



THE ACCESS AND
DELIVERY PARTNERSHIP

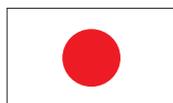
New Health Technologies for TB, Malaria and NTDs

HOW LOCAL PRODUCTION OF PHARMACEUTICALS CAN BE PROMOTED IN AFRICA

The case of the United Republic of Tanzania



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From the People of Japan



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About the Access and Delivery Partnership

The adverse impact of tuberculosis (TB), malaria and neglected tropic diseases (NTDs) on development outcomes has resulted in new approaches and partnerships to tackle the global deficiencies in research and development, and treatment access. One such initiative is the strategic partnership between the Government of Japan and United Nations Development Programme (UNDP), which promotes research and development, and expedites access to and delivery of health technologies used to address TB, malaria and NTDs. This partnership comprises two complementary components, which reflect the Government of Japan's and UNDP's strategic goals on global health:

The **Global Health Innovative Technology (GHIT) Fund**, which focuses on the promotion of innovation and research through the development of drugs, diagnostics and vaccines for TB, malaria and NTDs. The GHIT Fund stimulates research and development of new health technologies through funding research and product development partnerships between Japanese and non-Japanese organizations.

The **Access and Delivery Partnership (ADP)**, which aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver and introduce new health technologies for TB, malaria and NTDs.

Led and coordinated by UNDP, the ADP is a unique collaboration between UNDP, TDR (the Special Programme for Research and Training in Tropical Diseases, which is co-sponsored by UNICEF, UNDP, the World Bank and WHO) and PATH. Working together, the project partners leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs. The ADP emphasizes consultation, collaboration and implementation with partner-country governments and stakeholders, working to develop LMICs' capacities to access and introduce new technologies.

New health technologies are broadly defined as drugs, diagnostic tools and vaccines that are relevant for the prevention, treatment or cure of TB, malaria and NTDs, but are not yet available for market introduction or have not been introduced in LMICs. The introduction of new health technologies can place burdens on existing health systems, including new requirements for drug regulation, supply and distribution and health personnel training. Accordingly, the ADP will focus on providing LMIC stakeholders with the necessary skills to develop the systems and processes required to effectively access new health technologies, and introduce them to populations in need.

The ADP is a five-year project, running from April 2013 until March 2018.



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The paper relies substantially on interviews with officials of manufacturers and others in the United Republic of Tanzania and India. The report could not have been written without their active support and cooperation. In writing this report, the author has also used the results of interviews carried out in India, the United Republic of Tanzania and Ghana in connection with other projects, including those funded by the Economic and Social Research Council and the United Nations Industrial Development Organization. The author benefited from discussions with Maureen Mackintosh, Alastair West, Juergen Reinhardt and Cecilia Oh. The author would also like to thank Bwijo Bwijo, Frank Komakoma and Mami Yoshimura for their help in connection with the trip to the United Republic of Tanzania.

The views expressed are those of the author and do not necessarily represent those of the United Nations, including UNDP, or the United Nations Member States.



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List of abbreviations

GIZ	<i>Deutsche Gesellschaft für Internationale Zusammenarbeit</i>
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practice
IRP	international reference price
MSD	Medical Stores Department
TFDA	Tanzania Food and Drug Administration
TSH	Tanzanian shillings
UNDP	United Nations Development Programme
VAT	value-added tax
WHO	World Health Organization

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Executive summary



The United Republic of Tanzania is highly dependent on imported sources to supply its retail and institutional pharmaceutical market. In 2010, the market size was estimated at US\$144 million, of which only 35 percent was sourced from domestic production, while Novartis and GlaxoSmithKline, two multinational pharmaceutical companies, had a combined 16 percent share of the market. Even though several public and private pharmaceutical manufacturing facilities were established in the 1960s and 1970s, most have remained on a small scale and manufacture a relatively small list of simple formulations.

This paper argues that it is possible to promote a viable local industry without sacrificing affordability and accessibility of medicines. Recommendations in this paper to promote local production of pharmaceuticals have taken into account past experiences and the present status of the country.

Recommendations for policy action

To strengthen the viability of local pharmaceutical production as a strategy to achieve universal access to essential medicines, it is critical for the Tanzanian Government to be actively involved in addressing the barriers identified in this paper, by implementing policies that will improve, specifically, access to finance, technology and the market for local manufacturers.

Finance

A significant amount of capital is needed to set up good manufacturing practice (GMP)-compliant manufacturing facilities, to develop products that meet regulatory standards, and to market these products. Access to the necessary investment capital, either from foreign investment or from local commercial sources, is limited, however. If the indigenous pharmaceutical industry is to grow, it will need to rely heavily on efforts by local actors, particularly the Tanzanian Government and the local private sector. Local manufacturers need access to finances at interest rates that are comparable to the rates paid by their main competitors in India. Hence, cheaper credit may have to be provided directly by the Tanzanian Government. In Ghana, for instance, a scheme has been established for majority-owned local enterprises to access loans from the Ghanaian Government specifically for upgrading their manufacturing facilities, with an interest rate of only 12.5 percent.

Technology

Donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria insist on strict standards, such as World Health Organization (WHO) prequalification, when procuring medicines; and many countries, including Tanzania, are now starting to impose different variants of GMP compliance to ensure the manufactured product is effective and safe. The Tanzanian Government also has a leading role to play in strengthening the availability of the technical knowledge required to set up and run GMP-compliant manufacturing facilities, and in strengthening bioequivalence facilities and testing and quality-control laboratories. A potential source of such technical capacity is India, where the pharmaceutical technical knowledge is highly diffused, and there are numerous qualified individuals with the requisite knowledge and skills, ready and willing to provide technical support to a recipient country. The Tanzanian Government and international agencies involved in promoting local production in Africa are critical in facilitating the transfer of technical knowledge through this channel.

Market

Apart from a 15 percent price preference for Medical Stores Department procurement, local manufacturers do not have any other advantage. It is not enough to provide financial and technical assistance in pharmaceutical production; strategies also need to be put in place to improve the certainty of and accessibility to market for local manufacturers.

If local producers are to compete with foreign manufacturers, the local producers must be able to sell at a lower price and remain profitable and viable. A lower profit margin due to higher costs in the country can be compensated by a larger volume of sales. A simulation exercise using data from Indian manufacturers found that to earn a profit margin of 15 percent, the production level needs to be at 405 million tablets. Local manufacturers such as Mansoor Daya Chemicals Keko Pharmaceuticals, Shelys and Zenufa Laboratories already have such capacity but are currently underused. It is critical to ensure adequate access to market for the viability of the local industry.

To improve access to the retail market for local manufacturers, the Tanzanian Government may consider strengthening policy measures that limit the access of foreign companies to the domestic market and enhance the market share of local manufacturers. The Tanzanian Government may reintroduce import duty tax or impose an import ban on selected products, but only if capacities are adequately developed in the country. Abolishing import duty and value-added tax (VAT) on raw materials and packaging, and a more efficient VAT refund process, would significantly lighten the financial burden faced by local manufacturers. It may also be possible to use the bargaining power of insurance agencies to enlarge the market for local manufacturers, by fixing the prices for reimbursement of medicines and, where possible, restricting reimbursement only to locally manufactured products. Additional support could be provided to local manufacturing facilities to upgrade to GMP standards and to qualify for regulatory approvals and market access.

