceutical regulation
- Limited human resource capacity, skills and expertise devoted to, and covering, the full scope of modern pharmaceutical regulation;
- Emerging use of traditional/complementary/alternative medicines and the implications on patient health and safety;
- Inadequate framework for ensuring the safety and quality of other pharmacologically relevant products, such as food supplements and nutraceuticals (products derived from food sources that are believed to provide extra health benefits, in addition to the basic nutritional value found in foods);
- Inadequate framework for regulation of pharmaceutical personnel and practice;
- Inadequate legal framework for pharmaceutical quality control, hindering full development of the requisite institutional capacity to exploit effectively the opportunities in Kenya and the region;
- Inadequate mechanisms for effective collaboration with pharmaceutical regulators abroad and with other enforcement agencies;
- Inadequate funding for pharmaceutical quality control; and
- Duplication and poor training of pharmaceutical inspectorate.

Source: MoMS and MoPHS 2010

The National Drug Policy (NDP) (MoH, 2002), while aiming to improve local pharmaceutical technical capacity, does not make reference to foreign partnerships as a means of increasing the availability of drugs in Uganda. Similarly, the Uganda Health Sector Strategic Plan III (2010/11-2014/15) makes no reference to south-south partnerships or their role in addressing local technical and technology pharmaceutical capacity. The National Pharmaceutical Sector Strategic Plan (NPSSP) II ambitiously undertakes to, among other things: commission a pharmaceutical development research fund; develop a comprehensive protocol for industrial training; and develop a list of products that can be manufactured or prepared economically in a hospital. It has little mention of south-south partnerships. Further, the Uganda Investment Code regulates local and foreign investments in Uganda (GoU, 2000), envisages the possibility of foreign technology or expertise and requires that any agreement regarding such transfer be registered with the authority. The Act does not, however, provide any incentives to encourage such arrangements and instead imposes conditions on the agreements, which could possibly be prohibitive to any collaboration involving a component of technology transfer. As such, the policy and regulatory environment in Uganda in official documents has not considered south-south partnerships as a strategy to support the local pharmaceutical industry, despite its application in practice.

Uganda is seeking to produce a manufacturing environment that supports local production (Government of Uganda, Investment Code Act Cap 92:14). However, while the law provides incentives, the authorities do still not implement them effectively. For example, the national tax policy has not been set up to favour local investors and manufacturers since there are no import restrictions on pharmaceutical products that are already being manufactured (WTO 2012a). A chief executive at one plant said that this limits the market

access of the local manufacturers as they face competition from foreign producers. The National Drug Policy (NDP) promised to create a system of incentives for the local manufacture of essential drugs (e.g. tax incentives, tender preference, reduced import tariffs, reduced rates for electricity and water consumption) and to improve local pharmaceutical technical capacity by encouraging and assisting in the training of sufficient numbers of staff in pharmaceutical production techniques (MoH, 2002, para. 3.5), but this does not appear to have been operationalised, or at least not effectively. The Investment Code Act provides for the waiver of taxes to investors setting up manufacturing plants in all phases of the set up, yet when one manufacturer tried to import an air-handling system essential to the pharmaceutical plant, it was taxed as a luxury equivalent to a household air conditioning system. Further, the Public Procurement and Disposal of Public Assets Act makes provisions to give priority to local manufacturers through a 15% price preference as compared to outside manufacturers. This has not been operationalised simply because the regulations have not been developed.

Similar policy barriers to local production exist in Zimbabwe. While the government has put in place policies to develop the pharmaceutical sector in the country, the industry must confront a number of unfavourable practices and high import tariffs on their inputs. For example, imported finished pharmaceutical products enjoy a tariff free import status, while imported inputs needed for local manufacture incur a 5% to 15% duty on their value (UNIDO, 2011). One respondent noted that the local manufacturing industry has to contend with an uneven playing field as a result of various policy deficiencies:

The customs and excise laws allow a large number of finished medicines to land duty free, whilst raw materials such as the active ingredients and excipients used by local producers pay duty. Duty is also levied on packaging materials and this pushes the costs of local production up creating an unfair competition from importers of medicines. (Zimbabwe KI 5)

The introduction of legislation in South Africa allowing pharmaceuticals to only enter the country by air transport has made export of Zimbabwean medicines to South Africa more expensive. This particularly affects heavy goods such as liquid preparations and large volume parenteral (Zimbabwe KI 5). On the other hand, Zimbabwean import and export regulations allow goods from South Africa to enter by road as well as air. Such disparities raise concerns and need to be addressed. As noted by the pharmaceutical manufacturers association (PMA) in a media interview:

Imported drugs are exempted from duty and VAT through Statutory Instrument (SI) 220 of 2000 (Cap. 23:02). However, raw materials and packaging materials imported by local manufacturing companies attract duties of up to 40% and VAT of 15%. The high import tariffs on pharmaceutical raw materials and packaging materials increases the cost of drugs, thus making it cheaper to import than to produce locally. There is therefore urgent need to remove these duties to at least level the playing field. The current tariff structure promotes de-industrialisation and dumping of foreign products on the Zimbabwean market. (Ndlela, 2013:1)

PMA has recommended that duty and value added tax (VAT) be removed on all imported pharmaceutical raw materials and packaging materials as is the case with imported drugs to level the playing field.

Intellectual property has played a key role in denying the majority of people access to medicines as patents registered for them largely determine their cost. Despite flexibilities that exist within the TRIPS Agreement of the World Trade Organisation, it still remains difficult for developing countries to utilise those flexibilities as the process of issuing compulsory licences is reported to be cumbersome. An official from the Kenya Intellectual Property Institute (KIPI) noted that one of the local pharmaceutical companies in Kenya, Cosmos Ltd, was licensed by GlaxoSmithKline PLC (GSK) in 2004 to produce generic versions of two of its life-prolonging AIDS drugs, Zidovudine and Larnivudine, as well as a combination of the two, for sale only in Burundi, Kenya, Rwanda, Tanzania and Uganda (Kenya KI 6). This condition was seen as prohibitive and restrictive as it would stifle the opportunities to grow the industry beyond localised regional supplies.

In 2002, the Minister of Justice, Legal and Parliamentary Affairs of Zimbabwe, invoked Section 34 of the Patents Act (which allows use of patented inventions for the service of the state), issued a notice declaring a period of emergency on HIV/AIDS:

...for the purpose of enabling the State or a person authorised in writing by the minister to make or use any patented drug, including any anti-retroviral drug, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions, and/or to import generic drugs in the treatment of persons suffering from HIV/AIDS or HIV/AIDS-related conditions. (Maonera and Chifamba, 2012:45)

This was arrived at after the government realised that intellectual property on HIV/AIDS medicines was restricting access to medicines by the majority of the citizens as the prices were out of reach for many. At that time, two Zimbabwean registered companies made applications for compulsory licences pursuant to the declaration. In April 2003 Varichem Pharmaceuticals [Pvt] Ltd. was granted a compulsory license to manufacture Combivir, whose patent is held by GlaxoSmithKline, and was set to begin operations shortly thereafter. Another company applied for and was granted a compulsory license to import (Maonera and Chifamba, 2012). At the beginning of 2013, four companies were thus engaged in generic medicines manufacturing.

3.5 Research and development and technology transfer

Developing research and development (R&D) capacity in the ESA region would greatly push the pharmaceutical industry forward and facilitate local production of medicines. However, this capacity is underdeveloped in the region, albeit with some positive steps being made, as embodied by the CIPLA/QCIL partnership in Uganda.

Because of the partnership with CIPLA, QCIL has been able to set up a R&D unit, which, although in its infancy, is a step forward in developing the local pharmaceutical manufacturing capacity. It is the first manufacturer to set up an independent R&D division. QCIL has also been able to get training for its staff from CIPLA under staff exchanges and direct training. QCIL has technical teams working with CIPLA, while CIPLA sends some of its teams to come and work with QCIL. While initially the personnel at the joint venture may have been comprised of expatriates, QCIL currently has fewer than 10 expatriates working in the whole plant out of a workforce of about 220 (Uganda KI 7). QCIL is manufacturing under license from CIPLA, which creates an obligation to maintain high manufacturing standards. QCIL thus strives to maintain high standards of pharmaceutical manufacturing, which not only enhances its prestige but also its capacity to manufacture pharmaceuticals. According to officials at QCIL, the plant will begin to manufacture and market certain medicines at a cheaper price than those imported from outside the country, due to benefits of the partnership with CIPLA (Uganda KI 7). Furthermore, the plant seems to be moving towards more advanced processes, potentially leading to the manufacture of active pharmaceutical ingredients (APIs), which could further reduce the cost of production of pharmaceuticals, not only in Uganda but also in the whole east and central African region, since APIs are currently being procured from Asia at high cost.

QCIL has embraced the benefits of collaborating with CIPLA as its partner. The CIPLA-QCIL partnership highlights the positive benefits that can be realised by the promotion of south-south partnerships. This is the first partnership reported to have yielded tangible results in form of technological transfer through a southern partner, despite many years of co-operation with northern partners. However, the benefit is rather limited to the specific plant concerned, and as companies operate in a competitive environment, some respondents viewed it as difficult to extend such benefits of south-south co-operation across the wider pharmaceutical industry in Uganda. Nevertheless, the CIPLA/QCIL offers examples of how partnerships based on south-south co-operation can work.

The Kenyan government supported the establishment and maintenance of the Kenya Medical Research Institute (KEMRI) as recognition of the critical role of research and development in the promotion of quality health care. A tour of the KEMRI site showed that it has recognisable capacity with a well-established research infrastructure, including biomedical scientists. It also has linkages with the University of Nairobi,

which has an active health research programme. However, a senior management official at KEMRI bemoaned the poor funding the institute gets from the government. Consequently, the official noted, most of the research activities are donor funded and therefore do not necessarily address the national health priorities (Kenya KI 8).

The EAC Pharmaceutical Manufacturing Plan also points out that funding for R&D in the region is generally targeted at research of basic and operational level, with little scope for product development. Further, weak linkages between industry, research institutes and academia mean that collaboration in research and development is rare (EAC, 2011). Despite this challenge, Kenya has the basic infrastructure for addressing the R&D gap, if funded. In terms of south-south co-operation, China, which otherwise has strong linkages with Kenya (as will become apparent further on in this report), does not seem to have contributed to building Kenyan capacities for R&D. China and India dominate the supply of generic medicines to the country, limiting their incentive to develop Kenya's capacity for more advanced medicine's production. One respondent at the fast-talk consultations cautioned that countries seeking assistance through partnerships should not rely on the partner, but show leadership in themselves fulfilling their obligations (Zimbabwe KI 9). For example, the failure of the China-Kenya pharmaceutical project to take off was reported in part to have been due to lack of land and appropriate legislative support (Kenya KI 2).

