Literature review on bottlenecks to essential medicines production and procurement in east and southern Africa

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

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Executive summary

Access to essential medicines is one of the key requirements for achieving equitable health systems and better public health in east and southern Africa (ESA). One constraint to this is that the region's medicine production capacity remains weak. 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 in Africa. The PMPA includes six priority areas: mapping productive capacity; situation analysis; developing a manufacturing agenda; addressing intellectual property issues; political, geographical, economic considerations; and financing. The plan assesses the barriers and bottlenecks to medicine production in the region that need to be addressed. Equally, the Southern African Development Community (SADC) and the East African Community (EAC) plans 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 one policy goal is to create and sustain reliable regional pharmaceutical industries whose operations are relevant to the local economies and responsive to the disease burdens.

There are, however, impediments slowing application of these plans. Few countries in east and southern Africa have a domestic pharmaceutical industry. South Africa and Kenya have a larger number of local manufacturing plants compared to other countries in the region. This review compiles from existing literature bottlenecks to local medicine production in the region. It seeks to inform follow-up case study work on the extent to which relationships and agreements with Brazil, India and China are addressing the bottlenecks identified in the African Union (AU), SADC and EAC plans for pharmaceutical manufacturing.

This work is 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.* The EQUINET programme examines the role of global health diplomacy (GHD), including south–south diplomacy, in addressing selected key challenges to health and health systems in east and southern Africa. It seeks to inform African policy actors and stakeholders within processes of global health diplomacy.

To support the work on south–south diplomacy on medicines, a desk study of literature published between 1992 and 2012 was compiled by the authors covering ESA countries in relation to: access to medicines, local production, global health diplomacy and south–south co-operation in pharmaceutical production. There is limited documentation in this field and 48 documents met the inclusion criteria in terms of the period and focus.

The review presents evidence from the literature on:

- the state of pharmaceutical production in ESA countries,
- existing plans, policies and strategies for pharmaceutical production in the ESA region, and
- the challenges/bottlenecks to pharmaceutical production in the ESA region.

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The review found a number of bottlenecks to local production and over reliance on imports of medicines from developed countries. They barriers to expanding medicine production in the region are identified as:

- A weak policy environment and limited governmental support to encourage domestic investment in the pharmaceutical industry;
- High tariffs on imported inputs, high interests rates on credit, ageing and unreliable energy, water and transport infrastructure;

- Shortfalls in capital and skills, including in scientists and industrial pharmacists and in laboratories;
- Limited international linkages and mechanisms for and intellectual property constraints in technology transfer and in the sourcing of active pharmaceutical ingredients;
- Gaps in the regulatory framework and in enforcement capacities to ensure quality assured, safe and efficacious medicines;
- Small markets within individual countries, and
- Weak or non-existent capacities for research and development.

The bottlenecks can be grouped into:

- **Financial:** lack of working capital, high costs, high utility tariffs;
- **Technology:** old plant and equipment; inadequate technology; patent constraints;
- **Infrastructure:** transaction and information costs; unreliable utilities;
- **Capacities:** limitations in skilled personnel;
- **Governance:** weak leadership and corruption.

The literature also highlights that a number of policy options are emerging in support of local production, including south–south and public and private sector partnerships. There is evidence of new interest in medicines markets and production in east and southern Africa, with India, Brazil, Thailand, China and other emergent economies involved in medicines production and trade. These countries are setting up plants with varying degrees of collaboration and joint ownership with African producers. Regional production and distribution agreements provide wider markets for medicines produced, generating economies of scale, better use of installed capacities, and greater possibilities of local supply of active ingredients and other raw materials. Regional co-operation has also been important to harmonise medicine regulation and support skills development.

The review highlights important areas to address in diplomacy, including in south–south agreements on and investments in medicines production, to overcome constraints to building the local pharmaceutical industry. The review suggests measures to address in negotiated agreements and diplomacy to overcome bottlenecks that include:

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

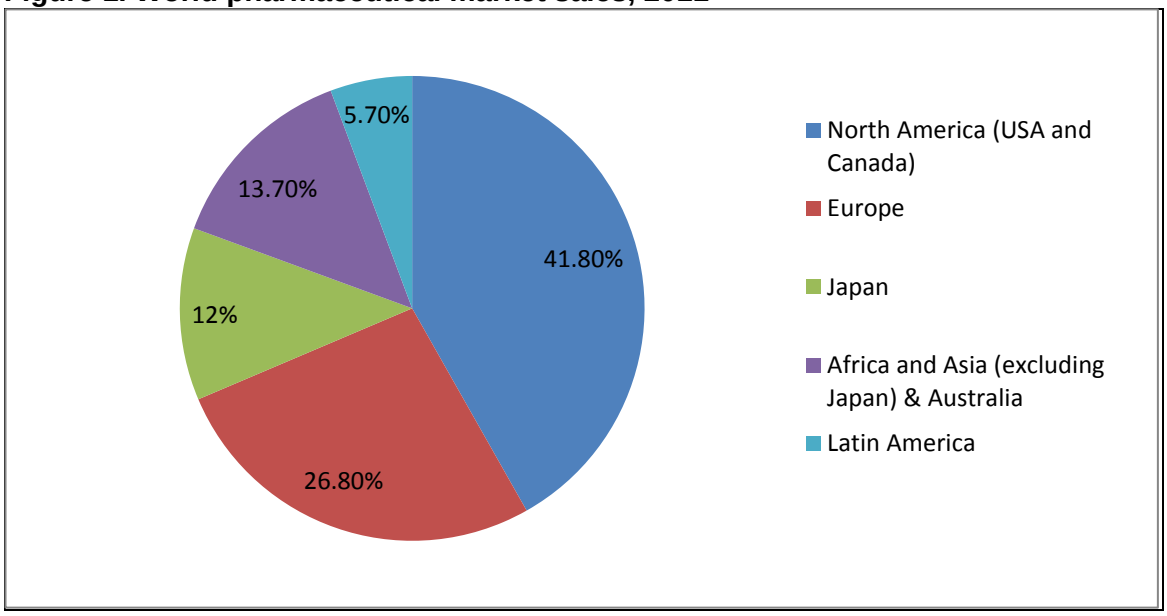
1. Introduction

Access to essential medicines is one of the key requirements for achieving equitable health systems and better health for the population. The United Nations Conference on Trade and Development (UNCTAD) noted 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 of the world's population, many of whom live in least-developed countries (LDC), lack regular access to essential medicines (UNCTAD, 2011).

Although considerable progress has been made in access to medicines, the benefits of this progress have been unequally distributed across the global population. 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). 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).

The world pharmaceutical market was worth an estimated $855,500 million at factory prices (excluding delivery or tax charges) in 2011. As shown in *Figure 1*, the North American market (USA and Canada) had the largest share of this market, with a 41.8% share, while Africa and Asia had only a 13.7% share, despite their larger populations combined compared to the other regions (EFPIA, 2012).

Figure 1. World pharmaceutical market sales, 2011



Source: EFPIA, 2012.

In 2008, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) observed that local production of pharmaceuticals was a key area for investment (WHO, 2011). The GSPA-PHI called for investment, capacity building, identification of best practices, north–south and south–south co-operation, collaboration with the pharmaceutical industry and building up of absorptive capacity, amongst other recommendations.

The policy intention is to support local medicines production in Africa. The African Heads of State and Government adopted the Pharmaceutical Manufacturing Plan for Africa (PMPA) 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 plan is the basis for a more co-ordinated approach to local medicines production based on countries' needs. Developing a local manufacturing capacity has advantages for employment, skills retention, foreign currency savings and to facilitate responsiveness to local health needs. The AU plan identifies six priority areas, including: mapping productive capacity; situation analysis; setting a manufacturing agenda; addressing intellectual property issues; and ensuring financing. The plan assesses the barriers and bottlenecks to medicine production in the region that need to be addressed. Equally, the Southern African Development Community (SADC) and the East African Community (EAC) plans for pharmaceuticals provide information on proposed policy measures to overcome barriers to medicines access, including measures such as pooled procurement to make medicines more affordable (SADC, 2007; EAC, 2011). The regional dimension is identified as important 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.

This review compiles existing literature on the bottlenecks to local medicine production in the region. It seeks to inform follow-up case study work on the extent to which relationships and agreements with Brazil, India and China are addressing the bottlenecks identified in AU, SADC and EAC plans for pharmaceutical manufacturing.

This work is 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.* The programme examines the role of global health diplomacy (GHD), including south–south diplomacy, in addressing selected key challenges to health and health systems in east and southern Africa. It seeks to inform African policy actors and stakeholders within foreign policy and global health diplomacy processes.

2. Methods

The literature review is based on a desk study of published literature that includes 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 pharmaceutical local 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 that there was almost no pharmaceutical production in ESA countries, despite being most affected by AIDS. The period saw the emergence of Brazil, India, China, Russia and South Africa (BRICS).

The reports were obtained from Medline, IDRC, Google and EQUINET databases and through Internet search. Searches were also done on multilateral agency websites, e.g., WHO, WTO, UNIDO, UNCTAD, World Bank; continental and regional organisation

websites, e.g., AU, SADC, EAC, UN Economic Commission for Africa; and mainstream international and regional media through Google Chrome.

The Internet and online library searches used the following search terms: access to medicines, local production, global health diplomacy, south–south cooperation + 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 200 documents specific to medicines in ESA countries, including the role of Brazil, India and China in ESA countries. A final set of 48 documents were included that met the inclusion criteria and terms noted above, shown in the reference list. The documents included in this review are not exhaustive of all literature on access to medicines, local production and south–south cooperation. 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 will be addressed through field work at a later stage of the work. However, the review was able in some areas 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.

The next section provides the findings from a review of these documents. The evidence is presented in three sections:

- The state of pharmaceutical production in ESA countries;
- Plans, policies and strategies for pharmaceutical production in the ESA region; and
- Challenges and bottlenecks identified in pharmaceutical production in the ESA region.

A final section discusses the lessons learnt and implications for follow-up work on health diplomacy and south–south co-operation in medicines production in ESA.