In the institutional market, changes to public procurement policy to increase access by local manufacturers can be used as an important instrument to promote local production. The Medical Stores Department may consider imposing a two-stage tendering process, where at the first stage of technical evaluation, only local manufacturers compliant with WHO GMP are eligible. Manufacturers that pass the technical evaluation are then invited to submit a financial bid. Based on the international reference price, a maximum purchase prices may be specified. This will ensure a larger market for local manufacturers without compromising on price. If no local manufacturer passes the technical evaluation stage, then the Medical Stores Department may opt for international tendering.



The context

As in most countries in Africa, the United Republic of Tanzania is dependent on imported sources for the supply of essential medicines required for the Tanzanian people. Efforts to promote local production of pharmaceuticals are sometimes questioned, on the grounds that the higher production costs would benefit neither the people nor the industry, as the industry would not be able to sustain itself against competition from cheaper imports. Several papers give some interesting insights into issues relating to local production in developing countries.^{1–8} This paper puts forward evidence that strongly suggest that it is possible to promote a viable local industry without sacrificing affordability and accessibility of medicines. We focus on Tanzania, but many of the arguments are relevant to other, similarly placed African countries. Recommendations in this paper to promote local production of pharmaceuticals have taken into account the past experiences and present status of the country. With a population of 48 million, Tanzania is one of the smaller developing countries, with a gross national income (purchasing power parity) of US\$76.6 billion and a per-capita gross national income of US\$1650 in 2012, which ranks Tanzania at 163 out of the 185 countries listed by the World Bank.⁹

Pharmaceutical industry in Tanzania

The pharmaceutical market in Tanzania in 2008–2009 was estimated at 182,940 million Tanzanian shillings (TSH) (US\$144 million) per annum, of which about 68 percent was supplied from imported sources and the remaining 32 percent from domestic production (table 1). The market size grew to US\$155 million in 2010, with imports accounting for about 65 percent of the market.¹⁰

Table 1: Domestic production and imports of pharmaceuticals in Tanzania^a

	2004–2005	2006–2007	2007–2008	2008–2009
Total domestic production (million TSH)	34,284	30,213	39,801	59,164
Total imports (million TSH)	81,978	87,009	100,557	123,776
Imports by private sector (million TSH)	41,532	42,660	55,890	57,989
Imports by Medical Stores Department (million TSH)	40,446	44,349	44,667	65,787
Domestic purchase by Medical Stores Department (million TSH)	11,667	9586	16,453	27,127
Total purchase by Medical Stores Department (million TSH)	52,113	53,935	61,120	92,914
Total market (million TSH)	116,262	117,222	140,358	182,940
Total market (million US\$) ^b	107	92	117	144
Domestic production/total market (%)	29.5	25.8	28.4	32.3
Total Medical Stores Department purchase/total market (%)	44.8	46	43.5	50.8
Domestic Medical Stores Department purchase/total domestic production (%)	34	31.7	41.3	45.9
Medical Stores Department imports/total purchase (%)	77.6	82.2	73.1	70.8

a Source: Ministry of Health and Social Welfare (2012). Strategy for Promotion of Domestic Pharmaceutical Production in Tanzania, 2013–2023. Dar es Salaam.

b Amount in Tanzanian shillings converted to United States dollars using the average exchange rate from July to June of the corresponding year.

Tanzania imported formulations from 53 countries worth US\$160.8 million in 2012. Just 16 countries accounted for 96.7 percent of the total imports. India is the largest source of these imports, with a share of 36.8 percent of total imports, followed by Kenya (25.4 percent), the United States (10.7 percent), Denmark (8.2 percent), Switzerland (7.7 percent) and China (6.3 percent). Among the other countries that export to Tanzania, each with a share of more than 1 percent, are Belgium, South Africa, the United Kingdom, Cyprus, Egypt and Germany (table 2).

Table 2: Formulations imports into Tanzania, 2012^a

	Imports (million US\$)	% of total
India	59.2	36.8
Kenya	40.9	25.4
United States	10.7	6.7
Denmark	8.2	5.1
Switzerland	7.7	4.8
China	6.3	3.9
Belgium	5.8	3.6
Netherlands	4.6	2.9
South Africa	1.9	1.2
Ghana	1.9	1.2
United Kingdom	1.7	1.0
Cyprus	1.5	1.0
United Arab Emirates	1.5	0.9
Egypt	1.2	0.8
Japan	1.2	0.7
Germany	1.1	0.7
37 other countries	5.3	3.3
Total (53 countries)	160.7	100.0

a Calculated from the United Nations COMTRADE database.

The pharmaceutical industry in Tanzania began in 1962, with the establishment of its first pharmaceutical manufacturer, Mansoor Daya Chemicals, a private company. This company still exists but operations have remained on a small scale, accounting for only about 3–4 percent of the total Tanzanian pharmaceutical production (table 3). The next two pharmaceutical manufacturers to be set up were public sector companies. Keko Pharmaceuticals was established in 1968 as a unit under the Ministry of Health to supply tablets, capsules and large-volume parenterals to the Government procurement agency Central Medical Stores (now the Medical Stores Department) for distribution through public health care facilities. Tanzania Pharmaceutical Industries was set up in 1978 by the Tanzanian Government, with assistance from the Finnish Government. Both companies experienced financial stress and were closed down in the early 1990s and subsequently rejuvenated in 1995 with 60 percent private equity. In 2008–2009, Tanzania Pharmaceutical Industries and Keko Pharmaceuticals were the second and third largest pharmaceutical companies in the country, accounting for about 17.5 percent and 15.3 percent of the value of pharmaceutical production, respectively (table 3).

Table 3: Pharmaceutical production and sales in Tanzania^a

	Value of production (million TSH)	Value of production (%)	Sales to Medical Stores Department (% of column 2)	Exports (% of column 2)
Tanzania Pharmaceutical Industries				
2004–2005	7,000	20.4	60.0	2.9
2006–2007	4,214	13.9	43.0	8.3
2007–2008	3,645	9.2	80.1	0.0
2008–2009	10,335	17.5	87.1	0.0
Shelys				
2004–2005	16,866	49.2	35.5	18.1
2006–2007	19,675	65.1	27.4	14.2
2007–2008	26,888	67.6	35.5	16.3
2008–2009	33,375	56.4	34.5	19.2
Interchem Pharma				
2004–2005	5,150	15.0	3.1	0.0
2006–2007	0	0.0	0.0	0.0
2007–2008	0	0.0	0.0	0.0
2008–2009	0	0.0	0.0	0.0
Keko Pharmaceuticals				
2004–2005	3,880	11.3	28.4	0.0
2006–2007	4,843	16.0	49.3	0.0
2007–2008	5,544	13.9	71.8	0.0
2008–2009	8,994	15.2	72.3	0.0
Mansoor Daya Chemicals				
2004–2005	704	2.1	7.0	0.0
2006–2007	1,327	4.4	0.0	0.0
2007–2008	1,662	4.2	0.0	0.0
2008–2009	2,000	3.4	0.0	0.0
Tanzansino				
2004–2005	540	1.6	31.6	0.0
2006–2007	0	0.0	0.0	0.0
2007–2008	0	0.0	0.0	0.0
2008–2009	570	1.0	0.0	0.0

	Value of production (million TSH)	Value of production (%)	Sales to Medical Stores Department (% of column 2)	Exports (% of column 2)
A.A. Pharmaceuticals				
2004–2005	144	0.4	0.0	0.0
2006–2007	154	0.5	0.0	0.0
2007–2008	169	0.4	0.0	0.0
2008–2009	170	0.3	0.0	0.0
Zenufa Laboratories				
2004–2005	0	0.0	0.0	0.0
2006–2007	0	0.0	0.0	0.0
2007–2008	1,893	4.8	0.0	0.0
2008–2009	3,720	6.3	2.6	0.0
Total				
2004–2005	34,284	100.0	34.0	9.5
2006–2007	30,213	100.0	31.7	10.4
2007–2008	39,801	100.0	41.3	11.0
2008–2009	59,164	100.0	45.9	10.8

a Source: Ministry of Health and Social Welfare (2012). Strategy for Promotion of Domestic Pharmaceutical Production in Tanzania, 2013–2023. Dar es Salaam; Ministry of Health and Social Welfare (2006). Strategies for Promotion of Local Production of Pharmaceuticals in Tanzania, 2006–2016: Draft Proposal. Dar es Salaam.