Zimbabwe also has relatively strong research bodies including the Research Council of Zimbabwe (RCZ), the Medical Research Council of Zimbabwe (MRCZ), the Scientific Industrial Research and Development Centre (SIRDC), the National Institute of Health Research and Human Capital in Science and Technology. For the pharmaceutical sector, the presence of SIRDC, which has twelve different specialised research institutes like the Biotechnology Research Institute (BRI) and the National Institute of Health Research, gives the industry an immediate advantage as specific research could easily be shared and disseminated. The Ministry of Health and Child Care also has its own research arm called the National Institute of Health Research (NIHR) that does research, training in the fields of disease control, biomedicine and public health. These research organisations give the local pharmaceutical industry the incentives and capacities to develop. Nevertheless, like in Kenya, much needs to be done to capacitate the research institutions, as the country is still reliant on imported active pharmaceutical ingredients (APIs).

The respondent from Lesotho at the policy dialogue forum highlighted that the issue of traditional medicines needs to be looked at as a viable alternative to the expensive medicines available on the market in the absence of adequate, affordable pharmaceutical medicines. Research in pharmaceutical production is more beneficial and valuable when utilising local products that exist in abundance in southern Africa. In this regard production of indigenous knowledge systems is fundamental to aid in research and development of pharmaceutical products. The need to utilise local resources for local medicines production is also highlighted in Tanzania where it has been noted that locally produced medicines are more accessible than imports for rural consumers, and "that medicines which are both imported and locally produced display greater rural and urban availability than those which are import-only" (Mujinja et al., 2014). For formal manufacture, there is report of the lack of will on the part of technology bearers (mostly from the developed countries) to transfer their knowledge to developing countries, with two types of problems noted: firm-level problems that derive from the specific characteristics of a firm and systemic problems that derive from the environment in which firms operate (Lunogelo and Baregu, 2013). These are further outlined in *Box 3*.

Technology bearers have themselves argued that for pharmaceutical technical transfers to be successful, critical factors must be fulfilled, namely:

- A viable and accessible local market;
- Political stability, good economic governance;
- Clear development priorities;
- Effective regulation;
- Availability of skilled workers;
- Adequate capital markets;
- Strong intellectual property rights (IPR) and effective enforcement;
- Quality of the relationship between industry and government and the extent they are able to work together effectively for long periods of time (IFPMA 2011).

Box 3: Barriers to technology transfer

At the firm level

Barriers to technology transfers can be categorised into three clusters: knowledge, financial capital and organisational.

Knowledge: inadequate knowledge about all ranges of technological alternatives; inability to identify the technology that best suits particular needs; and inadequate workforce skills and mechanisms for their upgrading;

Financial capital: limited access to finances;

Organisational: slower pace of technological development in downstream or upstream firms that inhibits the upgrading of technology and organisational rigidities within firms.

At the systemic level

Barriers to technology transfers may also be divided into three clusters, each requiring some special interventions: education system, research and development systems and institutionalised rigidities.

Education system: lack of education and skills and lack of resources, knowledge and capabilities within policy institutions;

Research and Development (R&D): lack of access to information on new technologies and innovations; ineffective institutions for carrying out R&D; and universities and research institutions disconnected from needs of the industry;

Institutional: market distortions, including barriers to trade; inadequate development of the financial and insurance markets and regulatory constraints.

Source: Lunogelo and Baregu, 2013.

There is a debate on what technology transfer entails. GlaxoSmithKline has argued that technology transfer includes both resources and know-how and that its collaboration with African research institutes in an effort to develop a malaria vaccine, as well as the conduction of clinical trials in the region, constitutes technology transfers. The company queries the disproportionate emphasis placed on manufacturing capacity over other types of technology transfer (GlaxoSmithKline, 2011). India has emerged as a global healthcare provider because of its ability to offer world-class expertise at relatively low cost, including to African countries, with the health sector in Africa among the beneficiaries of technology transfers from India (Lunogelo and Baregu, 2013). It has been providing medical expertise and support to establish local hospitals and health-related institutions as a contribution to technology transfer, such as for treatment of heart problems between services in New Delhi and services in Dar es Salaam, and through regular telemedicine consultations with high skill hospitals in India (Lunogelo and Baregu, 2013).

The Zimbabwean government has sought to facilitate technology transfer, as it promotes the concept by allowing companies in receipt of technology know-how and licences from external entities “to remit, in foreign currency, royalties and licence fees in respect of agreements concluded with external technical partners” (WTO, 2011). One interviewee in the pharmaceutical industry in Zimbabwe noted the opportunity from south-south co-operation to improve infrastructure and replace obsolete equipment. Although the government encourages technology transfer in different sectors, including the pharmaceutical industry, intellectual property laws, especially those related to the WTO, have played a negative role in the transfer of technology, in Zimbabwe and in other developing countries. The monopolistic nature of these exclusive rights may mean that patents can limit access to medicines, seeds, and technology, thus adversely affecting the protection of public health, food security, and availability of development technology. Trademarks, to the extent that brand names are associated with high prices for medicine, have also affected public health. Hence, the decision taken by the government of Zimbabwe in 2002 to declare HIV/AIDS an emergency and allow the use of patented ARVs was to respond in part to the damaging nature of intellectual property laws. A visit to the Kenya Intellectual Property Institute (KIPI) revealed how deep the challenge of technology transfer is as it is linked to intellectual property issues. It was noted that intellectual property has played

a negative role in Kenya with regard to access to medicines, just as in many other developing countries. A senior official at KIPi, specifically referring to the experience of the CIPLA/QCIL partnership in neighbouring Uganda, noted that:

Owners are not willing to transfer their technology. Where there are opportunities to transfer technology, as is the case with the joint venture in Uganda between CIPLA of India and Quality Chemicals of Uganda, they are not ready to completely transfer the technology. In this case, CIPLA brought its personnel from India. (Kenya KI 6)

This reservation towards the CIPLA/QCIL partnership seems somewhat unfounded as there appears to have been genuine co-operation and technology transfer on the part of CIPLA. Further, the expatriate personnel at the QCIL plant is minimal. It does indicate, however, that there are still challenges to building trust with regards to south-south co-operation.

3.6 Skills and capacity measures and issues in overcoming bottlenecks

Across the key processes it became apparent that human resource issues were a hindrance to the development of the pharmaceutical industry in the ESA region (although Zimbabwe appears to be an outlier in this area, a point to which we return shortly).

In Uganda, the CIPLA/QCIL partnership again shows how this bottleneck has been addressed through south-south co-operation. Staff training and staff exchanges have been undertaken within the partnership, with the result that the expatriate workforce at the plant is down to 10 out of a total of 220 individuals. In terms of capacity measures, as QCIL is manufacturing under license from Cipla, it creates an obligation to maintain high manufacturing standards and keep its technical processes up to date. QCIL thus strives to maintain high standards of pharmaceutical manufacturing, which not only enhances its prestige but also its capacity to manufacture pharmaceuticals. According to officials at QCIL:

...we did not put up this facility to compete with the existing medicines. We are looking at the newer generation drugs we are going to produce...that's where our advantage is going to be. Because now we need Tenofovir they have already started putting restraints on [it] under the intellectual property regimes, but then CIPLA said we are going to manufacture Tenofovir in Uganda and we are now producing it and [it] has been approved by the NDA. Now we are working on new medicines in our line that are going to become the premium treatment very soon. And these ones will be cheaper than the ones being manufactured outside Uganda. So we should as well pay attention to the long-term benefits of local manufacturing. (Uganda KI 7)

The south-south partnership with CIPLA, QCIL (with the support of the government) appears to have developed the capacity to produce pharmaceuticals and a potential for manufacturing cheaper medicines than those imported into the country. QCIL hope to begin manufacturing active pharmaceutical ingredients (APIs) as a result of this progress in skills and capacities at their plant. API manufacture is expensive, a QCIL official highlights, and its capacity to produce them will depend on progress in other bottleneck areas, including market size (which would, according to the official, require there to be a regional market for the APIs) and further government support. However, the case of CIPLA aside, no formal arrangements with Indian companies were made to share human resources. All other manufacturers interviewed relied on Indian technical experts due to the lack of technical capacity of the Ugandan pharmacists. An executive official of a manufacturer bemoaned the lack of practical experience of the pharmacists coming out of the country's academic institutions. He called for closer collaboration between the industry and academic institutions to ensure that students are learning about the practicalities of the pharmaceutical industry. Further, pharmacists reportedly prefer to remain in pharmacies rather than work in the manufacturing industry. On the positive side, two separate interviews with private sector representatives highlighted that the manufacturers offer internships for students to aid in the training of human resources. Unfortunately, many of those trained move abroad due to better employment possibilities, or are hired by government to work within quality control departments to the detriment of the manufacturing industry.

Countries in the sub-Saharan African region (SSA) have been affected by a human resources for health (HRH) crisis characterised by an absolute shortage of skilled health workers, poor investment in production and retention of health professionals (especially in rural and remote areas), disparities between private and public sectors, inappropriate skills mix, and low morale and low productivity of the existing workforce (Dambisiya et al., 2013). As a result, one organisation in the ESA region, the ECSA Health Community, has been instrumental in advocating for ESA governments to put in place strategies for training and retaining health workers (including pharmacists). Some of the key resolutions of the 2011 Ministerial meeting of the ECSA health community urged member states of east, central and southern Africa to:

- Put in place strategies and mechanisms to improve the value placed on health workers and improve motivation and retention as a matter of priority;
- Produce and disseminate information on the various strategies and options including financial and non-financial incentives on staff motivation and retention.

Source: ECSA HC, 2011.

In terms of training, key informants from the case study in Kenya, as well as respondents from Tanzania and Malawi at the policy dialogue forum, also highlighted the lack of pharmacists with the specific skills and abilities required to work within the industry. As noted earlier, a 2010 Sessional Paper by the Kenyan Ministry of Medical Services made clear that pharmacy training in Kenya does not adequately address the skills required for pharmaceutical manufacturing (MoMS and MoPHS 2010). To address these challenges, the government of Kenya committed to direct and support appropriate training, development and management of human resources required for delivery of pharmaceutical services through:

- Developing and implementing a national pharmaceutical human resource strategy;
- Enacting legislation to recognise pharmaceutical specialisations;
- Reviewing and implementing pharmaceutical schemes of service to attract and retain appropriate HR for the public service;
- Recruiting and retaining adequate numbers of pharmaceutical personnel in the public service in line with established health sector strategies, norms and standards;
- Expanding pharmaceutical training capacity and opportunities at colleges and universities and create mechanisms to enable access by trainees from other countries.