3. Review findings on medicines production in ESA countries

3.1 Pattern of medicine production in ESA

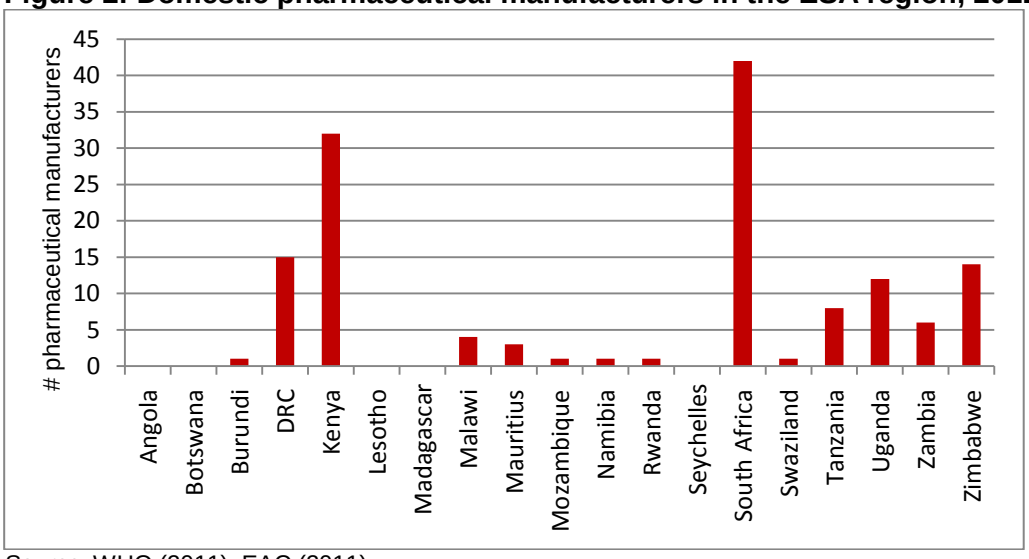
The World Health Organisation (WHO) noted that local production of drugs in low- and middle-income countries is one way of increasing access to medicines and also contributing to economic and industrial development and to technological capacity (WHO, 2006). Local production assists in meeting the Millennium Development Goal targets for access to medicines (that is goal 8, target 17, on co-operation with pharmaceutical companies to provide access to affordable, essential drugs in developing countries, and indicator 46 on the proportion of the population with access to affordable essential drugs on a sustainable basis). The objectives and expertise needed for local medicines production extend beyond public health to include research and development, intellectual property, trade and commerce, tax and tariff policies, drug regulatory and registration issues, finance, raw materials procurement, medicines, pharmaceutical manufacturing and marketing (COHRED and NEPAD, 2009). The issues that emerged from the literature commonly relate to business opportunities and issues in local production more than public health issues (Koivusalo, 2010).

Several policy sources consider that establishing local production facilities, including through south–south cooperation, would be one way of improving access to medicines in ESA countries (AU, 2007; EAC, 2011; SADC, 2007). African countries have been urged to pool their resources and strengthen their capacity to manufacture generic pharmaceutical products (Elbeshbishi, 2007). The AU PMPA asserts that “access to quality healthcare,

including access to all essential medicines that are affordable, safe, efficacious, and of good quality, is a fundamental human right." Promoting industrial development and safeguarding and protecting public health are identified as synergistic priorities. Production of quality medicines and the development of an international Good Manufacturing Practice(GMP) compliant industry in Africa are asserted to be both feasible and desirable (AU, 2012). South–south collaboration in health plays a role in capacity building and innovation in medicines production. By contributing their respective strengths, co-operation across countries has the potential to enhance research and development on new health products and services (Alden and Vieira 2005; Chaturvedi and Thorsteinsdóttir, 2012). The policy context for local production is reviewed in more detail in the next section. This section reports on the current state of pharmaceutical production in ESA countries as found in the literature.

The International Finance Corporation (IFC) estimated the sub-Saharan Africa pharmaceutical market to be worth $3.8 billion in 2006. Local final formulators created 25-30% of this value, or approximately $1 billion (IFC, 2008). While 37 sub-Saharan African countries have some pharmaceutical production, South Africa dominated the sector with more than 70% of the region's annual pharmaceutical production. Nigeria, Kenya, and Ghana together represent another 20% (see *Figure 2*). Nigeria and Ghana's production focuses more on local consumption whereas 35-45% of Kenyan manufacturers' revenues come from exports to east African and Common Market for Eastern and Southern Africa (COMESA) countries. The sector is growing: The IFC estimated that 40% of the cumulative $1.6-$2.9 billion projected investment in health care in the region between 2007 and 2016 will be invested in generic final formulation manufacturing (IFC, 2008).

Figure 2: Domestic pharmaceutical manufacturers in the ESA region, 2011



Source: WHO (2011), EAC (2011).

While 37 sub-Saharan African countries have some pharmaceutical production, in 25 countries this is limited to packaging or labelling. Only South Africa has a limited degree of active pharmaceutical ingredient (API) production. Further, most production outside South Africa consists of non-complex, high-volume essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs and vitamins (IFC, 2008). Local production in Africa therefore largely relies on imported active ingredients and contingent on foreign funding and manufacturing, with a dependency on imports (COHRED, NEPAD 2009). Pharmaceutical research and development is limited by low capacity (EAC, 2011; SADC, 2007; COHRED and NEPAD, 2009; WHO 2009).

3.2 South−south links in medicine production in ESA

International actors thus have an influence on medicines production and markets in the region. A number of ESA countries rely on India and China for imports of affordable generics and raw materials, although through unreliable medicine supply systems (Elbeshbishi, 2007).

Indian exports to African markets

African countries provide a small market for India's drugs and pharmaceuticals exports. Europe and America accounted for 57.8% and Asia, including the Middle East, for another 26.9% of India's total pharmaceutical exports in 2006-07. Africa's share was only 14.1%. But Africa is an expanding market for India. Its share has gone up from 10.7% in 1994-95 to 14.1% in 2006-07. The African market has grown faster than all other regions except America. Six countries (Nigeria, South Africa, Kenya, Ghana, Uganda and Tanzania) accounted for more than half of India's drugs and pharmaceuticals exports to Africa in 2006-07. Among the major Indian companies that dominate both the domestic and the export market, Africa is a substantial foreign market only for Cipla. Africa accounted for 14.1% of Cipla's sales in 2006-07. This is more than Europe's share in Cipla sales (10.6%) and comparable to that of sales to the Americas (16.6%). In contrast for Ranbaxy, Dr Reddy's and Ipca, other Indian firms, Africa's share is less than 10%.
Source: Chaudhuri, 2008.