Although several companies have ceased operations over the past decade, including Interchem Pharma and Tanzansino, a new company, Zenufa Laboratories, was established in 2007. This company initially functioned as an importer and distributor of products made by multinational pharmaceutical companies, but has since diversified to manufacturing through establishing a strategic collaboration with the Belgian Investment Company for Developing Countries. In 2008–2009 Zenufa Laboratories accounted for 6.3 percent of Tanzania's total pharmaceutical production (table 3), and it has since further expanded its operations. The largest pharmaceutical producer in Tanzania is Shelys Pharmaceuticals, which accounts for more than half of the total domestic pharmaceutical production (table 3). Shelys Pharmaceuticals was established in 1979 and was acquired by the Sumaria group in 1984 and subsequently by Aspen of South Africa in 2008. Shelys Pharmaceuticals is now a substantial exporter of pharmaceutical products, with operations in several African countries. In 2008–2009, it exported about 19 percent of its total production (table 3).

Although the indigenous pharmaceutical industry in Tanzania has existed for some time, the financial health and growth of the industry have been unsatisfactory.³ The local industry continues to manufacture a relatively small list of simple formulations such as antibiotics, cough and cold preparations, analgesics, antipyretics, sedatives, supplements, anthelmintics and antimalarials. The local industry does not produce intravenous fluids, injectables or more technologically sophisticated formulations.⁴

Quality control has been a key challenge faced by local manufacturers. None of the older manufacturing facilities currently meets good manufacturing practice (GMP) standards. In 2000, after an inspection by the Pharmacy Board (the predecessor of the Tanzanian Food and Drugs Authority [TFDA]), three registered manufacturing facilities were ordered to stop production.¹¹ Since then, production facilities have been upgraded, with substantial investments in a number of pharmaceutical companies, but much more needs to be done to attain GMP standards.¹² With financial assistance from the European Union and the German non-governmental organization Action Medeor, Tanzania Pharmaceutical Industries began a

project to establish a GMP-compliant manufacturing facility for antiretroviral medicines. Shelys was the first company in Tanzania to comply with World Health Organization (WHO) GMP requirements. However, at the time of its mandatory review, TFDA has yet to renew its GMP certification. Currently, only Zenufa Laboratories satisfies WHO GMP requirements in Tanzania and is about to be certified by TFDA.

Pharmaceutical manufacturers in Tanzania suffer from significant underuse of existing production capacity. For example, a study by the Tanzanian Government found that Mansoor Daya Chemicals uses only 52 percent of its capacity, Keko Pharmaceuticals, 39 percent and Shelys, 36 percent.¹² According to the manufacturers, a major reason for this underuse is the significant competition within the Tanzanian retail pharmaceutical market,¹³ which is dominated by branded products from larger, more resource-rich multinational pharmaceutical companies and generic companies from countries such as India.

Like many other developing countries, Tanzania has some inherent cost disadvantages. Investigations by the Ministry of Health and Social Welfare^{12,13} and a survey by Mwilongo¹⁴ identified the following major problems for local production of pharmaceuticals:

- Access to working capital and long-term credit has been limited, largely due to the high cost of finance in Tanzania. This has prevented most local companies from undertaking improvements in operations and expansion.
- The unreliable, insufficient supply and high cost of electricity and water not only substantially increase the operating costs but are also barriers against maximization of production capacity. The cost of electricity in the Tanzania is the highest in the Southern African Development Community region.
- The weak conditions of roads and communication services have proven to be a major challenge, often causing large delays in clearing the imports of raw materials and their delivery to manufacturers.
- The country lacks local expertise in pharmaceutical manufacturing, resulting in the need to pay higher salaries to foreign experts and skilled technical personnel. Additional costs are also incurred in training staff at different institutions inside and outside the country.
- The industry has to bear the higher costs of imported materials and machinery.

The local pharmaceutical industry in Tanzania has deteriorated over the past several years, and several large companies have closed manufacturing facilities. Shelys, which was the pioneer in Tanzania in commissioning a world-class penicillin manufacturing facility to meet WHO GMP and United States Food and Drug Administration standards, is unable to compete with imported products and remain viable. Shelys has reduced the size of its product portfolio from more than 200 products several years ago to about 50 products currently, and has begun marketing imported products, mainly from India. After Aspen took over Shelys, there was some investment in building manufacturing capacity, but this has not led to a diversification of production beyond over-the-counter preparations and simple products. However, it has initiated the process for obtaining WHO pre-qualification for zinc sulphate.

Pharmaceutical market structure in Tanzania

The pharmaceutical market can be broadly classified into the institutional market and the retail market. The institutional market is dominated by the Tanzanian Government's Medical Stores Department (MSD). The other actors in the institutional market are private hospitals and non-governmental and faith-based health care organizations. MSD is the single largest distributor of drugs in Tanzania. The institutional market comprises about half the total market: purchases of drugs by MSD in 2008–2009 (92,914 million Tanzanian shillings) constituted about 51 percent of the total market (table 1).

Medicines distributed by MSD include those procured with international donor funding, such as from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and those purchased with national resources. Donor funding plays a very important role in the health care sector in most African countries. Of the total health care expenditure of US\$1030.9 million in Tanzania in 2011, donors contributed 34.3 percent, public expenditure 39.3 percent and private expenditure 26.3 percent; 83.3 percent of private expenditure was out-of-pocket.¹⁵

Donor-funded procurement of medicines to treat HIV, tuberculosis, malaria, diarrhoea, influenza and neglected tropical diseases and for reproductive health care are made through the process of competitive bidding restricted to manufacturers with WHO pre-qualification for the products concerned. None of the products manufactured in Tanzania has achieved WHO pre-qualification. Thus, a significant segment of the medicines market in Africa is outside the reach of local manufacturers. As seen in Ghana, the market for certain diseases such as malaria was made out of reach for local manufacturers when international funding bodies such as the Affordable Medicines Facility for Malaria started procuring pre-qualified medicines manufactured in other countries.

About 71 percent of MSD purchases are sourced from foreign countries; the remaining 29 percent are from local manufacturers (table 1). The reasons for the high proportion of imported medicines are the restrictions related to pre-qualifications imposed by donors and the limited capacity and capability of local manufacturers to produce many essential technologically complex medicines.

Even if they have the capacity to produce formulations, local manufacturers are required to compete with international suppliers, although local manufacturers are given a 15 percent price preference. For companies such as Tanzania Pharmaceutical Industries and Keko Pharmaceuticals, MSD purchases account for a significant proportion of their total sales (table 3). In 2008–2009, for example, MSD procurement made up 87.1 percent and 72.3 percent of the total production output of Tanzania Pharmaceutical Industries and Keko Pharmaceuticals, respectively. For Mansoor Daya Chemicals and Zenufa Laboratories, MSD sales are insignificant. MSD does not announce the schedule of its purchases in advance, but instead buys medicines as and when it requires them; but imposes a penalty if medicines are not supplied on time. To be in a position to supply medicines on time and avoid penalties, companies need to manufacture products in advance, which requires a substantial increase in working capital. Given the low prices paid by MSD, such additional costs make sales to MSD uneconomical. Therefore, Mansoor Daya Chemicals has stopped responding to tenders from MSD.