Some such steps have been taken towards increasing the training capacity in Kenya. Whereas the School of Pharmacy at the University of Nairobi had been the only institution training pharmacists since its inception in 1974, over the last five years the Pharmacy and Poisons Board (PPB) has accredited 17 more institutions to offer diplomas, and in 2009 one public and one private university started offering degrees in pharmacy. Thus, the number of pharmacists graduating from the country's academic institutions has increased, as noted by the FIP World Pharmaceutical Workforce Report (Thoithi and Okalebo (2009). Such investment in regional industrial pharmaceutical training seems to be important to build local manufacturing capabilities. The China Africa Co-operation Forum Beijing Action Plan 2013-2015 conveys a commitment on China's part to train health personnel such as doctors, nurses and public health workers, but does not make reference to the training of pharmacists or scientists. The official documents emphasise trade between China and African countries and the need to take advantage of such trade especially in developing active pharmaceutical ingredients and other medical products. The Beijing Declaration of the Ministerial Forum of China-Africa Health development includes:

Support corporate co-operation between China and Africa, encourage health technology transfer to reduce the price of health commodities including pharmaceuticals, diagnostics, vaccines and equipment, and increase their affordability. (Beijing Declaration, 2013)

From the policy dialogue forum it emerged that in Tanzania trainees are educated in clinical and commercial pharmacy rather than industrial pharmacy. The few people who are trained in industrial pharmacy are absorbed outside the country, especially if they receive training abroad. For Malawi, the small pharmaceutical market and subsequent lack of opportunities mean that while the country has many skilled professionals, especially pharmacists, these professionals are employed abroad.

The Zimbabwe study findings differed somewhat from the situation in Kenya and Uganda, as the lack of industry-specific training was not apparent. Here, the capacity to build skills in the pharmaceutical sector exists as the University of Zimbabwe has a department of Pharmacy in the Faculty of Medicine, which was established in 1974. The department has the responsibilities for training pharmacists for Zimbabwe, but also for the rest of the southern Africa region. There is no doubt that Zimbabwe has the infrastructure and facilities to train, build the capacities and retain pharmacists, scientists, technicians and all the other human resources required for the pharmaceutical industry, and that the challenges lie in the wider economy, as raised earlier. The National Economic Consultative Forum (NECF) in 2009 recommended introduction of:

Special skills retention allowances or tax rebates for professional and highly skilled personnel to assist in the recovery and growth of the sector. This should be extended to supporting institutions such as the College of Health Sciences, School of Pharmacy at the University of Zimbabwe and Medicines Control Authority of Zimbabwe. (NECF, 2009)

The recommendations by the NECF address the long-term requirements of the industry in terms of human resources. However, in the short to medium term, the government has been looking to other countries in the south for provision of pharmacists: “Through government to government agreements pharmacists have been recruited from the Democratic Republic of Congo and Cuba” (Zimbabwe KI 15)

3.7 Development of producers, markets and market access

The lack of a sizable market and the dominance of those markets by foreign pharmaceutical companies are seen as big obstacles to increased local production. However, the ability of QCIL to compete in international markets with bigger manufacturers is testimony to the benefits of south-south partnerships in the local manufacturing industry. Due to its partnership with CIPLA, QCIL is now the leading manufacturer of anti-retroviral drugs and anti-malarial drugs in the east and central African region. Further, the proposed upgrading to the manufacturing of APIs would further strengthen QCIL’s position in the market for the entire region – for example, the government of Rwanda has expressed an interest in procuring APIs from QCIL, as have other governments in the region according to QCIL’s corporate secretary.

However, other pharmaceutical manufacturers in Uganda are still seeing their access to the local market impacted by external imports. An example was cited of methylated spirit, which is sold at 1000 Uganda shillings (USh) by those that import and sell it, while the same product costs up USh1300 to manufacture locally. Respondents emphasised that some of this competition comes from would-be south-south partners. The managing director of one national pharmaceutical plant thus bemoaned competition from India and Pakistan, in particular, as well as China, as their manufacturing costs are much lower than in Uganda, and thus sell their products at a lower price. One of the respondents from Uganda stated that before we even start talking about south-south collaborations, it is imperative that these kinds of challenges are dealt with. Indeed, one respondent emphasised that it would be difficult to have more Indian companies partner with Ugandan companies with such small markets. According to him, it makes more economic sense for these companies to sell raw materials to Ugandan companies, as he states below:

...economies of scale do not make sense when we are only producing for Uganda. If you are producing for Uganda it is a very small market. But you find companies in India manufacturing for the whole world. They would rather deal with us as purchasers of their raw materials because it makes more economic sense ... and for us even when you are negotiating for the purchase of APIs or other raw materials the volume of the load will increase costs with our purchases of low quantities. Can't we, as East Africans, also agree that we are going to buy from within and we have a policy where we give priority to those companies that invest and attain those standards Or those that promise to improve standards as time goes on because we are not looking at ourselves only... but those who commit themselves to improving or raising standards ... the global standards to be given priority. Do we put conditions on trade of pharmaceuticals like the Ghana model where if there is sufficient capacity in the region we don't import at all? (Uganda KI 7)

All companies included in the study emphasised the importance of some protection of the local industry to enable it to achieve the global standards required by the regulatory authorities. They called for adoption of the Ghana Model, in which the government restricts importation of pharmaceutical products that local manufacturers are capable of manufacturing by raising taxes and encourages importation of products that the local manufacturers do not have capacity to make. This way local manufacturing is encouraged and access to medicine remains guaranteed. To these companies it is only when they achieve some level of competitiveness that they can start talking about smart south-south partnerships with Indian and Chinese companies. Similarly, the market for locally produced medicines in Kenya is shrinking as a result of the government's failure to support local companies, leading indirectly to a suppression of the growth of the pharmaceutical industry. As the biggest buyer of medicines, the government's reduction in purchases of essential medicines is suppressing the growth of the industry, as the local companies cannot manufacture essential medicines without a market.

Voluntary pooled procurement (VPP) is a process where external funders identify medicines to buy especially from well-established companies, negotiate the price and supply the medicines to Uganda (especially through aid programmes). Respondents from Uganda reported that national manufacturers cannot effectively compete in the process and that the bid process for procurement was not transparent, limiting the ability of local manufacturers to compete. Further, respondents from Uganda emphasised the high operating costs of manufacturing in the country as being particularly restrictive for the establishment of local pharmaceutical production. Uganda, as a landlocked country, relies on the port of Mombasa in Kenya for the transport of raw materials, adding to high costs of production, and has the most expensive unit of electricity in the region. Furthermore, common power cuts force manufactures to rely on diesel-run generators that are even more expensive to manage. In fact, the 2012 trade policy review by the WTO notes that Uganda's per capita electricity consumption rates is one of the world's lowest, estimated at 69.5 kWh (WTO, 2012a):

It is significantly lower than Africa's average of 578 kWh per capita. Low levels of access to modern forms of energy, particularly electricity, are one of the major infrastructure bottlenecks to socio-economic growth in Uganda. (WTO, 2012a:A5-43)

While local manufacturers have the capacity to manufacture quality essential medicines, they cannot compete with external manufacturers when it comes to price because they incur the highest costs of production in the region. This was one area where QCIL had not noticeably benefitted from its partnership with CIPLA. The director of marketing at QCIL thus emphasised the expensive operating environment as keeping their prices high. The fact that APIs are still not manufactured in Uganda (although QCIL is aiming to change this, as noted previously) but imported from abroad also drives costs up. In importing technology, key resources, such as raw materials, and operating at a lower scale for a smaller market, QCIL is still unable to compete on prices with other global manufactures, for example those from India. The director of marketing further argued that it is in the long-term interest of the country to purchase medicines at a higher cost from local producers, as it would drive the industry forward.

Kenya also has high electricity costs, due to inadequate generation and distribution facilities (WTO, 2012b):

The base rate per kWh for domestic electricity is KSh2 for electricity consumption up to 50kWh; KSh 8.10 for 50 to 1,500 kWh; and KSh18.57 for usage above 1,500 kWh. Commercial electricity tariffs are remarkably high in Kenya (and) high electricity consumers subsidise the low consumers. (WTO, 2012b:A2-232)

The trade policy review further notes that in general:

...each tariff consists of a fixed charge equivalent to meter rent, and for industrial customers, a demand charge based on average power requirement; a fuel cost charge (based on the cost of fuel purchased by KenGen (electricity company) during the month of billing); foreign exchange rate fluctuation adjustment applied per kWh of consumption; inflation adjustment applied per kWh of consumption; Energy Regulatory Commission levy (fixed at KSh 0.3 kWh); Rural Electrification Programme levy (fixed at 5% of the base rate); and 12% VAT applied on the base rate, including all previous surcharges. (WTO, 2012b:A2-232)

The local capacity of the pharmaceutical industry and market needs to be strengthened to encourage investment. This includes providing information on what medicines are essential for supply, which manufacturers are making what in the country and what medicines are being imported. This guides investment and informs investment plans and policy priorities. In the Uganda case study, interviewees reported lack of information on the industry made it difficult for local manufacturers and potential foreign partners to define areas of co-operation and investment (Uganda KI 7). In consultations, senior officials in the region noted that there was no continuous monitoring and reporting of the use of public resources, especially funds earmarked for capital developments. It was proposed that legislation compel government departments to monitor the use of funds to create investor confidence and encourage investment in the sector.

While Kenya was noted earlier to be the biggest producer and exporter of pharmaceuticals in the EAC and COMESA sub-regions, there is no evidence to suggest that it is expanding its markets beyond these regions. Instead, the country has been opening up its market more to Chinese pharmaceutical companies, which has reportedly led to over 100 Chinese companies establishing themselves in Kenya, with more willing to do so in the future. Thus, while Kenya is a major source of medicines for Uganda, Tanzania and South Sudan, the country remains a net importer of pharmaceuticals, including many generic medicines that can be manufactured locally. Pharmaceutical imports originate from more than 20 countries, which, in addition to China, include India and several countries in Europe.