While African countries have not provided a significant market share for international producers, as indicated in the box above, the literature provides evidence of rising international interest in local production of medicines across African countries, especially in ESA countries (WHO, 2006; WHO, 2011; Anderson 2010; Seiter 2005, UNCTAD 2011a). This is reportedly generated by:

- Increased interconnectedness and vulnerability to global health threats. For example, with 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 of 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.
- Increased pressure for equitable access to medicines (WHO, 2006; WHO, 2011; Tempest 2011; Owoeye 2011; Moon 2011; Lanoska 2003 Hoen et al 2011; Sampath and Roffe 2011).

Brazil and India have established partnerships in medicines production in Mozambique and Uganda respectively. A partnership was proposed between a Chinese company and the government of Kenya but has not taken off. While the follow-up work will explore such case studies in detail, this review explores published information on the context, motivation and scope of the agreements signed with such partners.

Brazil-Mozambique ARV plant: The government of Mozambique, in partnership with Brazil, is 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. A regional office of the Oswaldo Cruz Foundation (FIOCRUZ, Fundação Oswaldo Cruz) was officially installed in Maputo in 2008 to facilitate co-ordination on the ground, and is its first field office opened abroad

(World Bank, 2011; Panapress 2012). According to FIOCRUZ, during the first phase, equipment and drugs will be brought from Brazil, packing 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 should produce medicines. Brazil currently provides the formulations and technology for production. This raises questions about future sustainability, such as whether government or external funders will allocate adequate funds to purchase medicines produced and what will happen to viability if the market prices drop.

Notwithstanding these challenges, the development of the plant confirms Brazil's commitment to south–south cooperation in medicines production. All twelve of the former Brazilian President Lula da Silva's presidential missions to Africa included a health component, and as of 2011, Brazil had signed 53 bilateral agreements on health with 22 African countries (World Bank, 2011). Small-scale projects on malaria and HIV/ AIDS arising out of these agreements were at the heart of Brazilian co-operation on health until 2008, when a new approach encouraged development of structuring projects (see *Table 1*). Such projects (like the ARV plant in Mozambique) typically aim at building critical human resource capacities and strengthening relevant local and national institutions. They have proven to have greater impact than small-scale projects. The longer-term approach emphasises local engagement and capacity development.

Table 1:Structuring health projects: Brazil–Africa development co-operation, 2010

Partnering Country	Structuring Project	Brazil Investment $ '000 (2010)
Angola	Pilot project in the Programme to Fight Anaemia	240
	Technical support to implement a centre of hygiene and epidemiology	490
Ghana	Support to implement a national system for treating sickle-cell anaemia	7,000
Mozambique	HIV/AIDS pharmaceutical plant	23,000
São Tomé and Príncipe	Support to the nascent Programme to Prevent and Control Malaria in São Tomé and Príncipe	600
Senegal	Support to the National Programme to Fight Anaemia	250

Source: World Bank, 2011.

Quality Chemical Industries (Uganda) and CIPLA (India) ARV plant: Upon request by the government of Uganda, Cipla Ltd, one of the world's leading pharmaceutical manufacturers based in India, agreed to extend technical assistance to Uganda through a joint venture with local partner Quality Chemicals Ltd (QCL). This was to enable Uganda to manufacture antiretroviral drugs locally to combat HIV/AIDS and anti-malarial drugs under licence from Cipla Ltd (Quality Chemical Industries, 2012). In October 2007, a $38 million pharmaceutical plant was set up on a 15-acre site southwest of the capital Kampala. Cipla, which holds a 42% stake in Quality Chemical Industries, provided the technology and the expertise to set up the plant. The plant now provides an outlet for Cipla to produce these medicines for the African market. In November 2009, TLG Capital acquired a 8.2% stake in the plant. Capitalworks Investment Partners of South Africa also owns an 8.2% stake (Quality Chemical Industries, 2012).

These examples of south–south cooperation in medicines production indicate new possibilities for local production in Africa. They also raise questions of sustainability, and how they can be commercially viable while offering subsided medicines to low income populations. Thus, the relationship between these plants and government initiatives, such

as bulk procurement and payment for medicines, is an important feature of the co-operation.

Emerging economies like Brazil, China and India also provide important experiences of research, innovation and development of their own pharmaceutical industries (Holt et al., 2012; First 2007 Robinson 2008; UNIDO 2006). These are shown in the box below:

Experiences of Brazil, India and China in medicines production

Brazil, which has the world's fifth largest population, has used compulsory licenses to promote access to essential medicines. Although the country has repeatedly obtained concessions from major pharmaceutical firms through these threats, in April 2007 Brazil finally granted compulsory licenses for the non-commercial, public use of the patented AIDS drug efavirenz. Over the years, Brazil has developed a successful programme to provide free, universal access to the treatment of HIV/AIDS. Its national STD/AIDS programme "has reduced AIDS-related mortality by more than 50% between 1996 and 1999. In two years, Brazil saved $472 million in hospital costs and treatment costs for AIDS-related infections." The programme has been widely recognised as a model for the less-developed world. For decades, Brazil has been a leading voice for less-developed countries on medicines access. During the TRIPS negotiations, it was one of the ten hardliner countries that refused to expand the mandate of the General Agreement on Tariffs and Trade (GATT) to cover substantive intellectual property issues. During the fifth WTO Ministerial Conference in Cancún in 2003, Brazil choreographed the G–20, whose demands and resistance led to the collapse of the ministerial conference.