Public procurement can be used as an important instrument to promote local production, but much more needs to be done to procure from local manufacturers.

The Tanzanian retail pharmaceutical market constitutes about 49 percent of the total market (table 1), stocked largely by generic medicines that are either produced locally or, more likely, imported. Not only patented drugs, but also prescription generics and over-the-counter formulations are sold primarily under brand names.

All medicines marketed in Tanzania are required to be registered with the TFDA. More than 50 companies supply medicines to Tanzania, each with 20 or more drugs registered. These companies include local manufacturers, foreign generic companies and multinational pharmaceutical companies. The Indian generic manufacturer Cipla has the largest number (165) of products registered in Tanzania. Other important players include GlaxoSmithKline (a multinational pharmaceutical company with 130 products registered), Shelys (a Tanzanian generic company, 99 products registered), Elys (a Kenyan generic company, 81 products registered), Remedica (a Cypriot generic company, 81 products registered) and Ranbaxy (an Indian generic company, 79 products registered) (table 4). In addition to GlaxoSmithKline, other major multinational pharmaceutical companies that market their products in Tanzania are Pfizer Pharmacia (49 products), Sanofi (40 products), Bristol-Myers Squibb (37 products) and Novartis (33 products). Multinational pharmaceutical companies' products are registered not only by the parent companies but also by their local subsidiaries in various countries. For instance, GlaxoSmithKline's products have also been registered from Kenya, Egypt and India; Pfizer's products from Italy, South Africa, Belgium and Puerto Rico; and Bristol-Myers Squibb's products from France, Italy, the United Kingdom and Puerto Rico. Of the 3388 drugs registered for sale in Tanzania in 2007, 269 products (about 8 percent) are from only eight registered manufacturers located in Tanzania.

Table 4: Major companies with pharmaceutical product registrations in Tanzania, 2007^{a,b}

Company	Countries	No. of products registered
Cipla	India	165
GlaxoSmithKline	United Kingdom, Kenya, Belgium, Egypt, India, Italy	130
Shelys	Tanzania	99
Elys	Kenya	81
Remedica	Cyprus	81
Ranbaxy	India	79
Interchem Pharma	Tanzania	70
Ipca Laboratories	India	59
Medochemie	Cyprus	54
Mansoor Daya Chemicals	Tanzania	50
Pfizer Pharmacia	Canada, Italy, Belgium, United States, Puerto Rico, South Africa	49
Regal Pharmaceuticals	Kenya	46
Aurochem Laboratories	India	44
Cosmos	Kenya	43
Panacea Biotec	India	41
Sanofi	Hungary, France, United Kingdom, Spain	40
Dr. Reddy's	India	40
Unichem Laboratories	India	40
Bristol-Myers Squibb	France, Italy, United Kingdom, Puerto Rico	37
Aurobindo	India	37
Intas Pharmaceuticals	India	37
Sun Pharmaceuticals	India	36
Lincoln Pharmaceuticals	India	36
Cadila Pharmaceuticals	India	36
Glenmark Pharmaceuticals	India	36
Laboratory & Allied	Kenya	35
Warner Lambert	South Africa	34
Wockhardt	India	34
Novartis	Switzerland, Germany	33
Medopharm	India	31
Denk Pharma	Germany	30
Shin Poong Pharm	Republic of Korea	29

Company	Countries	No. of products registered
Bayer HealthCare	Germany	28
Eli Lilly	United Kingdom, Mexico, Italy	28
Alembic	India	28
Ivee Aqua EPZ	Kenya	27
Keko Pharmaceuticals	Tanzania	26
Alpharma	United Kingdom	25
AstraZeneca	United Kingdom, United States, Sweden, Germany	25
Beta Healthcare	Kenya	24
Emcure Pharmaceuticals	India	24
Vital Healthcare	India	24
Schering-Plough	Canada, Belgium, Spain	23
Mepha Pharma	Switzerland	22
Janssen Pharmaceuticals	Belgium	21
Pharmamed	Malta	21
Unique Pharmaceutical Laboratories	India	21
Cadila Healthcare	India	21
Camden Industries	Malaysia	20
Chemical Industries Development	Egypt	20
Schering NV	Germany	20
Medreich Sterilab	India	20
Simrone Pharmaceutical Industries	India	20

- a Source: S. Chaudhuri (2008). Indian generic companies, affordability of drugs and local production in Africa with special reference to Tanzania. IKD Working Paper No. 37 (The Open University); TFDA website. Available from <http://www.tfda.or.tz>.
- b Only companies with 20 or more product registrations are included.

Multinational pharmaceutical companies

Patented pharmaceutical products produced by multinational pharmaceutical companies are often sold at relatively high prices, even post-expiration, mainly in urban areas primarily in Dar es Salaam. Accurate figures are not available regarding the share of patented drugs in the Tanzanian market, but it is estimated to be quite small.

As seen in table 2, imports of medicines from the United States, Denmark, Switzerland, Belgium, Netherlands, the United Kingdom, Japan and Germany amounted to US\$41 million in 2012, constituting a quarter of the total Tanzanian medicine imports. France is a major player in some francophone countries, such as Algeria and Tunisia, but not in Tanzania where imports from France were valued at only US\$0.6 million. To appreciate the extent of multinational involvement in the Tanzanian market, these import figures need to be adjusted by deducting imports by generic companies from developed countries and adding imports from other developing countries, but these data are not available.

Some multinational pharmaceutical companies are important players in Tanzania. Novartis and GlaxoSmithKline are among the top five companies, accounting for 10 percent and 6 percent of the market in 2010, respectively. Also in the top five are the local company Shelys (21 percent market share) and the Indian generic companies Cipla (10 percent) and Ranbaxy (8 percent). Roche, AstraZeneca and Sanofi-Aventis are also notable participants.^{10,16}

Multinational pharmaceutical companies enjoy a monopoly for patented drugs. After their patents expire, these companies continue to use the same brands and continue to charge high prices. This has helped generic manufacturers, particularly from India, which typically adopt the strategy of undercutting multinational pharmaceutical companies to enter and grow in the market for patent-expired products. Armed with lower prices and active brand promotion, Indian companies such as Cipla, Ranbaxy, Sun Pharmaceuticals, Cadila and Glenmark Pharmaceuticals have been able to dominate the market with many generic products. As a global strategy, the multinational pharmaceutical companies traditionally focused on large markets in developed countries. This situation has changed in recent years, and the multinationals have introduced lower-priced generic brands to compete in the generic pharmaceutical markets, particularly in developing countries.

Indian generic companies

India dominates the Tanzanian pharmaceutical market. India is by far the single largest source of imports, mainly of generic drugs. India also has the largest number of products registered with TFDA for sale in Tanzania. Previously, Indian companies exported their generic drugs to Africa through European companies such as Missionpharma, HELM and Troge Medical. Now, they export directly to the private retail market through local logistics partners, which are usually local importers and distributors.