Similarly, Zimbabwe's pharmaceutical manufacturers had developed a market in the SADC region and beyond, exporting an average of 10% of output. The export destinations for Zimbabwean medicines include South Africa, Botswana, Swaziland, Namibia, Lesotho and the Caribbean (Zimtrade, 2009). However, since Independence in 1980, the pharmaceutical industry has not seen any significant growth (Mujuru, 2011). Instead, production is dwindling after the closure of CAPS Pharmaceuticals, and pharmaceutical manufacturers in Zimbabwe are grappling with:

- Intensive competition from cheaper Indian generics;
- Liquidity problems, with no lines of credit available to companies;
- Inadequate or non-existent purchasing power in the private sector;
- Vast supplies of imported pharmaceuticals provided by donors;
- Imports of non-registered products (UNIDO, 2011).

In an interview, an industry expert in Zimbabwe noted that although Zimbabwe's pharmaceutical industry is developed, it is lacking in investment in newer formulations that are off patent because of the difficult challenges the economy is facing:

The economic situation over the years has strangled and arrested further development. Co-operation, in particular on licensing and outright purchase of dossiers, is required as the form of co-operation. Newer technologies for existing and new dosage forms will also assist in improving development. This I believe would change the state of affairs in the industry. (Zimbabwe KI 4)

Although Zimbabwe's pharmaceutical companies had cut a niche of their market within the SADC region and the Caribbean, their ability to service that market and expand it was and is significantly affected by the current economic situation. Interview respondents noted that Indian companies export to Zimbabwe using intermediaries, mainly owned by Indian nationals (Zimbabwe KI 4). Such competing imports can dampen rather than encourage local production, especially when there is a more favourable tariff regime on imported finished products compared to the raw materials for manufacturing. UNIDO has noted that during the period 2003-2007 CIPLA entered the local market in Zimbabwe (through imports of its pharmaceutical products) and registered a massive 24 products, including seven ARVs in the period when most local generic companies' approved product portfolios were weakening (UNIDO, 2011:30). This adds to problems of access to credit noted in the January 2014 Monetary Policy statement by the Reserve Bank of Zimbabwe (RBZ). The RBZ noted that the country remains saddled with:

...a severe and persistent liquidity crunch, which has made it very difficult for local productive sectors to access sufficient credit to oil the wheels of our economy; lack of competitiveness of locally produced goods due to high costs of production resulting in the huge importation of finished goods, hence the widening current account deficit; infrastructure bottlenecks especially around key economic enablers such as energy, transport, communication. (RBZ, 2014:6)

These bottlenecks are observed to have eroded the viability and competitiveness of local producers in key economic sectors.

It is also worth mentioning that all three case study countries are members of the Common Market for Eastern and Southern Africa (COMESA) Customs Union, launched in June 2009, and the COMESA Free Trade Area (FTA), in operation since 2000. Although implementation of the Customs Union commenced in June 2009, it is not yet fully operational as the Common External Tariff (CET) is not yet in force and other trade policy instruments are yet to be harmonised. This regional economic organisation could facilitate trade for pharmaceutical companies in the ESA, widening markets for Kenya and Zimbabwe. The SADC FTA offers similar potential for Zimbabwe. Negotiations are currently underway between three regional groupings – COMESA, SADC and the East African Community (EAC) – to establish a tripartite FTA, with the harmonisation of trade policies covering the three regions increasing potential market opportunities for companies from the region.

Zimbabwe also has bilateral trade agreements with Botswana, Malawi, Namibia, South Africa, DR Congo and Mozambique although the relevance of the bilateral agreements has diminished with the emergence of the SADC FTA. According to government officials (particularly from the Ministry of Trade), bilateral agreements offer more preferential treatment and flexibility (WTO, 2011), and Zimbabwe is already exporting medicines to half of those six countries.

The policy dialogue forum confirmed the importance of these regional trade agreements. Respondents from Malawi and Swaziland noted that the existence of a sizable market is a major determinant for setting up pharmaceutical production, and that a regional market was needed to justify investing in such a complicated industry. The respondent from Tanzania mentioned – without elaborating – that it was easier to import medicines than to establish local production because the pharmaceutical industry is in the hands of a few monopolies, and that local elites with connections in India were establishing companies in India to produce medicines that would eventually be imported into Tanzania.

3.8 Financial investment, incentives and financing issues

Financial concerns also pose various hindrances to local medicine production in the region. In Uganda, in addition to small markets and poor economies of scale, pharmaceutical manufacturers also highlighted the negative effect of poor funding structures for medicines, and complex conditions on where medicines have to be procured. As a senior private sector informant stated:

Funding related to the health sector in this country mainly comes from the western world and they dictate where to buy the medicines. When they dictate they do so in our disfavour. Again the issue they raise is about price. Sometimes we have been cheaper and have not been favoured so in a way we, the local manufacturers, feel that they are doing it deliberately to promote their own companies. (Uganda KI 19)

Local pharmaceutical manufacturing is completely privately financed, with no government commitment to providing financial resources, except for the case of QCIL. Both officials from QCIL and government respondents indicated that the government of Uganda played a central role in the institution of the joint venture (Uganda KI 7 and 19). Government provided a wide range of incentives that encouraged CIPLA to partner with QCIL to set up its GMP compliant plant in Kampala, including financial support and land for the plant site. These included free land to build the plant, tax-free setup of the entire infrastructure including factory and production facilities, an agreement to procure ARVs worth \$30 million per year for seven years from the plant and a ten-year tax break for the joint venture. Nevertheless, all the interviews

with the pharmaceutical manufacturers revealed difficulties in setting up a pharmaceutical manufacturing plant in Uganda. In one of the cases, the director recalled how they (as the founders) had to mortgage all that they owned to get start-up capital in an uncertain business venture. Several other actors echoed the problem of limited access to finance in the business. They stressed that the government does not provide any funds for pharmaceutical manufacturers. Small manufactures also said that without secure funding they felt safer maintaining small-scale operations (Uganda KI 7 and 19).

Through the interviews we probed the respondents to ascertain whether south-south partnerships could provide an avenue to deal with this problem, with negative responses. For instance, although QCIL had a partnership with CIPLA and the government of Uganda, QCIL had to make a solid contribution to the venture before any discussions could happen. CIPLA was only willing to partner after QCIL had proved that it was sound enough financially to support the weight of the partnership, and had the government not intervened by providing land and other incentives the venture would have been impossible to accomplish.

A senior official of the Kenya Pharmacy and Poisons Body noted that while Kenya is already on the path towards ensuring local production of medicines – as evidenced by a significant number of local pharmaceutical production companies operating at national and regional levels – the low levels of investment in the sector due to the low returns are a major challenge to realising this goal (Kenya KI 10). He noted that the lack of long-term financing at low interest rates, as is the case with Kenya, was a barrier to local pharmaceutical production (Kenya KI 10). This view was echoed by a government official who stated that financing local production was a major challenge despite the country's commitment to align the health budget to the 2001 Abuja commitment (Kenya KI 11). The private sector similarly noted that the banking industry is not willing to finance the operations of the pharmaceutical sector as it “is always viewed as a risky business” (Kenya KI 2). In addition, he noted that from a government point of view, the lack of funding to support local production creates a myriad of associated challenges. For example, medicines that are on the essential drug list (EDL) – which are considered the minimum required to meet basic medicinal requirements – are not easily available due to funding constraints (Kenya KI 2). As such, of the 343 items on the Kenya EDL, the government, through the Kenya Medical Supplies Agency (KEMSA), only procures about 117 based on the availability of funds (Kenya KI 2).

Zimbabwe, as already indicated, is facing economic challenges with consequences for financing in the pharmaceutical industry, which has long been regarded as risky and with long delays to returns on investment. As UNIDO states:

Local manufacturers are finding it difficult to source appropriate financing mechanisms to fund either working capital or capital expenditure. Currently, companies are receiving credit from suppliers, mostly local, with a few foreign suppliers also extending credit to Zimbabwean companies. (UNIDO, 2011:50)

In 2011, Commercial banks in Zimbabwe offered short-term financing (30- to 90-day loans) at annual interest rates of around 15%. This was seen as not suitable for the pharmaceutical industry, given the long cash conversion cycle inherent in the production and sale of medicines (UNIDO, 2011).

In its Medium-term Plan (MTP) government included the pharmaceutical sector as one of the priority sectors for investment, to be implemented through public-private partnerships (PPPs) and joint ventures with local investors (Ministry of Finance, 2013). The investments in the pharmaceutical sector in Zimbabwe have mostly been taking place through the companies' own initiatives to source private financing. High interest rates have had far-reaching implications for struggling industries, increasing the cost of capital. Commercial bank weighted average lending rates for both individuals and corporates stood at 14.4% and 9.7% respectively in July 2013 (Makoshori, 2013). Recognising these constraints to policy, in February 2014 the Reserve Bank of Zimbabwe signed a memorandum of understanding (MoU) with banks aimed at lowering borrowing costs for the country's struggling industrial sector and encouraging domestic savings. While both parties undertook to cap interest rates at 12.5 % annually, this is reported to have not been implemented in full (Makoshori, 2013).

Multilateral actors like the UN institutions have, however, assisted with infrastructural developments. UNDP assisted in upgrading the facilities at Varichem Pharmaceuticals in 2007. UNDP provided \$2.1 million to upgrade machinery and to train personnel in the use of the machinery (Chipunza, 2008). A key industry player suggested that the country could reap huge benefits from such co-operation with countries like India in particular on licensing and outright purchase of dossiers. He added that newer technologies for existing and new dosage forms would also assist in making “cost-effective products available with consequential economic and health improvements” (Zimbabwe KI 5).

From the policy dialogue forum it emerged that an existing pharmaceutical plant in Lesotho had closed due to a variety of factors, including lack of investment and capital. While the government of Lesotho is seeking to revive the plant by fostering public-private partnerships, a number of companies wanted tax exemptions if they were to partner the government in reviving the production facility (Lesotho KI 12). Conversely, the official from Zambia at the policy dialogue forum pointed out that financing is available, but that pharmaceutical production is a question of priorities, and that Zambia has focused more on physical infrastructure like hospitals and schools (Zambia KI 13).

Raw materials in the pharmaceutical industry are subject to high import duties as compared to finished products, particularly in Zimbabwe. Interview respondents noted that lower import and export duties for raw materials would encourage investment in local pharmaceutical production, as fiscal incentives (Zambia KI 16). Senior officials from ESA countries also suggested in consultations that ESA countries could create ‘free economic zones’ to incentivise production by domestic and foreign companies and to encourage innovation in the area of traditional medicine, using a range of ‘fiscal incentives’ including reduced corporate tax rates or tax holidays and investment tax credits, drawing learning from China on its use of economic free zones. They noted that licensing requirements and authorisation procedures were an essential part of strengthening the health system of a country and so did not approve of ‘regulatory incentives’ that would imply any derogations on legal standards. A range of ‘financial incentives’ were suggested to induce investment in the pharmaceutical sector, including government funding relevant infrastructure, providing seed money to lever oversight on investments and procuring medicines from local producers. However, it was also observed that any subsidy given to industry should be time bound to ensure competitiveness and avoid reliance on public funds.