India, the world's largest democracy and second most populous country, is another important southern voice. When Brazil requested consultations with the United States through the WTO dispute settlement process, India was the only other country that requested to join those consultations. India's active lobbying on behalf of less-developed countries for lower intellectual property protection and special and differential treatment dates back to reforms introduced in the country shortly after its becoming an independent state. These reforms included differential treatment for food, medicine, and chemical inventions; the prohibition of patents in pharmaceutical products (as compared to processes used to manufacture those products); and the provision of compulsory licensing to encourage the local working of patents. Shortly before 1 January 2005, the deadline by which the TRIPs Agreement required all developing countries to introduce protection for both pharmaceutical products and processes, India introduced a new patent law. Although this new law is likely to have a major impact on the development and availability of cheap, generic drugs and related ingredients, it does not affect the production of drugs that have already been developed. The new law also includes specific provisions to allow generic manufacturers to continue to sell drugs that are already developed by paying reasonable royalties to patent holders. Notwithstanding these safeguards, commentators have been particularly concerned about the impact of the new law on the global supply of generic drugs, because India "makes more than a fifth of the world's generic drugs."

China, the world's most populous country, is a new member in the WTO. On 11 December 2001, the country formally became the 143rd member of the international trading body. China has had longstanding bilateral disputes with the US over patent breaches and counterfeiting, less so in recent years. China is developing its industries in the areas of computer programmes, movies, semiconductors and biotechnology. While the country wants stronger protection for its fast-growing industries, it prefers weaker protection in fields related to pharmaceuticals, chemicals, fertilisers, seeds, and foodstuffs, due to its huge population, continued economic dependence on agriculture, the leaders' worries about public health issues and their concerns about the people's overall well-being.

Source for all cases: Yu, 2008.

Brazil, India, China and South Africa are now playing an important role within the global institutional landscape supporting health initiatives. The four countries together contributed nearly $200 million to global health initiatives such as Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund to Fight AIDS, Tuberculosis and Malaria during 2007-2008 (Chaturvedi and Thorsteinsdóttir, 2012). They bring new information, skills and experience to dialogue in the south on local production.

4. Policies, strategies and plans for pharmaceutical production

4.1 International policies

The literature review provides evidence of a number of national, regional and global policies, plans and strategies on or affecting access to medicines that have been negotiated, developed or implemented in recent decades, summarised in *Table 2*.

Table 2: International policies and instruments on pharmaceutical production

Plan/Policy/Instrument	Outline	Affected Institution
WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) 1994	This is a legally binding agreement on all countries in the ESA region, given that they are WTO members. The agreement mandates global minimum standards for the protection of intellectual property.	WTO Ministries of Trade
Doha Declaration on TRIPs and Public Health 2001 (Under the auspices of the WTO)	The declaration affirms that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". Paragraph 6 of the declaration recognises that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. “We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”	Ministries of Trade
WTO 30 August 2003 decision in relation to TRIPS	Provides interim waiver on requirement that compulsory licensing be predominantly for the supply of the domestic market.	Ministries of Trade
WHO (2003) Commission on Public Health, Innovation and Intellectual Property Rights	The report that the Commission submitted to member states in April 2006 contained 60 recommendations grouped into five categories: discovery, development, delivery, fostering innovation in developing countries and supporting a sustainable global effort for the creation of new medicines and other products against diseases that disproportionately affect developing countries. The recommendations are not legally binding but focus attention on policy areas where governments and relevant stakeholders need to act.	WHO and the Ministries of Health
WTO (2005) The Agreement to operationalise the 30 August 2003 decision by amending the TRIPs Agreement	Few ESA countries have ratified this agreement, so the permanent amendment of the TRIPs Agreement has not yet been done. It requires ratification by two-thirds majority of the WTO membership.	Ministries of Trade
The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property (GSPA) 2008	The strategy and plan resulted from the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. In 2008, the 193 WHO member countries adopted the plan after a six-year consultation and negotiation process. It is a mechanism to ensure long-term, needs-driven, research and development and a funding framework for medicines for developing countries. The strategy and plan propose clear objectives and priorities for promoting innovation, building capacity, improving access and mobilising resources. The funding levels called for are $149 billion between 2009 and 2015 – an average of $21 billion per year.	WHO Ministries of Health

Source: WTO 1994, 2001, 2005; WHO, 2003, 2008, Moreira 2007.

The international policy environment has shaped development of the pharmaceutical industry especially with regards to the role of intellectual property rights in research and development around medicines. The WTO was created in 1995 as a global body to promote liberalisation of trade in goods and services after a lengthy negotiation process that lasted from 1986 to 1994, the so-called Uruguay Round of trade negotiations. The global application of minimum standards for intellectual property under TRIPS was controversial, given its potential impact on public health. This led governments to clarify the relationship between the TRIPS agreement and public health in the Doha Declaration on TRIPs and Public Health of 2001 (WTO, 2001). Subsequent meetings and decisions to operationalise the use of TRIPs flexibilities were thus convened and adopted over the years as shown in *Table 2*. More recently WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property adopted a strategy that sought to ensure long-term, needs-driven, research and development and a funding framework for medicines for developing countries, as shown in *Table 2*.

4.2 African policies

African Union (AU), SADC and East African Community (EAC) plans were developed to identify the priorities, opportunities and challenges to be addressed to establish pharmaceutical manufacturing capacity in Africa, east Africa and southern Africa respectively. The plans, as is indicated in *Table 3*, have a number of common features.