Ensuring the quality of imported and locally manufactured pharmaceutical products has long been a major issue in Tanzania, largely as a result of an encumbered registration system, particularly before 1999.¹¹ To address this issue, the Tanzanian Government passed the Tanzania Food, Drugs and Cosmetics Act (2003) and soon after established TFDA in an attempt to strengthen the registration system. Quality of drugs sold in Tanzania has since improved gradually. TFDA approves products on the basis of product dossiers submitted by the manufacturers, facility inspection and laboratory tests to ensure the manufacturing facilities follow GMP safeguards and procedures. Registration is valid for only five years, after which re-registration is required. This has resulted in improved manufacturing practices of both local and foreign manufacturers and the edging out of the international traders who procured products manufactured in India on a contract basis. The problem of substandard quality of medicine still exists, however, and manufacturers with larger overheads and larger investments in GMP facilities find it very difficult to compete with less quality-conscious suppliers in the highly competitive segments of the market.

The larger reputable Indian companies active in the Tanzanian market primarily target the market where entry barriers are high and competition is lower. These companies promote their products through branding; their main competitors are the multinational pharmaceutical companies and generic companies from other countries. Indian companies often enter and grow in local markets with lower prices and partnering with one or more local importers and distributors. Some of these local importers or distributors have country managers who oversee the local operations or medical representatives to promote their products. These and other marketing costs are incurred by the companies themselves; incurred by the importers and distributors and subsequently reimbursed by the companies; or incurred by the importers and distributors and subsequently adjusted through sales commissions. Promotional literature of each product is usually provided by the company.

Cipla is currently the second largest company in the Tanzanian retail market, with a market share of 16 percent. Among the other notable Indian companies are Ranbaxy, Sun Pharmaceuticals, Unichem Laboratories, Cadila and Glenmark Pharmaceuticals.^{10,16}

Local manufacturers

The local company Shelys is the largest player in the Tanzanian retail market, with a 21 percent market share. There are few other local manufacturers. Domestic production accounted for only 32.3 percent of the market in 2008–2009, 45.9 percent of which was sold to MSD and the remaining 54.1 percent in the

retail market (table 1). In the retail market, locally-manufactured products have largely been restricted to over-the-counter formulations and simple prescription medicines. Depending on the product, local players compete against the multinational pharmaceutical companies and reputed foreign generic companies, as well as the less quality-conscious foreign suppliers that charge very low prices. Local manufacturers have been able to compete with multinational pharmaceutical companies and reputed foreign generic companies by charging much lower prices. For example, Mansoor Daya Chemicals' paracetamol and chlorphenamine cost, respectively, about a third and half the price of GlaxoSmithKline's. Local companies also compete by brand recognition. Local over-the counter brands are well known and trusted by consumers who have been using them for years. However, low-priced imported products exert significant downward pressure on the prices of local manufacturers, resulting in very low profit margins for local manufacturers.

To remain competitive and sustainable, local companies will need to diversify into the prescription drug market, which is higher on the value chain. One key barrier to entering this market, however, is the significant marketing resources and efforts required to compete against the multinational pharmaceutical companies and large Indian generic companies that currently dominate the market. Another key hurdle is obtaining the requisite financial resources and technical skills required to manufacture complex medicines to a quality level high enough for regulatory approval. The lengthy TFDA approval period may also be an impediment to market access; for example, some applications made in 2011 are still pending.

Aggregate figures suggest that Tanzania is dependent on imports. Foreign suppliers cater mainly to the urban market, while the rural market largely depend on local products.¹⁷

If local manufacturers are to improve their financial viability and play a much bigger role in the country's pharmaceutical industry, diversification beyond the over-the-counter and simple formulations is required and the essential medicines that have been, up to now, imported, will need to be manufactured locally. Currently, local manufacturers are unable to compete against the more resource-rich multinational pharmaceutical companies and generic companies, especially from India. Local manufacturers need resources, technical support and a conducive policy environment.

Drug prices in Tanzania

In the institutional market, purchases of drugs by MSD are done through international competitive bidding among eligible suppliers. In this market, the quoted price is all that matters and branding plays no part in decision-making by MSD. This results in a more level playing field for local manufacturers.

The retail market, however, is driven by branding and marketing, and many consumers are not fully aware of the varying prices and quality of all available products. Due to challenges in regulatory implementation, available medicines manufactured by different companies may not be of equal quality and efficacy. The larger, more reputed companies promote and differentiate their products through branding and have the highest profile. Doctors and consumers are often not aware of the existence of the lower-priced products that are not promoted as actively; even when they are aware of these products, doctors and consumers appear to prefer using branded products of reputed companies, which has enabled the latter to continue charging higher prices while maintaining dominant market share.

In 2004, a survey by the Tanzanian Ministry of Health and Social Welfare and WHO compared the local prices of 44 medicines with international reference prices (IRP) obtained from the price lists of large, non-profit-making generic medicine suppliers around the world.¹⁸ The multinational pharmaceutical companies continue to market drugs at very high prices, even after patents expire. For the three innovator brand products among the 44 medicines surveyed, the prices in the private retail pharmacies were 12 times, 95 times and 19 times higher than the IRP for pyrimethamine with sulfadoxine, albendazole and carbamazepine, respectively. The generic versions of these medicines were much cheaper than the innovator products, but still four times, 19 times and five times higher than the IRP. In private pharmacies, the median lowest-priced generic product was found to be three times higher than the IRP; and range between 0.4 times (for losartan) and 19 times (for albendazole) higher than the IRP. With imports accounting for about 70 percent of the market, this survey suggests that import prices are very high. The survey concluded that the majority of Tanzanians cannot afford such prices. More recent data are needed to confirm if this is still the case.

The Indian generic companies operate with similar marketing and branding strategies and structure in India and Tanzania. Information is not available for pricing comparison, but in another study, retail prices in Ghana and India were compared.¹⁹ This study shows that medicines sold in the retail market in Ghana are significantly more expensive than the same medicines sold in the retail market in India, particularly for products that are not manufactured locally in Ghana. In other words, Indian companies sell their medicines at far higher prices in Ghana than in their domestic market. Thus, lower costs of production in India do not necessarily mean lower export prices to Ghana. Depending on the market structure and the nature of competition, Indian exporters can and do enjoy substantial profit margins. Ghana and Tanzania have similar retail market structures, and the behaviour of Indian companies is unlikely to be significantly different in these two countries, and so we can assume the information from the study on Ghana is also relevant for Tanzania.

The high prices and high profit margins of imported pharmaceutical products provide an opportunity for local Tanzanian companies to enter these markets. Local companies can afford to charge lower prices and can be viable despite cost disadvantages. Such sales by local producers have, however, remained small. The biggest problem has been the unequal competition with large importers. Appropriate government policies can ensure market viability for local manufacturers. In competing with the large international companies from countries such as India, Tanzania faces additional challenges related to cost disparities, but a bigger constraint is the uncertainty of the local pharmaceutical market. Cost disadvantages of locally-manufactured products can be compensated by a larger market share, thus making manufacturing viable and profitable without sacrificing affordability.

Changes in the global pharmaceutical environment and possible implications.