4. DISCUSSION

4.1 Progress and gaps in overcoming bottlenecks

Across the key processes of this study it became apparent that there are still many bottlenecks to the development of local pharmaceutical manufacturing capacities, but also that some positive strides forward have been taken by countries and companies in the region. As noted in *Section 3* local production of medicines faces challenges of:

- Small national markets, making it difficult for local manufacturers to achieve economies of scale in production;
- Importation of most active pharmaceutical ingredients, offering little value addition in local production;
- Inadequate funding and resource challenges;
- Sustainability, as local production relies on government support or protection at its initial stages, and difficulties with sustaining production due to lack of finance;
- Lack of technology;
- Limited human resource capacity and skills;
- Shortage of locally available raw materials;
- Prohibitive intellectual property regime; and
- Lack of policy implementation.

Some of these bottlenecks have been addressed. Both Kenya and Zimbabwe produce pharmaceutical products that are consumed locally and exported to other countries in the region. Regional trade is an avenue to improve market size. Unfortunately, Zimbabwe's industry has declined from a position of relative strength in the 1980s due to the prevailing economic situation, characterised by lack of trade finances, competition from imported drugs, drug donations, declining government spending on drugs, prolonged registration times, and electrical power shortages. A lack of credit lines has hampered the industry's ability to participate significantly in the export market. Despite these challenges Zimbabwe has put in place a sound legal and regulatory policy framework for the pharmaceutical sector. Additionally, there are research institutions with the requisite infrastructure to support the sector. Kenya and Uganda also have extensive legal and policy frameworks in place to regulate the pharmaceutical industries and support local production, but the supportive measures have not been fully operationalised. In Uganda, the partnership between QCIL and CIPLA shows the potential of south-south co-operation in establishing viable and WHO GMP-compliant production in the ESA region.

Overcoming bottlenecks appears to need local, regional and global action. The issues raised as requiring local or national action included:

- infrastructure and governance, with government and the private sector playing key roles (Zimbabwe KI17; Lesotho KI12);
- human resources (Zimbabwe KI17; Swaziland KI18).

The National Economic Consultative Forum (NECF) of Zimbabwe, which has brought together different stakeholders to discuss national economic and development issues recommended measures to help the local pharmaceutical industry to improve, including:

- Short-term credit lines at favourable interest rates with a reasonable grace period of 3-6 months, and repayment period of 12-26 months to finance production, including raw materials, repairs and maintenance of plant and machinery, marketing, distribution and other operational costs;
- 25% local preference in all public and government tenders by public institutions. This means the government can procure locally produced products whose prices are at most 25% more than imported products. The current rules allow 10% local preference to protect local industry against dumping and to give it time to recover; and
- Removal of duties and VAT on pharmaceutical raw materials and packaging materials to reduce cost of locally produced drugs. This has to be a deliberate policy and levels the playing field against competition from imported finished products. (NECF, 2009)

Regional support from COMESA, EAC, and SADC was seen to be needed for:

- Country specialisation in medicines production, e.g. Zimbabwe focusing on ARVs while Tanzania specialises in the production of anti-malarials, to overcome market size and skills capacity constraints (Tanzania KI 14);
- finance and infrastructure issues (Zimbabwe KI17; Lesotho KI12; Swaziland KI18);
- technology transfer patents on machinery. Suppliers of plant and machinery need to share expertise with developing countries (Zimbabwe KI17; Lesotho KI12);
- human resources through sharing skills, e.g. through providing specialised training to countries that do not have the requisite facilities (Zimbabwe KI17; Swaziland KI18; Lesotho KI12).

The Lesotho respondent highlighted the challenges in technology transfer (Lesotho KI12). Despite flexibilities that exist within TRIPS, it remains difficult for developing countries to utilise those flexibilities due to the cumbersome processes, such as for granting compulsory licenses or in the requirements for notification to the WTO. Notwithstanding this, there have been attempts at the World Health Organisation level to implement a global strategy and plan of action on public health, innovation and intellectual property. A WHO-mandated Consultative Expert Working Group on Research and Development: Financing and Co-ordination (CEWG) established to look into the issue considered a number of proposals from different stakeholders. It concluded with a set of recommendations on financing and co-ordination, including delinking R&D costs from prices of medicines, indirect progressive taxes, an international R&D observatory and minimum funding percentages for the same end (WHO, 2012c). At the 65th World Health Assembly (WHA) in 2012, Kenya proposed a resolution that would request the director general to convene the Intergovernmental Negotiating Body to draft and negotiate a WHO Convention on Research and Development Financing and Co-ordination and to allocate the necessary resources to it. Since the turn of the millennium, Kenya has been an active member of the WTO playing a key and pivotal role in negotiations, particularly on the TRIPs agreement. Participating in global health diplomacy in this way is key for African actors to pursue their policy interests globally.

4.2 Government roles and leadership

Respondents consistently highlighted that government has a key role in encouraging local production of pharmaceuticals, especially given the dominant foreign competition. The low prices of foreign producers - due to subsidies from their governments - means that if local manufacturing is to grow, then ESA governments need to subsidise the costs of production and galvanise markets for local manufacturers. This is shown in the Uganda QCIL/CIPLA partnership. One of the enabling factors to the implementation of the joint venture was reported to be the support by government in form of: land grants for the plant site; tax waivers for both factory and production facilities; and an agreement to procure \$30 million worth of ARVs from the joint venture every year for seven years. This partnership shows that the governments of countries encouraging local manufacture need to support companies that start up the south-south partnerships.

The field interviews indicated, however, that while QCIL and CIPLA were able to access such incentives and concessions to purchase ARVs, the same benefits have not been available to other manufacturers. This can partly be attributed to the absence of a comprehensive policy framework for such incentives. One key informant representing a manufacturer that had received an incentive highlighted that this was achieved informally, rather than through a specific policy framework (Uganda KI 7). Supporting south-south partnerships thus appears to include: provision of and clarity on how incentives such as access to land and tax incentives can be obtained from government.

The Kenyan government has put in place such laws, policies and a regulatory framework to encourage the growth of the pharmaceutical industry. The Kenya national industrialisation policy framework (2010) includes measures to promote procurement of locally manufactured pharmaceutical products; enforce the Anti-counterfeit Act 2008; and promote the use of local raw materials for the manufacture of pharmaceutical products (Government of Kenya, 2010).

However, as noted in the findings, there are challenges in implementing these across many regulatory agencies. The regulatory framework was identified as a major bottleneck in local production. Key informants suggested that instead of the state solely playing a role as regulator it should get involved in taking up equity in companies to ensure that financial resources are made available for capitalisation and to increase capacity utilisation, and to train industrial pharmacists (Kenya KI 2; 6).

The Zimbabwe government has similarly put in place policies to support the pharmaceutical industry, including drug regulatory policies. The most recent 5-year development plan is the Zimbabwe Agenda for Sustainable Socio-Economic Transformation (GoZ, 2013). Zim Asset recognises the need “to fully exploit the internal relationships and linkages that exist between the various facets of the economy” including facilitating “local production of selected vital pharmaceutical products” under the social services and poverty eradication cluster (GoZ, 2013:9). As indicated in the findings, such policies on their own may remain unrealised unless they are translated into measures that address imbalances in import and export duties, interest rates and other factors impeding production.

This is seen to demand transparent state leadership. Lesotho’s Pharmaceutical Corporation (LPC) was supplying the region with essential medicines, but collapsed in 2010, according to a BTI 2012 Lesotho country report, not because of poor performance but “because of the abuse of power” (Bertelsmann Stiftung (BTI), 2012:24). Although there are no further details of the nature of this abuse of power in the report, the assertion was corroborated in the interview at the policy dialogue forum when it emerged that, in addition to lack of capital and investment, the corporation collapsed because of corruption and lack of effective leadership (Lesotho KI 12).

4.3 Medicines and research and development

The pharmaceutical industry is a high technology industry. Transfer of technology is essential not only for the growth of the pharmaceutical industry but also for overall economic development. Technology transfer has the ability to guarantee the reliability of supply, decrease reliance on imports and raise the competence of the local labour force. This points to the significance of negotiating for technology transfer in international co-operation.

The cost of developing a single drug is now estimated to amount to \$1.3 billion compared to \$138 million in 1975 (IFPMA, 2012), due to various technical, regulatory and economic challenges facing R&D pipelines. While not expected to have access to this kind of money for the development of new medicines, countries in the region have developed pharmaceutical experience over the years and have the operational research capacities to adapt technology and to start manufacturing generic medicines. Research institutes, such as KEMRI in Kenya and the SIRDC in Zimbabwe, can build collaboration regionally and with other developing countries without the challenges of intellectual property provisions. China has done so and is now a leading manufacturer of generic medicines. However, for this to happen the government needs to provide not only political support but also financial capital to the institutes to support national and regional research and medicines development. Such collaborations would ensure the diffusion of technology into the different sectors of the industry.

In addition, strong linkages between academia, research institutes and industry should be fostered to facilitate collaboration in research and development. Such linkages would also help overcome the limited industrial and practical experience of graduates from the region’s academic institutions, highlighted in *Section 3.5* of this report, and the shortages in health and pharmaceutical personnel. Training strategies need to be complemented by strategies for retention and for strengthening local absorption of these skills. In the United States, each job created within the industry was reported to support five jobs outside the sector (IFPMA, 2012), suggesting the wider benefits from such capacity investments at national and regional levels. As an example, strategies identified by the government of Kenya for the development and retention of industrial scientists and pharmacists may be applicable to the region as a whole and need to be operationalized, viz:

- Improved retention, especially in the public sector to ensure guaranteed and sustainable local production;
- Workforce supply requires a central co-ordinated planning effort, involving stakeholders in both the public and private sector;
- Involvement of academic institutions, pharmaceutical industries and research institutes in the workforce-planning process to meet supply needs is fundamental;
- Professional associations have an important role in enforcing and improving pharmacy practice (Ministry of Medical Services and Ministry of Public Health and Sanitation, 2012).