Table 3: African policies and instruments on pharmaceutical production

Plan/Policy/Instrument	Outline	Affected Institution
Pharmaceutical Manufacturing Plan for Africa-African Union 2007	The 2005 AU Assembly decision 55 mandated the AU Commission to develop a pharmaceutical manufacturing plan for Africa "to pursue the local production of generic medicines on the continent and to make full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health". This is not a legally binding instrument but a plan of action that African countries agreed to on issues related to access to medicines on the continent.	Ministries of: • Foreign Affairs • Health • Trade
SADC Pharmaceutical Business Plan 2007-2013	This plan in line with the SADC Health Protocol and the SADC Health Policy aims to enhance the capacities of Member States to effectively prevent and treat major public health burdens in the Region.	Ministries of Health
East African Community Regional Pharmaceutical Manufacturing Plan of Action: 2012-2016	The plan provides a regional roadmap to guide the EAC towards evolving an efficient and effective regional pharmaceutical manufacturing industry that can supply national, regional and international markets with quality medicines.	Ministries of Health
African Network for Drugs and Diagnostics Innovation (ANDI) (2009)	The African Network for Drugs and Diagnostics Innovation (ANDI) was proposed by WHO/TDR, in conjunction with several African institutions as well as Africans in the diaspora, as a strategic initiative to help drive the GSPA. Its objective is to promote and sustain health product R&D led by African institutions and aimed at controlling and treating diseases of high prevalence in the continent. The expected result is the discovery, development and delivery of affordable new health tools (drugs, vaccines and diagnostics), including those based on traditional medicine.	Ministries of Health
Abuja Declaration-African Union 2001	In April 2001, AU heads state pledged to allocate 15% of their annual budgets to improve the health sector. This is not a legally binding agreement. African countries have largely not met this commitment.	Ministries of: • Finance • Health

Source: AU, 2001, 2007; SADC, 2007; EAC, 2011; ANDI, 2009.

All note the over reliance on imports of medicines from developed countries particularly Europe, the United States, India and China, especially for AIDS treatment. They all note price disparities raising import costs as a driver of local production. Further, while imports from developed countries are noted to be expensive, cheaper and subsidised imports from Asia and poorer quality medicines make local production uncompetitive (AU, 2007; SADC, 2007; EAC, 2011).

The plans reflect a range of reasons for pursuing local production, including security of supply, localised quality control, products that are more aligned to population needs, reduced costs in the long run and the sector as a contributor to economic development. The challenges raised from the importation of medicines are raised in the plans. They include the fact that relying on imports makes the supply chain vulnerable to corruption, that it does not lead to technology transfer and it depends on a sustained flow of financing to purchase imports.

The plans identify critical constraints or issues that should be looked at when establishing local pharmaceutical production, namely:

- A market size that would ensure sustainability and technical and financial viability.
- The availability of capital, technology and knowledge since pharmaceutical production is knowledge intensive/driven. Technical expertise is critical, both in terms of sufficient numbers and appropriate skills.
- A legislative framework conducive to regional and local production. This includes legislation to ensure Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP) and extends to legislation regulating related duties on imported raw materials and intermediates and related taxes.
- Supporting Infrastructure, including electricity, water and transport - a challenge in most ESA countries.
- Medicines regulation to deal with quality and counterfeit issues (AU, 2007; SADC, 2007; EAC, 2011).

These issues suggest that local production of medicines demands a developed infrastructure, a sound legislative and regulatory framework, skills, capital and other resources. While the need for access to medicines is embodied as a principle, business considerations appear to be the focus of the plans. Attention to the balance between measures for access necessary for health and measures for trade and production necessary to ensure commercial viability is limited.

The next section explores the bottlenecks identified in the plans and in other literature. Making these constraints clear is important when assessing whether joint investments, partnerships and agreements on pharmaceutical production being negotiated consider them.

5. Bottlenecks in local pharmaceutical production

The literature provides examples of national experiences on the feasibility of local production. It also provides evidence on theoretical modelling of the economic viability of local production (WHO, 2006; WHO, 2011; Kaplan and Laing 2005). The literature raises challenges (or bottlenecks) to local pharmaceutical production in the ESA region that will be important to address through more detailed studies.

5.1 Finance, technology and infrastructure

Both global and regional sources in the literature review confirmed that pharmaceutical manufacturers operating from 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, although "with a relatively large and well-diversified manufacturing sector", faces challenges to local production and international competitiveness due to:

- High production costs related to very old plant and equipment
- Power shortages
- Exorbitant utility tariffs, high by regional standards
- Lack of working capital
- Lack of access to capital for recapitalisation
- Lack of technology (as products are becoming less competitive).

In the SADC region, Zimbabwe's pharmaceutical industry is second to South Africa in size and development, producing more the 65% of the essential drugs list and less than 15% of Zimbabwe's special essential drugs list. Nevertheless, the industry has performed poorly due to the wider economic decline and the impact of low financing and falling public spending on health, competition from imported and donated medicines, long registration times (about 24 months) and electricity shortages. The lack of credit lines hampered the industry's ability to participate significantly in the export market. Pharmaceutical products receive low tariff protection and medicine imports are subject to an average tariff of 4.2%. (WTO, 2011).

5.2 Human resources challenges

A number of documents identify challenges to local pharmaceutical production from shortages of skilled professional personnel and point to infrastructure and skills as major determinants for technology transfer (COHRED and NEPAD, 2009; WHO, 2011; UNCTAD, 2011; EAC, 2011; Loewenson, 2011). The same publications note that the willingness of the pharmaceutical industry to transfer its know-how and techniques is not sufficient for successful transfer of technology. 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 that is conducive to pharmaceutical innovation. This absorptive capacity is determined by the existence of a sustainable and efficient cadre of highly skilled scientists. 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, 2011; AU, 2007; SADC, 2007; EAC, 2011; WTO, 2011).