Major pharmaceutical markets are located in developed countries, the largest of which is the United States, with a market size of US\$343 billion. The United States, Western Europe (US\$241.4 billion) and Japan (US\$129.5 billion) accounted for about two-thirds of the global pharmaceutical market of US\$1052.1 billion in 2012. To put this into perspective, Africa and the Middle East collectively accounted for only US\$31.7 billion (about 3 percent of the global market). Larger developing countries such as China (US\$82.1 billion), Brazil (US\$26.8 billion) and India (US\$15.7 billion) have much bigger markets compared with Africa, but are still dwarfed by the markets in many developed countries.²⁰

This disparity is changing rapidly, however, with emerging country markets expected to grow much faster than those of developed countries. It is estimated that India, China and the top 10 African countries will have a 10–12 percent compound annual growth rate between 2012 and 2018, whereas major developed country markets will remain stagnant (Japan and United Kingdom), increase only marginally (United States) or decline marginally (Germany and France). The key factors driving this growth in Africa include increasing political stability, rapid economic development, increasing investment in public health, maturing regulatory environment, and rising consumerism due to growth of urbanization and the middle class.^{7,21}

Response of multinational pharmaceutical companies to the changing global pharmaceutical market

As a result of the growing purchasing power of African countries, multinational pharmaceutical companies are altering their approach to African pharmaceutical markets. Traditionally, due to colonial or other links, some multinational pharmaceutical companies (e.g. GlaxoSmithKline, formerly Glaxo) had offices in several African countries. But as the companies started to focus on the larger, more lucrative developed country markets, they began to downsize their coverage of the African market, particularly in smaller countries, and to transition much of their distribution to local importers and distributors.

More recently, multinational pharmaceutical companies have returned to the African continent as a result of the anticipated market growth, coupled with declining research and development productivity and a smaller pipeline of new patented drugs that can be sold in developed country markets.

The multinational pharmaceutical companies have rejuvenated their country operations in Africa, while markedly increasing investment in marketing and brand promotion. To increase sales, they have started to offer credit facilities to retailers. They have also improved their distribution networks, using specialized supply chain management services such as those offered by Imperial Health Services, with operations in Ghana, Kenya, Malawi, Nigeria and South Africa, where medicines are received, stored and distributed in countries across Africa.

Many companies continue to market their products under the same brands after patent expiration and continue to charge very high prices; as a result, they lose market share to companies from countries such as India, which sell generic products at much lower prices. The multinational pharmaceutical companies are now increasingly trying to make their presence felt in the generics market without diluting their innovator branded products. There is brand loyalty associated with innovator products and there is a price-insensitive segment where multinational pharmaceutical companies continue to achieve good sales volumes, despite high prices and despite the availability of competing cheaper generic products. To enlarge their market, companies are introducing new brands and selling these branded products at significantly lower prices than their innovator brands, enabling them to have a presence in both the price-insensitive and price-sensitive (generic) segments of the market.

The most active multinational pharmaceutical company in obtaining a foothold in the generics market is GlaxoSmithKline. The innovator brand for the anthelmintic drug albendazole is Zentel, but GlaxoSmithKline has introduced a new generic brand for the same product named Alzental. Another example is the antibiotic co-amoxiclav, which GlaxoSmithKline sells at a high price as the innovator brand Augmentin. GlaxoSmithKline also sells co-amoxiclav at a lower price under a different brand, Clavulin, to compete against similarly named generic brands such as Clavam, which is produced by India's generic company Alkem. These multinational pharmaceutical generic brands are priced significantly below the innovator price, often discounted at 50 percent or more. Even though these generic branded products are still priced above other generics, multinational pharmaceutical companies can rely on their reputation and perception of higher quality for increased share in the generics market, reducing the space for local generic manufacturers.

Now that multinational pharmaceutical companies have started to compete on price, the matter of production costs has become important. The companies are starting to manufacture their generically branded products in cheaper locations, particularly India. GlaxoSmithKline, AstraZeneca and Abbott have entered into supply agreements with Indian companies such as Dr. Reddy's, Aurobindo, Cadila and Torrent. Dr. Reddy's, for example, will produce about a hundred different types of branded formulations for GlaxoSmithKline to supply various emerging markets, including in Africa.

These deals enable multinational pharmaceutical companies to get access to low-cost, high-quality, reliable products without undergoing the lengthy process of getting regulatory approvals in different markets and without incurring any capital expenditure for setting up manufacturing facilities. The Indian companies also benefit from this arrangement as they have access to the formidable marketing resources of the multinationals.²² All evidence suggests, however, that the multinationals are unlikely to start manufacturing in Africa in any significant scale, at least in the near future, and are far more likely to invest in bigger emerging markets such as India.

Response of Indian generic companies to the changing global pharmaceutical market

Indian generic companies are already important in the African pharmaceutical markets. It is clear that Indian companies will continue to play a very active role in Africa, particularly in the light of the anticipated growth in Africa. The composition of Indian generic companies, however, is changing in Africa. With improvements in the regulatory environment in Africa, Indian companies without stringent quality assurance practices are finding it increasingly difficult to maintain market share. In contrast, larger Indian

companies are focusing more attention and investment in growing their presence in the African generics market, driven largely by the potential market growth in the region, but also partly by the disappointing returns from the highly-competitive patent-expired sector in large markets such as the United States. Even though the gains in the value-added segments are still substantial, the declining research and development productivity and a reduced flow of new patented drugs have resulted in aggressive entry of multinational pharmaceutical companies into the generics market and crowding out of Indian companies.

If the Indian companies, in particular the smaller Indian companies, set up manufacturing facilities in Africa, this will be a positive direction from the perspective of the African pharmaceutical industry, because Africa can benefit from the technological, managerial, entrepreneurial and marketing resources of the Indian pharmaceutical industry.

A few Indian companies have established a manufacturing base in some African countries, for example Cadila in Ethiopia and Cipla in Uganda. The question is whether the Indian companies in general are likely to be involved at any significant scale in investing in Africa. The indications are that Indian companies still do not find Africa commercially attractive to undertake direct investments for manufacturing.

To understand the behaviour of Indian (and other foreign) companies, it is important to note that most African countries do not have policy measures in place to pressure foreign companies in establishing local manufacturing facilities. For instance, Ghana has put in place restrictions relating to payment of import duties and a restricted import list, but countries such as the Tanzania do not restrict the importation of medicines, making it easy and cheap for foreign companies to import without the need to establish a local facility in Tanzania. Although they are more technologically advanced, Indian companies experience similar challenges to those faced by their African counterparts, including high finance costs, poor infrastructure, high costs of power and other utilities, lack of skilled labour and inadequate support industries. Exporting is also much less risky as it does not require any long-term commitment. Therefore, there is no significant incentive for Indian companies to relocate their manufacturing to Africa.

If African governments were to strengthen their policies to further limit the access of foreign companies to the domestic market, Indian companies would lose much of their market access unless they undertake investments in domestic markets in Africa. Whether Indian companies are likely to invest under these circumstances is unclear. If smaller countries in Africa combine their markets through free trade or other arrangements, the size of the market will be attractive enough and investments from India are not unlikely. Provision of funds at a reasonable rate of interest and some guarantee for the safety of investments will increase the likelihood of Indian companies undertaking investments abroad.

Industrial policy to promote local production

The challenges that Tanzania is facing are not unusual for a country trying to develop an industry. These challenges include high costs of production, deficiency of technical knowledge, difficulty of competing against more resource-rich foreign companies and dependence on imports. Another critical issue is the scarce availability of financing. Commercial sources often neglect industries and companies that are currently facing financial difficulties, even if there is potential to succeed. Local private entrepreneurs are unwilling or unable to invest in developing the nascent industry. Hence, as has been demonstrated in the past, the roles of government and foreign enterprises are critical to industrial development.

Industrial policy in the Indian pharmaceutical industry

A comparison with India is not inappropriate at this stage, given the fact that India is the largest source of drug imports into Tanzania and the Tanzanian pharmaceutical market is dominated by Indian companies.