In *Section 3*, key informants pointed to a range of bottlenecks beyond technology transfer that affect the viability of local pharmaceutical production in the region. These included small national markets, limiting economies of scale; dependence on import of active pharmaceutical ingredients offering little value addition in local production; and heavy reliance on government support or protection, including for financing, in initial stages.

Overcoming such bottlenecks, as outlined also in the AU, EAC, and SADC plans implies establishing:

- A market size that would ensure sustainability and technical and financial viability;
- Available capital, technology and technical expertise;
- A legislative framework conducive to regional and local production, ensuring Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and regulating duties on imported raw materials and intermediates and related taxes and addressing quality and counterfeit issues; and
- Infrastructure, including electricity, water and transport (AU, 2007; EAC, 2011; SADC, 2007).

The study findings add to this the need expressed in case study countries to:

- Bring down the cost of utilities like electricity, water and other public services;
- Increase funding for research and development;
- Link industrialisation policies with policies for pharmaceutical production;
- Implement a legal and regulatory framework that balances industry with public health concerns;
- Provide incentives for local producers and manufacturers;
- Use government procurement to support domestic producers;
- Protect infant industries from unfair competition, through tariffs on medicines to give domestic producers a competitive advantage;
- Build capacity on trade facilitation and negotiations to facilitate value addition and diversification of products and markets, information and capacity building in regional trade agreements (SADC, COMESA, WTO EPAs); on procedures for importing and exporting; on tariff issues;
- Update regional integration initiatives like the North-South corridor, one-stop border initiatives and others.

All these measures require governments to take a leading role in formulating strong policies and regulatory frameworks (as some have done) and implementing these policies (as few have done). Many of these factors were noted in the findings to point to the need to advance regional co-operation in pharmaceutical manufacture. This is a south-south issue within countries of the region and is seen as necessary to strengthen other forms of south-south or international co-operation or national level action. Increased regional complementarities were identified as necessary in production, manufacturing, trade, and development,

- to overcome some of the market size bottlenecks
- to local pharmaceutical production;
- to support trade and tariff policies that give incentives for local production, and
- to give attention to the balance between measures necessary for population health and measures for trade and production.

4.4 Roles of south-south co-operation – potentials and limitations

Follér (2013) noted that support for south-south co-operation exists in different constellations and on different levels in society. He notes that since 1989, the Group for South-South Consultation and Co-ordination (G-15) has been promoting bilateral south-south co-operation:

The changes are evident and indicate a 'new' horizontal communication involving a transfer of resources, human and economical, and exchange of technical knowledge and capacity building within health, education, energy, climate and other areas. The constructions of the co-operation can be the establishment of bilateral, triangular and multilateral networks. (Follér, 2013:179)

The principles for south-south co-operation, shown in *Box 4*, were articulated in various forums including: the Ministerial Declaration of the 33rd Annual Meeting of the Ministers of Foreign Affairs of the Member States of the Group of 77 and China, 25 September 2009, New York; the Twelfth Session of the Intergovernmental Follow-up and Co-ordination Committee on Economic Co-operation among Developing Countries (IFCC-XII), 10-13 June 2008, Yamoussoukro, Côte d'Ivoire; and the Ministerial Declaration of the 32nd Annual Meeting of the Ministers of Foreign Affairs of the Member States of the Group of 77 and China, 26 September 2008, New York (South Centre, 2009:2).

The study was not able to explore whether these principles were being achieved on local production to the depth desired due to the limitations in the methods described in *Section 2*. There was some evidence of opportunity for south-south co-operation reported in *Section 3* in terms of the:

- Setting up of the only WHO GMP compliant plant in East and Central Africa (the QCIL plant in Kampala, Uganda);
- Establishment of an R&D division at the QCIL plant with the help of CIPLA, with positive results for technology transfer. This is the first partnership reported to have yielded tangible results in this respect;
- Potential for local production of APIs due to advancement of manufacturing processes and capacity improvements at QCIL plant as a result of partnership – would lead to the production of cheaper pharmaceutical products;
- Human resource development and skills capacities through training and exchange programmes in the QCIL/CIPLA joint venture;
- Government-to-government agreements on the recruitment of pharmacists from the Democratic Republic of Congo and Cuba to Zimbabwe;
- Bilateral agreements between Zimbabwe and other countries in the SADC region that offer more preferential treatment and flexibility for medicines, including South Africa, Botswana, Swaziland, Namibia, Lesotho and the Caribbean;
- Co-operation between Tanzania and India, such as the telemedicine and specialist exchanges on heart problems between hospitals in New Delhi and in Dar es Salaam;
- Co-operation with China where the China Africa Co-operation Forum Beijing Action Plan 2013-2015 conveys a commitment on China's part to train health personnel from Africa such as doctors, nurses and public health workers.

This limited evidence of co-operation in various aspects of medicines production suggests that south-south co-operation in medicines production is taking place, albeit at a limited level. The QCIL example is perhaps the most developed example we found. The failure to include the Mozambique case and the collapse of Kenya's co-operation with China suggests that such co-operation is either nascent or fragile. Even in Uganda, the CIPLA-QCIL partnership has yet to lever wider benefits beyond the plant itself. The partnership has been in existence for six years and its wider impact on investments, economic and skills contribution and access to medicines needs to be measured, outside the terms of reference and resources of this case study. This study points to the efforts that governments in the ESA region would need to make to encourage such partnerships and achieve wider benefits, including: improving provision of inputs such as electricity, good road systems, providing access to credit on favourable terms for south-south partnerships, and being clear and transparent on how land, tax and other incentives can be obtained from government.

Box 4: Features of south–south co-operation

South-south co-operation

- is a common endeavour of peoples and countries of the south and must be pursued as an expression of south-south solidarity and a strategy for economic independence and self-reliance of the south based on their common objectives and solidarity;
- its agenda must be driven by the countries of the south; not as a replacement for north-south co-operation. Strengthening south-south co-operation must not be a measure of coping with the receding interest of the developed world in assisting developing countries;
- is a development agenda based on premises, conditions and objectives that are specific to the historic and political context of developing countries and to their needs and expectations;
- deserves its own separate and independent promotion;
- is based on a strong, genuine, broad-based partnership and solidarity; on complete equality, mutual respect and mutual benefit; and the collective self-reliance of developing countries;
- respects national sovereignty in the context of shared responsibility; and strives for strengthened multilateralism in the promotion of an action-oriented approach to development challenges;
- promotes the exchange of best practices and support among developing countries in the common pursuit of their broad development objectives (encompassing all aspects of international relations and not just in the traditional economic and technical areas); and
- seeks to enable developing countries to play a more active role in international policy and decision-making processes, in support of their efforts to achieve sustainable development.

Co-operation between countries of the south must not be analysed and evaluated using the same standards as those used for north-south relations. Financial contributions from other developing countries should not be seen as official development assistance from these countries to other countries of the south. These are merely expressions of solidarity and co-operation borne out of shared experiences and sympathies. The modalities and mechanisms for promoting south-south co-operation are based on bilateral, sub-regional, regional and interregional co-operation and integration as well as multilateral co-operation.

Source: South Centre, 2009.

At the same time the literature suggests that there is rising international interest in local production of medicines across African countries, especially in ESA countries (WHO, 2006; WHO, 2011; Seiter, 2005, UNCTAD, 2011a). This is reportedly generated by:

- Increased interconnectedness and vulnerability to global health threats. The globalisation of trade, travel and pathogens, insufficient global production capacity for drugs can create shortages that affect all countries and reduce aggregate global capacity to respond to pressing health threats. Recent controversies around stockpiling of drugs and vaccines for pandemic flu (e.g. with respect to the H5N1 and H1N1 viruses) highlight the urgency of better understanding current policies and practices around local production and technology transfer;
- A changed global intellectual property regime, with issues raised by implementation of TRIPS in countries with well-developed pharmaceutical production capacities;
- Growing capacity to produce and develop medicines in middle-income countries, especially Brazil, India, China, Kenya and South Africa;
- Globalisation of the pharmaceutical supply chain and the expansion of developing country pharmaceutical markets, such as in Kenya, Uganda and South Africa; and
- Increased pressure for equitable access to medicines (WHO, 2006; WHO, 2011; Tempest, 2011; Owioye, 2011; Moon, 2011; Lanoszka, 2003; Hoen et al., 2011; Sampath and Roffe, 2011)

Brazil has made a commitment to south-south co-operation in medicines production in Mozambique. The government of Mozambique, in partnership with Brazil, is reported to be building a plant to produce generic drugs for treating HIV/AIDS and other diseases. This has been described as the largest project involving Brazil's development co-operation, with an investment of about \$23 million (World Bank, 2011; Panapress, 2012). According to the Oswaldo Cruz Foundation (FIOCRUZ, Fundação Oswaldo Cruz) (Panapress, 2012), during the first phase, equipment and drugs will be brought from Brazil, packaging will be done in Mozambique, and medicines will be distributed in the country free of charge. This phase includes development of local expertise and labour capacity to run the factory. During a second phase in 2013, the factory was expected to be producing medicines. As noted in Methods in Section 3, however, we could find no documented evidence that production had commenced by 2013, and the team could not access respondents to ascertain whether the project had built the critical human resource and institutional capacities for local production.

In the last two decades China has strengthened its existing diplomatic links across African countries, especially in areas such as bilateral trade and economic co-operation (Zakaria, 2005). Buttressed by the China–Africa Co-operation Forum of 2000, the new economic and development co-operation has assumed a different approach from the western model of development (the 1990s Washington Consensus requires countries to reform their political and economic institutions to receive development assistance). At the heart of the Chinese approach is the “desire to have equitable, peaceful, high-quality growth...and a belief that there are no uniform solutions for every situation” (Ramo, 2004:4). China's development approach is state led with inducements of corporate investment, cheap loans and aid packages (*Economist*, 2007), an approach that has been termed the Beijing Consensus (Ramo, 2004). The only ‘conditionality’ for African countries to receive China's development aid is to support its ‘One-China Policy’ (concerning Taiwan, the unfinished business of China's civil war). China's non-interference in countries' internal affairs makes it a welcome partner in Africa, with formalisation of relations through the China-Africa Co-operation Forum (FOCAC).

The 2000 Beijing Declaration of the FOCAC set the parameters for the growing relationship. It states that the interests of China and Africa exhibit the solidarity among developing countries towards establishment of a new international order. The strategic relationship encompasses co-operation in economic, political, social, cultural, trade and military spheres (*Peoples Daily*, 12 October 2000). This is in line with China's 2006 “Five Principles of Peaceful Co-existence” of mutual respect for sovereignty and territorial integrity; mutual non-aggression; non-interference in each other's internal affairs; equality and mutual benefit; and peaceful coexistence (Ministry of Foreign Affairs of the Peoples Republic of China, 1998).