Chaudhuri (2008) notes that the business environment for setting up pharmaceutical production is not always favourable. 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; and although government still holds 40% equity in both the companies, it has stopped providing any funds to these companies – limiting the growth of these units or their capacity to attract and retain personnel.

5.3 Governance challenges

Bate (2008) observes that governance issues are a challenge to local production of pharmaceuticals. Local production that is 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 markups 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). These authors call for legislative and regulatory frameworks and stronger governance policies as fundamental to the successful development and establishment of local pharmaceutical production.

5.4 Intellectual property constraints

At the international level, patents on medicines have been seen to pose the largest 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 Doha Declaration extended the deadline for least-developed country WTO members to grant or enforce pharmaceutical patents until at least 2016.

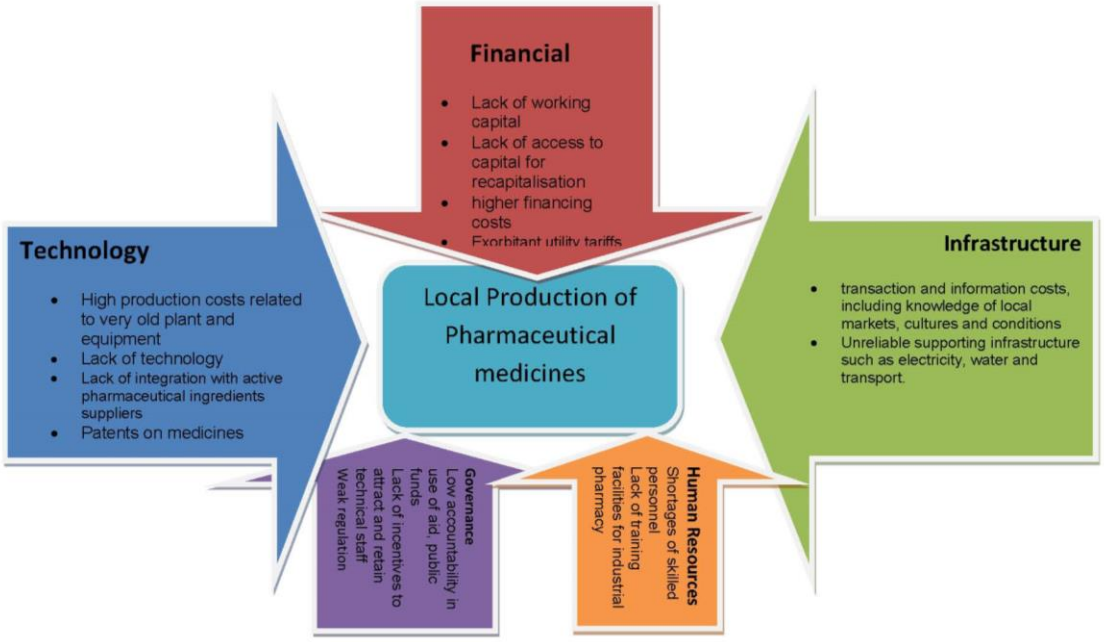
The 2001 WTO Doha Declaration increased interest in exploring the possibilities for pharmaceutical production, particularly in least-developed countries, due to the waiver they received up to 2016 to make their laws TRIPs compliant. Countries in east Africa are, for example, reported to be taking advantage 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).

The literature thus highlights the range of bottlenecks to expanding medicine production in the region as:

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

Figure 3 summarises the barriers and indicates 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 3: Flow chart of constraints to local production



6. Conclusions

The literature reviewed points to a number of bottlenecks and challenges to local production, undermining implementation of the policy intention to pursue it. However, there is some evidence of emerging south–south public and private sector partnerships and policy options for regional level production agreements that can address some of these bottlenecks. Regional agreements and co-operation can widen markets and generate economies of scale, making better use of installed capacities, enhancing feasibility of local supply of active ingredients and other raw materials, strengthening negotiating positions on prices and quality control.

Emerging economies and other developing countries that have succeeded in developing their local pharmaceutical industries provide crucial lessons for ESA countries in the quest to set up local production. They have invested in research and development and a solid human resources base and tapped markets in the south, such as in Africa (Chaudhuri, 2008). It would appear that there is an opportunity for strengthened negotiations to link the heightened interest in medicines in Africa and the capabilities in Brazil, India, China and other emergent economies with measures to address the bottlenecks to local production in ESA countries. Their expertise, resources and capacities can be tapped for example 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). Diplomacy can play a role in this, in negotiating agreements that address bottlenecks identified in the region. The constraints identified in this review suggest that such negotiations with investors in medicines production, whether government or private, should address some elements of the following:

- **Strengthening government support and policy** to ensure a balance in the policy focus on public health and business needs and to set up policies and long-term government support and measures needed to attract public–public and public–private partnerships.
- **Setting laws and policies and strengthening the enforcement capacity** by developing national standards, strengthening quality management systems for regulatory authorities and ensuring that biotechnology development goes hand-in-hand with regulation.
- **Research and development (to deal with the challenges of technology)** to include investments in building science capacities to promote linkages and exploit existing strengths; use local biodiversity, indigenous knowledge and science-based innovations; develop local R&D infrastructure and capacities and promote domestic integration to spur innovation.
- **Building the human skills and capacities** to assess needs, invest in training and train local professionals in the requisite fields to widen the availability of training, resource centres to improve knowledge and skills and to apply incentives to attract and retain the necessary capacities for local production; and
- **Developing producers and markets** through agreements to enable a wider population base for the market and a mix of participation in production from large and small firms and link regional and international interests that exploit existing strengths.