After independence in 1947, India invited multinational pharmaceutical companies to invest in establishing manufacturing facilities in the country as part of developing a local pharmaceutical industry. Like Tanzania today, India then was dependent on imports and foreign enterprises dominated the market. India's plan was to leverage foreign direct investment to develop its industries. This plan was strategically sound as foreign enterprises had the technological and financial resources. However, the response of

multinational pharmaceutical companies was poor. They were reluctant to invest in building manufacturing capacities and structures in India and preferred the reliance on imports to serve the market. This is similar to the reluctance by multinational and Indian pharmaceutical companies to invest in Africa today. It was largely as the result of such reluctance, that the Indian Government decided not only to undertake such production in the public sector, but also to initiate several other steps with the specific objective of supporting the indigenous sector and developing the industry.²³

The public sector company set up by the Indian Government, in collaboration with the former Soviet Union, had a tremendous impact in generating technical knowledge required for the pharmaceutical industry. Indian technicians were actively involved in setting up the facility together with technicians from the Soviet Union. This led to technological absorption and diffusion that otherwise may not have taken place. Another major initiative of the Indian Government was to set up a number of public sector research laboratories. These contributed significantly to the development of the industry by collaborating with the private sector. Another important factor was the role played by the state development financial institutes: term loans were provided to entrepreneurs at low rates of interest, and no separate collateral was required – the facility itself as collateral was sufficient. Most of the Indian companies that are now global enterprises started as small-scale units. For example, the promoter of Dr. Reddy's learned his technical skills while working at the public sector facility; when he set up his own company, funds were provided by the public sector financial institute at a low interest rate.²³

Industrial policy in the Tanzanian pharmaceutical industry

In the Tanzanian pharmaceutical industry, the public sector played an important role. Two public sector companies were among the first to be set up in the country. These companies remained small and did not have the impact that the much larger public sector company had in India. The companies were eventually privatized, with the Tanzanian Government holding 40 percent equity. However, with cessation of funding from the government and minimal action taken to revitalize and expand their operations, one of these companies have since closed.

The Tanzanian Government has a critical role to play in revitalizing pharmaceutical research and development. An important initiative was the establishment of a pharmaceutical research and development laboratory in 2007 in the School of Pharmacy, Muhimbili University of Health and Allied Sciences in Dar es Salaam. This was funded by the German organizations GIZ (formerly GTZ) (55 percent) and Action Medeor (30 percent). The remaining 15 percent was contributed by Muhimbili University of Health and Allied Sciences in the form of salaries for the laboratory personnel. The basic aim was to build pharmaceutical research and development capability in the country. The specific objectives included imparting training to pharmacy professionals and technicians and offering research and development services to industry, including development of formulations. The German partners funded the purchase of equipment and other infrastructural facilities and visits by foreign technical experts. The laboratory delivered training programmes that were attended by participants not only from Tanzania, but also from other eastern African countries. Substantial progress was made in developing several antiretroviral formulations. Since the end of the project and cessation of foreign funding, and due to the lack of commitment of funds from the Tanzanian Government, however, the laboratory has remained inactive. The anticipated revenue from industry did not materialize as the industry was unable or unwilling to pay for the research and development services provided by the laboratory.

The Tanzanian pharmaceutical industry was initiated mainly through local efforts. With the takeover of Shelys by Aspen, there is now a foreign-owned local manufacturer in Tanzania. This generated much expectation because Aspen has the technological and financial resources to contribute to the expansion of the local industry. However, these expectations have not materialized. The decision by a foreign company to invest locally depends on its corporate objectives and the options it has in different countries. If the activities of Shelys in recent years are any guide, Aspen is not yet willing to commit to any significant manufacturing investments in the country. As illustrated above, other foreign enterprises, both from developed countries and from developing countries such as India, are unlikely to begin investing in establishing manufacturing operations in Tanzania in the immediate future.

If the indigenous pharmaceutical industry is to grow in Tanzania, it will need to rely heavily on efforts by local actors, particularly the Tanzanian Government and the local private sector. To its credit, the

Tanzanian Government acknowledges the importance of local production of pharmaceuticals and the need to support its growth. The Tanzanian Government has declared more than once – in the National Drug Policy (1991) and in the National Medicine Policy (2008) – that promoting local production is an important strategy to satisfy the objective of universal access of essential medicines in the country. A recent governmental study pointed out that the “lack of clear incentives and policies that promote local pharmaceutical production” has been one of the key policy gaps in Tanzania.¹²

One survey shows local manufacturers have indicated that they want additional support from the Tanzanian Government in implementing policies and initiatives to boost local production.¹⁴ Although the Tanzanian Government has rolled back the 10 percent import duty tax on formulations (except for antiretroviral medicines, antimalarial medicines, anti-TB medicines and MSD imports), it has imposed a 9.9 percent VAT on raw materials. The VAT is refundable, but the refund process often takes some time and with interest rates at nearly 20 percent, this results in a substantial financial burden. Similarly, for packaging materials, the manufacturers need to first pay the 18 percent VAT and then claim refunds.

The 15 percent price preference offered by MSD seems to be the only incentive provided to local manufacturers. In an industry where local companies do not have the capacity to manufacture many of the essential medicines sought by the MSD, however, this incentive has often not been realized. Moreover, even for products manufactured by local companies, the advantage provided by the 15 percent price preference is easily negated by marginal cost pricing offered by some large importers. Africa is not the main market for the large Indian generic companies, but because of the economies of scale, it is possible for these companies with large production outputs to quote a price below their full cost of production. Given the production capacities already installed, they are still able to be profitable when they sell at low prices, provided variable costs are sufficiently covered.

With support from international agencies, the Tanzanian Government has made significant investments in strengthening the structures and processes of TFDA and MSD. TFDA, in particular, has undergone a radical transformation, with enhancement of technical capacity and the opening of a new office building, and its storage and distribution facilities have been upgraded. The Tanzanian Government needs to be actively involved if the country is to develop a vibrant pharmaceutical industry. What is required is a proper industrial strategy. It is clear that the Tanzanian Government is committed to providing the needed funds to ensure these institutions are fully functional.

Recommended policies for promoting local industry

If the local pharmaceutical production is to expand and significantly improve its share of the market, it is critical for the Tanzanian Government to be actively involved in addressing the barriers identified in this paper. As a priority, policies need to be put in place to improve the access to finance, technology and the market.

Finance

Funds are required to expand the growth of companies. Under the current conditions in which they operate, local companies are not able to generate large enough profits to be adequately reinvested in the company. Foreign investment has not been a feasible option, as multinational pharmaceutical companies and Indian generic companies are evidently not willing to commit as yet. Even in the case of Shelys, which is now a subsidiary of the foreign company Aspen, investments remain tardy. Thus, domestic sources of funding provide the only plausible solution. However, commercial banks in Tanzania charge interest rates of nearly 20 percent per annum on loans, which is not a viable option for most companies. A significant amount of capital is needed to set up GMP-compliant manufacturing facilities, develop products that meet regulatory standards, and market these products. The companies that were interviewed for this paper have highlighted the significant challenge in accessing investment funding. The companies do not want subsidies, but request equitable access to financing at interest rates that are comparable to the rates paid

by their main competitors in India. It should be noted that in India at the time of writing, the interest rates on loans is less than half of that in Tanzania.

Access to cheaper credit is unlikely to be possible from commercial sources in the Tanzania. Hence, if any serious effort is to be made for the growth of the industry, cheaper credit may have to be provided directly by the Tanzanian Government. Tanzania may wish to learn from the approach taken by Ghana, where a scheme has begun for majority-owned local enterprises to access loans with an interest rate of only 12.5 percent specifically for upgrading manufacturing facilities.