The health sector has a key place within this co-operation framework. At a workshop organised by the East Africa Community and China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE) in September 2013 in Nairobi, the Chinese Ambassador to Kenya, Liu Guangyuan, pointed out that healthcare is a priority area for Chinese assistance to Africa, that China recognises the east African region as one of the most important regions for China's medical and health co-operation with Africa, and that Chinese pharmaceutical companies and high-quality pharmaceuticals and medical devices to east African countries will change the nature of the pharmaceutical industry in the region. (*Xinhua*, 13 Sept. 2012). African co-operation with China in the health sector, including health technology transfers aimed at reducing the price of, among other things, pharmaceuticals, is also emphasised in the August 2013 Beijing Declaration of the Ministerial Forum of China-Africa Health Development (Government of the Peoples Republic of China, 2013), as summarised in Box 5.

Whilst such statements point to the policy intentions for co-operation, in the policy dialogue forum some respondents were concerned that south-south co-operation might not be premised on principles of equality given that the technical partner providing finance and technology (such as Brazil, China, and India) will be the major shareholders. Such issues of equity in the relative power of parties to the agreement and mutuality of benefits are as pertinent in south-south co-operation as in any other form of international co-operation, notwithstanding the policy intentions. The fact that China and India dominate the supply of generic medicines to countries like Kenya raises questions about how far there will be real willingness to support local African production.

If co-operation in medicines production is to be established, then it could start in those areas where there are already some market structures in place. Emerging economies like India and China may be more concerned to consolidate their own trade position than investing in building local production in ESA countries. This is particularly so given a perception of weak or disabling local policy and regulatory environments. It suggests that African countries may need to negotiate exchanges that better position themselves in the medium and long term to act in their own interests, such as by focusing on capacity building and infrastructure to facilitate future investment in manufacture than on partnerships in pharmaceutical manufacturing. The Zimbabwe case suggests that countries can, with the right conditions, build their own pharmaceutical industry through domestic investors, without relying on south-south co-operation.

Box 5: Africa-China co-operation in FOCAC on medical care and public health

The two sides noted with pleasure their deepening co-operation in the health sector. In particular, Chinese medical teams to Africa, training of African doctors, nurses and administrative personnel in China, the hospitals China built for Africa and the medical materials China provided for Africa played a positive role in improving the health of African people and promoting the health development of African countries. The two sides committed to:

- step up high-level exchanges in the health field and hold a China-Africa high-level health development workshop at an appropriate time;
- expand their exchanges and co-operation in the prevention, treatment and control of HIV/AIDS, malaria, tuberculosis and other major communicable diseases, health personnel training, maternal and child health, health system building and public health policies. China committed to:
- provide support to the medical facilities it has built in Africa to ensure their sustainable development and upgrade the modernisation level of the hospitals and laboratories;
- train doctors, nurses, public health workers and administrative personnel for African countries;
- conduct the 'Brightness Action' campaign in Africa to provide free treatment for cataract patients;
- send medical teams to Africa. In this respect, it will send 1,500 medical workers to Africa in the next three year.

Source: China Africa Co-operation (FOCAC), 2012.

It also suggests a need to address constraints in regional and global agreements – such as the TRIPS agreement and the patent regimes in the bilateral and multilateral trade agreements. In the case of Uganda, the policy space and flexibilities provided under the TRIPS agreement was a factor in encouraging CIPLA to invest in Uganda. However, unclear definitions of counterfeiting that infringe on these flexibilities, such as the limiting of exports of generic medicines, could adversely affect south-south partnerships and need to be addressed. The regional co-operation to build markets implies measures that build trust and co-operation first amongst countries within the region (Lesotho KI 11), including through advancing implementation of regional trade agreements cited earlier.

5. CONCLUSION

This paper points to the range of bottlenecks to local pharmaceutical production in ESA countries, outlined in the paper and not repeated in this section. The infrastructure, resources, capacities, markets and research and development needed to establish and sustain local production are argued to call for co-operation among local manufacturers, technical and research institutions, personnel and training institutions and governments within countries. It is also seen to call for co-operation on key areas of investment, markets, R&D and trade across countries of the region, as articulated in the regional and continental plans. This in itself needs a conducive legislative and policy framework, present in many countries but not always fully implemented.

There is an argument that the rationale and need for establishing local pharmaceutical production in developing countries far outweigh the fears, viz that:

- The 250 million people in the SADC region alone and 15 countries are a ready market for pharmaceuticals.
- Examples such as the establishment of an R&D division at the QCIL plant with the help of CIPLA, with positive results for technology transfer, show the potential for local production of APIs due to advancement of manufacturing processes and capacity improvements from partnerships that could lead to cheaper products.
- Some major components (ingredients like APIs) of local production are already in place linking ESA countries and some emerging economies. In Kenya, Uganda and Zimbabwe - the case study countries - pharmaceutical firms already import active pharmaceutical ingredients (APIs) mostly from India and China, setting an entry point for wider forms of co-operation on production.
- The possibility of establishing local pharmaceutical production is already demonstrated in Kenya and Zimbabwe, particularly if supported by capital injection, with plants already exporting to east and southern Africa.
- Research and development institutions already exist, as in Zimbabwe, that could facilitate the upgrade of technology for local production.

At the same time the limited finding in the study of new local production initiatives through south-south co-operation suggest that many obstacles remain in advancing a policy goal of local production, despite the intentions in the AU and regional plans.

One issue may be for more work in the region, including in south-south interactions, to explore and draw lessons from emerging economies and other developing countries that have succeeded in developing their local pharmaceutical industries. India, Brazil and China invested in research and development and a solid human resources base and tapped markets in the south, such as in Africa (Chaudhuri, 2008). Brazilian and Indian pharmaceutical industries, for example, have become some of the major suppliers of medicines in Africa, especially generic ARVs. India:

- i. Invested in public research and development (R&D) in certain high-tech areas, such as information technology (IT) and pharmaceuticals, with public R&D responsive to the needs of both private sector producers and populations;
- ii. Improved both the quantity and quality of scientific personnel by investing in new tertiary institutions, focusing on science and engineering education to catalyse science and technology improvement. Some of these tertiary institutions have set up branches in African countries;
- iii. Encouraged collaboration with foreign R&D institutions, increasing the number of foreign R&D centres from 100 in 2003 to about 750 by the end of 2009, many to support information and communication technologies (ICTs) and pharmaceutical industries;
- iv. Invested in foreign markets as a way of acquiring technology;
- v. Provided government support to private and government-owned companies to expand their business interests in established and emerging markets; and
- vi. Ensured consistency in commercial and foreign trade policies over longer time frames (Lunogelo and Baregu, 2013).

China and Brazil have made similar investments and also provided state support to companies to venture into foreign markets (Cisse and Antony, 2013; *Economist*, 2012).

The QCIL-CIPLA case suggest that there is some opportunity for the technical expertise, resources and capacities that already exist in these countries to be tapped to incentivise medicines development, support smaller firms in international markets, support regulatory capacities, distribution channels, financing, and build links with international partners (Holt et al., 2012). In Zimbabwe, one respondent suggested that co-operation with emerging economies could usefully involve “licensing and outright purchase of dossiers” and the development of relevant technologies.

The findings of this study suggest, however, that the policy principles stated in forums of south-south co-operation cannot be assumed and need to be more actively negotiated in agreements. They further suggest that African countries need to strengthen domestic strategies and capacities, co-operation between domestic private and public sectors *within* ESA countries, and regional co-operation *across* ESA countries to address bottlenecks. The evidence further suggests that some areas of investment and co-operation, such as in areas of infrastructure and personnel capacities, may be important groundwork for others, such as in technology transfer and R&D. We thus propose some areas to be considered for national, ESA regional policy and programme implementation and for negotiation and inclusion in international co-operation agreements.

5.1 Proposals for the short and medium term

In the short to medium term (up 10 years) we propose various measures on policy, law, infrastructure and capacities:

On law and policy

- i. Operationalising the Abuja Commitment of 15% government funding to health and improving health funding to 5% of GDP to improve domestic resources for procurement of medicines;
- ii. Strengthening oversight and reporting of policy *implementation*, given the lack of implementation of policies observed in this study;
- iii. Enacting and implementing laws that require government to monitor and report on use of public funds, including those provided in co-operation agreements, to raise confidence in the use of funds and encourage investment in the sector, especially of funds earmarked for capital developments;
- iv. Establishing and capacitating institutions and management systems for oversight of the pharmaceutical supply, including dealing with corruption, lack of transparency in procurement practices and unregulated Internet purchases;
- v. Harmonising laws, and providing stiffer penalties on importers of substandard medicines.

On pharmaceutical capacities and infrastructure

- i. Establishing dialogue among governments, pharmaceutical companies and training institutions on human resource requirements projected for the pharmaceutical industry;
- ii. Developing, implementing and harmonising regionally national pharmaceutical human resource strategies;
- iii. Enacting laws to recognise pharmaceutical specialisations, i.e. clinical, industrial pharmacists, laboratory technicians, scientist and engineers;
- iv. Recruiting and implementing pharmaceutical service schemes to attract and retain appropriate personnel in the public service in line with established health sector strategies, norms and standards;
- v. Expanding pharmaceutical training capacity and opportunities at colleges and universities and providing for access by trainees from other countries in the region;
- vi. Implementing infrastructure projects agreed on water, energy and transport corridors under regional integration programmes in the EAC and SADC regions.

On trade and investment

- i. Providing support to local pharmaceutical industries through measures such as restricting importation of medicines produced locally, raising import taxes on imported pharmaceutical products that can be manufactured locally, while encouraging importation of products that local manufacturers do not have capacity to make;
- ii. Exempting duty and value added tax (VAT) on imported pharmaceutical raw materials and packaging materials to stimulate local production. In Uganda locally produced drugs and medicines are zero-rated for VAT;
- iii. Providing state incentives to companies that utilise local resources for local medicines production;
- iv. Developing through ministries of trade and health a template and database on essential medicines, and whether they can be sourced from local production or imports, and using this information to inform investment plans;
- v. Considering creating ‘free economic zones’ that encourage domestic and foreign companies to set up production through fiscal incentives (reduced corporate tax rates and investment tax credits), but without any reduction on legal standards;
- vi. Negotiating for a share of external funds to be used for local procurement from companies prequalified by WHO.