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Appendix 1: African pharmaceutical plans

Plan	Main Findings/Issues Raised	Key Lessons Raised in the Plan
African Union (2007) Pharmaceutical Manufacturing Plan for Africa, CAMH/MIN/7(III), AU, Addis Ababa The AU Assembly decision 55 taken during the Abuja Summit in January 2005 mandated the AU Commission to develop a harmaceutical manufacturing plan for Africa "to pursue the local production of generic medicines on the continent and to making full use of the flexibilities within the Trade and Related Aspects of Intellectual Property Rights (TRIPS) and DOHA Declaration on TRIPS and Public Health	• Policy decisions about whether to import essential medicines from reputable sources or to promote local manufacturing should be based on careful situation analysis and realistic appraisal of the technical feasibility and financial viability underpinned by sound regulatory systems. • A market size that would ensure sustainability as well as technical and financial viability was considered imperative. • A number of countries in the continent largely rely on India and China for imports of affordable generics and raw materials • Unreliable medicine supply systems continue to hamper access. • Out of 46 countries in the WHO African Region, 37 have pharmaceutical industries, 34 have secondary level production and 25 have tertiary production. Only one has limited primary production. Nine countries have no production capacity. • Pharmaceutical production is capital, technology and knowledge intensive/driven. Technical expertise is absolutely critical, both in terms of sufficient numbers and appropriate skills. • The legislative framework needs to be conducive to regionalised local production. This extends beyond legislation that ensures Good Manufacturing Practice (GMP), Good Distribution Practice (GDP),Good Laboratory Practice (GLP), Good clinical Practice (GCP) and other aspects of product regulation but also extends to legislation regulating related duties on imported raw materials and intermediates and related taxes	• Local production of medicines can only be successful in the presence of not only relevant infrastructure but also sound legislative and regulatory framework. • The market size for setting up production plants is considered a critical factor in the setting up of local production. • The need for access to medicines and vaccines is not coming out as a determining factor for setting out local production (a question of profits before people?). • The presence of institutions of higher learning and research organisations with a special focus on producing skilled scientists is a prerequisite for the establishment of sound local production. • A balance between health and trade objectives is necessary to ensure a win-win situation especially in the case of imported raw materials.
EAC (2011) East African Community Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPoA): 2012-2016, EAC Secretariat, Arusha Development of a regional roadmap to guide the East African Community towards evolving	• Pharmaceutical manufacturers operating from within the EAC region generally produce at a cost disadvantage to larger generic product manufacturers internationally due to reasons including scale, expensive asset bases coupled with older technology, higher financing costs plus a lack of integration with active pharmaceutical ingredients suppliers. • Other challenges facing the local pharmaceutical production industry in East Africa include shortages of skilled professional personnel and unreliable supporting infrastructure such as electricity, water and transport. • The plan recommends strategic interventions to be applied at firm,	• There is some pharmaceutical manufacturing already taking place in the region but these are facing competition from imports, especially from India. • A combination of cross-sectoral policies is fundamental to the development of local pharmaceutical industry. • The setting up of local pharmaceutical production is not limited to the health sector but should combine the

Plan	Main Findings/Issues Raised	Key Lessons Raised in the Plan
an efficient and effective regional pharmaceutical manufacturing industry that can supply national, regional and international markets with efficacious and quality medicines.	institutional, national and regional levels to improve the business environment for pharmaceutical manufacturing, strengthen associated regulatory capacity and further develop human resource capacity through a programmatic approach. • The anticipated cost of implementation of the plan of action is approximately $45 million, to be raised from EAC partner states, development partners as well as the regional pharmaceutical industry. • National health and industrial development ministries are expected to support the implementation of the plan by assigning and availing the necessary resources.	leadership of health, trade, finance, economic development and legislative ministries. • Government should take the lead in setting up pharmaceutical industry but working closely with the private sector.
SADC (2007) SADC pharmaceutical business plan: 2007-2013, SADC Secretariat, Gaborone SADC has identified the need to develop and implement a pharmaceutical programme in line with the SADC Health Protocol and the SADC Health Policy. The purpose of the programme is to enhance the capacities of member states to effectively prevent and treat diseases that are of major concern to public health in the region.	• The SADC region has developed pharmaceutical guidelines for medicines regulation and other strategies aiming to improve access to medicines • predominance of private sector expenditure on essential medicines in a region with high poverty levels and substantial price disparities, which has implications on affordability particularly for the poor and disadvantaged population. • Over dependence on imported medicines both patented and generics. For instance, about 85% of the generic ARV medicines used in the region are imported from India and 15% are manufactured within the SADC region. • There is a large regional market for the pharmaceutical manufacturing industries, which was estimated in 2000 at $2.5-$3 billion • The plan emphasises rationalising and maximising the research and production capacity of local and regional pharmaceutical industry of generic essential medicines and African traditional medicines. • Promoting joint procurement of therapeutically beneficial medicines of acceptable safety, proven efficacy and quality to the people who need them most at affordable prices.	• The conditions for engendering local production in medicines based on south−south cooperation are there. • There is a gap especially in government-to-government collaboration as part of south−south co-operation. Private sector is dominant. • Region is already importing drugs from other large developing countries. The potential to establish local production based on south−south co-operation could be seen as a threat to the already established market by the large developing countries e.g. India. • African traditional medicine could be the starting point for ensuring south−south co-operation in medicines production especially where existing capacity is limited.

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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