5.2 Proposals for the longer term

In the longer term (up to 20 years), we propose strengthening and sustaining regulation, R&D capacities and negotiating enabling partnerships:

Strengthening R&D and oversight and regulation of medicines

- i. Improving the monitoring of the GMP status of foreign pharmaceutical factories producing medicines for local consumption, with inspectors visiting foreign plants before drug registration, and ensuring that medicines are produced under contract at the facilities inspected;
- ii. Developing regional capacity and guidelines for testing locally produced and imported medicines;
- iii. Investing in, capacitating and using R&D capacities in the region to support domestication of medicines production and innovation in the sector;
- iv. Exchanging information between regulatory authorities as a statutory requirement within the ESA region.

Negotiating enabling south-south partnerships

- i. Negotiating partnership agreements that support the above measures for the establishment of local pharmaceutical production with a clear and sustainable plan for how this will lead to manufacture of medicines at lower cost than those imported into the country;
- ii. Providing time bound and specific state support and subsidies to encourage companies to establish local production, develop and expand production and to widen market linkages;
- iii. Using memberships of COMESA, SADC, the EAC to negotiate for a tripartite Free Trade Area between the three blocs to widen their market for medicines and to harmonise trade policies covering the three regions to improve market opportunities for pharmaceutical companies from the region.

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ACRONYMS

APIs	Active Pharmaceutical Ingredients
ART	Anti-Retroviral Therapy
AU	African Union
BRI	Biotechnology Research Institute (Zimbabwe)
BRICS	Brazil, Russia, India, China, South Africa
COMESA	Common Market for Eastern and Southern Africa
DFID	Department for International Development (UK)
EAC	East African Community
ECSA-HC	East Central and Southern Africa Health Community
EDL	Essential Drug List
EML	Essential Medicines List
EQUINET	Regional Network for Equity in Health in East and Southern Africa
ESA	East and Southern Africa
FEAPM	Federation of East African Pharmaceutical Manufacturers
FEZ	Free Economic Zones
FTA	Free Trade Area
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good manufacturing Practice
IFPMA	International Federation of Pharmaceutical Manufacturers Association
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Agency
KRA	Kenya Revenue Authority
LPC	Lesotho pharmaceutical Corporation
MCAZ	Medicines Control Authority of Zimbabwe
MRCZ	Medical Research Council of Zimbabwe
NECF	National Economic Consultative Forum (Zimbabwe)
NIHR	National Institute of Health Research (Zimbabwe)
NPP	National Pharmaceutical Policy (Kenya)
PMPA	Pharmaceutical Manufacturing Plan of Africa
QCIL	Quality Chemicals International Limited (Uganda)
R&D	Research and development
RBZ	Reserve Bank of Zimbabwe
RCZ	Research Council of Zimbabwe
SADC	Southern Africa Development Community
SEATINI	Southern and Eastern African trade Information and Negotiations Institute
SIRDC	Scientific Industrial Research and Development Centre
TARSC	Training and Research Support Centre
TRIPs	Trade Related Aspects of Intellectual Property Rights
UNAIDS	United Nations AIDS Organisation
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Organisation
UPMA	Uganda Pharmaceutical Manufacturers Association
VAT	Value Added Tax
WHO	World Health Organisation
WTO	World Trade Organisation

Medicines
production and
procurement
in east and
southern Africa
and the role
of south-south
co-operation

APPENDICES



Appendix 1: Profiles of sampled pharmaceutical manufacturers in Uganda

Company	Kampala Pharmaceutical Industries (KPI)	Quality Chemicals Industries Limited (QCILL)	Abacus Parenteral Drug Limited (APDL)
Date Established	1996	2005	1995
Ownership capitalisation and links within industry and other sectors	Part of Aga Khan Development Network (company website at: http://kpi.co.ug/index.php/about-us/our-company), No subsidiaries abroad	Privately owned by CIPLA Ltd, QCIL, Capital Works Investment Partners of South Africa and TLG Capital of UK	Owned privately by Kiboko Group of Companies with a share capital of up to UGX2 Billion Locally owned with no subsidiaries abroad
Medicines produced	60 products many of which are Over-the-Counter preparations and some pediatric formulations including making anti-malarials, pain killers, medicines for cough, colds and allergies. Launching a line of products for diabetes and one for blood pressure to address rising NCD.	Produces pharmaceuticals under license courtesy of a partnership with CIPLA International Ltd. Produces mainly anti-retroviral medicines (Duovir-N, Duovir, Effavir 600, Nevimune) and anti-malaria drugs (Lumartem). QCIL has also planned to manufacture a new line of products including Ciprin, Ciprofloxacin 500, Fluconazole and Lumartem Forte among others	Manufactures intravenous fluids and eye/ear drops including X-Beta, X-Beta – N, Abchlor Ear, Abchlor Eye, X-Sone – N, Ab-Genta, Ab-Nal Nasal Drops, Hydricort, X-Zoline, Atrop, Ciprocine, Ab-Solone, Ab-Tol and Tocin among others. Has more than 200% capacity to produce the parenteral products needed on the local markets
Market	Main market is Uganda but exports about 5% of its products to mainly Tanzania and Southern Sudan	WHO prequalification has widened the scope of its market reach and QCIL supplies anti-malarial and anti-retroviral pharmaceuticals to the east and central African market including Uganda, Kenya, Tanzania, South Sudan, DRC, Sudan, Rwanda and Burundi	Uganda comprises up to 50% of its markets with the other half being exported to neighboring countries including Rwanda, Burundi, Congo and the Southern Sudan
Other		Has received the largest amount of incentives from the government, including land to set up the plant and more land to set up an API manufacturing plant. The only WHO GMP compliant plant in east and central Africa giving it a competitive edge regionally in bidding processes. The only manufacture currently benefiting from a south-south partnership	

Sources: QCIL, 2013; APDL, 2013, Kampala Pharmaceuticals Ltd, 2013.

Appendix 2: Investment plans of Zimbabwe pharmaceutical manufacturers

Datlabs

Datlabs is one of the oldest pharmaceutical companies in Zimbabwe and was set up in 1950. The company has a relatively modern GMP compliant, large-volume parenteral facility in which products are manufactured under licence from Baxter Healthcare International. As with Plus Five, Datlabs intends to upgrade or build a completely new facility to achieve GMP compliance. This project will entail construction of a modern tableting suite, construction of a modern encapsulation suite, construction of a modern, fully automated liquids unit and provision of complete service units.

Plus Five Pharmaceuticals

Plus Five Pharmaceuticals is the second largest indigenous pharmaceutical company in Zimbabwe, after Varichem Pharmaceuticals. It is also the youngest, having been established in 1996 and, as such, is one of the most receptive companies in terms of new thinking in the industry. Despite the financial constraints faced by many local companies, Plus Five has recently refurbished its facility located in Bulawayo to improve GMP compliance, and it intends to carry out a phase two expansion of its facility. This will include the following activities: construction and equipping a new modern laboratory; construction and equipping a new R & D facility; construction of an administration block and training facility; extension of the current Oral Solid Dosage form manufacturing unit; extension of the warehouse and addition of a sampling booth; installing a heating, ventilation and air conditioning (HVAC) system; expansion of the finished goods warehouse and quarantine area and construction and equipping of a facility to cater for external dosage forms. To date, the company has been financing its capital expenditure from its reserves. The second phase of the expansion programme will be partly financed from an offshore facility being negotiated with a regional bank.


Varichem

Varichem Pharmaceuticals was the first indigenous pharmaceutical company established in Zimbabwe in 1985. Together with Aspen, it was one of the first companies in southern Africa to pioneer local production of generic anti-retrovirals, and it introduced its first generic ARV in October 2003. The company embarked on a facility upgrade in 2007 with the assistance of the United Nations Development Programme (UNDP) and, to date, the Varichem commercial manufacturing facility is the only GMP compliant OSD facility in Zimbabwe.

Source: Adapted from UNIDO, 2011.

Appendix 3: Key informant interviews

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| 1. Kenya KI1 | Civil society, Nairobi, June 2013 |
| 2. Kenya KI2 | Private sector consultant, Nairobi, June 2013 |
| 3. Kenya KI3 | Senior lecturer, School of Pharmacy, University of Nairobi, June 2013 |
| 4. Kenya KI4 | Senior official, Ministry of Health, Nairobi, June 2013 |
| 5. Zimbabwe KI5 | Senior industry official, Zimbabwe, Harare, February 2014 |
| 6. Kenya KI6 | Senior official, Kenya Intellectual Property Institute, Nairobi, June 2012 |
| 7. Uganda KI7 | Respondent, QCL, Kampala, November 2013 |
| 8. Kenya KI8 | Senior official, KEMRI, Nairobi, June 2013 |
| 9. Zimbabwe KI9 | Geneva-based diplomat, interviewed in Harare, April 2014 |
| 10. Kenya KI10, | Senior official, Kenya Pharmacy and Poisons Board, Nairobi, June 2013 |
| 11. Kenya KI11 | Official, Ministry of Health, Nairobi, June 201 |
| 12. Lesotho KI12, | Senior official, Ministry of Health, Lesotho, interview in Arusha, 2012 |
| 13. Zambia KI13 | Senior official, Ministry of Health, Zambia, interview in Arusha, Dec 2012 |
| 14. Tanzania KI14 | Senior official, Ministry of Health, United Republic of Tanzania, Dec 2012 |
| 15. Zimbabwe KI15 | Senior official, Medicines Control Authority of Zimbabwe, Harare Feb 2014 |
| 16. Zambia KI16 | Geneva-based diplomat, Interviewed in Harare April 2014 |
| 17. Zimbabwe KI17 | Senior official, Ministry of Health and Child Care, Arusha December 2012 |
| 18. Swaziland KI18 | Senior official, Ministry of Health, interviewed in Arusha, December 2012 |
| 19. Uganda KI19, | Senior government official, Kampala, December 2013 |



***Equity in health** implies addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region. EQUINET is primarily concerned with equity motivated interventions that seek to allocate resources preferentially to those with the worst health status (vertical equity). EQUINET seeks to understand and influence the redistribution of social and economic resources for equity-oriented interventions. EQUINET also seeks to understand and inform the power and ability people (and social groups) have to make choices over health inputs and their capacity to use these choices towards health.*

EQUINET implements work in a number of areas identified as central to health equity in east and southern Africa

- Protecting health in economic and trade policy
- Building universal, primary health care-oriented health systems
- Equitable, health systems strengthening responses to HIV and AIDS
- Fair financing of health systems
- Valuing and retaining health workers
- Organising participatory, people-centred health systems
- Social empowerment and action for health
- Monitoring progress through country and regional equity watches

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