Technology

When pharmaceutical manufacturing started in Tanzania, technical requirements were simpler and the transfer of technology was often arranged through informal channels. The promoter of Mansoor Daya Chemicals is himself a pharmacist and used his knowledge and professional network to establish a small-scale manufacturing facility. But the technological requirements and production standards in recent years have changed substantially and technology transfer has become more difficult. If local manufacturing in Tanzania is to be strengthened, the availability of and access to technical knowledge and expertise need to substantially improve.

Manufacturing facilities need to be compliant with WHO GMP, which comprises a set of safeguards and procedures at each stage of the production process to ensure that the manufactured product is effective and safe. All aspects of the production process are covered by GMP, including the starting materials, premises, equipment, and training and personal hygiene of workers. Detailed written procedures and documentation of implementation and practice are crucial aspects as they monitor whether GMP is being followed consistently at every stage of the manufacturing process. Quality control and assurance are required, not only for producing the final products but also for the processing of raw materials and products at different stages of the production chain.

To set up a GMP-compliant facility, significant additional costs, particularly fixed costs, will be incurred. Costs include maintaining hygiene in the factory building and premises and avoiding risks of contamination; installing a proper heating, ventilation and air-conditioning system to maintain the necessary conditions, including temperature, humidity and air quality; installing equipment that is properly designed with the right materials; setting up an in-house quality-control laboratory staffed by qualified personnel, with separate areas for chemical, instrumentation, biological and microbiological testing; keeping documentation as per specified; and strictly following cleaning procedures when equipment is used for more than one material.

In the past, the regulatory authorities of many developing countries, including Tanzania, did not insist on GMP compliance, but now many countries have started to impose different variants of GMP compliance. Ghana is trying to impose WHO GMP compliance, which is stricter than India's GMP (Schedule M). Donors such as the Global Fund insist on even stricter standards, such as WHO pre-qualification. The requirements of different GMP standards vary with respect to factors such as the heating, ventilation and air-conditioning system and the quality of filtered air.

In addition to GMP compliance, manufactured products need to be approved for marketing by TFDA. Companies are required to undertake various studies (e.g. bioequivalence studies) and to generate data and submit dossiers. Marketing approval is granted after various types of review by TFDA, including chemistry review, bioequivalence review and facility inspection. As in the case of GMP, these requirements vary in different countries.

The technical knowledge required to set up and run GMP-compliant manufacturing facilities and to develop products that meet regulatory requirements for marketing are almost non-existent in Tanzania and other African countries. It is vital that such a resource is made accessible if the domestic industry is to develop.

A potential source of such technical knowledge is India. There are numerous individuals with the requisite knowledge and skills, most of whom are currently employed by pharmaceutical companies or consultancy companies, and are ready and willing to provide technical support to a recipient country. The

example of China is relevant in this case. Much like India, China has a well-developed and sophisticated pharmaceutical industry. So far as drug intermediates and large-volume active pharmaceutical ingredients are concerned, China is much more advanced than India. One area where India has been more successful in is the exportation of finished formulations to highly regulated countries such as the United States. India has developed significant expertise in setting up facilities conforming to United States Food and Drug Administration standards and getting the products approved for marketing in the United States. To address this deficiency, China began to import technical support from India. Chinese companies have not sought help from Indian companies, however, as it is not in the interests of Indian companies to provide such support to their key competitors; but instead, they have recruited technically skilled Indians with the relevant qualifications and experience to provide this support. Therefore, it is possible to use such a resource in India by exploiting 'pull factors' (opportunity to work in a foreign country, higher salary, etc.) and 'push factors' (dissatisfaction with the present role, personal reasons, etc.) for the individual, resulting in a mutually beneficial arrangement between the technical support provider and the recipient.

African countries may follow a similar strategy to China in mobilizing technical support from India. An attempt can be made to narrow the technological gap, not necessarily through formal technology transfer arrangements but through informal channels of importing technical human resources. This is already the case for some African companies. For instance, Zenufa Laboratories, a Tanzanian company, has been using the services of Indian technical experts to upgrade its manufacturing facilities to meet GMP standards and preparing dossiers for marketing approvals. The CEO of Zenufa Laboratories was originally from India and has established links in India, but other companies may not have such links to the appropriate individuals. Small pharmaceutical companies in Tanzania and other countries may not be able to do what the more resource-rich Chinese enterprises can do. Therefore, the Tanzanian Government and international agencies involved in promoting local production in Africa have a critical role to play in providing the necessary support to facilitate the transfer of technical knowledge and investment.

Furthermore, the Tanzanian Government has a leading role to play in strengthening its bioequivalence facilities and testing and quality-control laboratories, and in incorporating best practices into established mechanisms. Additional fixed capital investment may be required for infrastructure, equipment, furniture and fixtures, and staff expenses for quality-control laboratories. This additional expenditure is not only large but also independent of the volume of production. If common quality-control facilities can be created, unit costs will go down as local production output increases.

Market

In promoting local production of pharmaceuticals, perhaps the most important issue relates to the cost of production. It is widely believed that due to higher costs, the Tanzanian people will not gain the benefits, nor will the local industry be able to sustain itself. This argument against local production is based on two questionable assumptions: that higher production costs necessarily lead to higher domestic prices, and that import prices are invariably lower than domestic prices.

As discussed above, import prices are not necessarily cheap. In the branded prescription drugs market, multinational pharmaceutical companies and Indian generic companies enjoy substantial profit margins. In the import-dependent retail market in Tanzania, local prices are very high relative to IRP, particularly for medicines sold by multinational pharmaceutical companies. If local manufacturers are able to enter these markets, they can be very competitive by charging a price lower than that of imported medicines, while still generating profits and remaining viable despite relatively higher production costs. These prices may still be relatively high compared with the paying capacity of consumers in Tanzania, but local production can at least result in medicines that are more affordable compared with higher-priced imports. If finance and technology can be made available and mobilized, and a market can be assured, then local production can be viable and will contribute to improvement in the affordability, accessibility and overall health outcomes of Tanzanians.

A key concern is the viability of local manufacturers in the highly competitive segments of the markets. Local manufacturers have relatively higher production costs but need to charge a low price to remain competitive. If the sale price is so low that the cost of production is barely covered, then local production will not be viable.

To determine if this is indeed the case, we need to know the actual production cost and price structure. Again, it should be noted that the price of imported medicines are not necessarily that low – it could be higher than the cost of domestic production. When competing with foreign companies with relatively smaller production costs, the profit margin per unit of production of local manufacturers will need to be lower. The lower profit margin can be compensated by a larger production and sale volume, which will generate the level of profits necessary for local production to be viable. But how large a market is required to make local production viable and sustainable? The answer depends on how large the cost disadvantages are and how low the import prices are. This should not be a matter of opinion but one of concrete analysis. But such empirical analysis is conspicuous by its absence in the literature. In the absence of empirical investigations, what is implicitly assumed is that the market size required to make local production viable is beyond the reach of small developing countries.

An attempt has been made to fill this analytical gap in the literature.¹⁹ In African countries with under-developed pharmaceutical industries, it is very difficult to obtain relevant data, with reliable data on costs completely unavailable. It is important to not only manufacture medicines, but to do so at an acceptable standard of quality. Most African countries are yet to enforce GMP compliance, and thus existing cost data relating to non-GMP-compliant facilities cannot be used for the purpose of analysing issues relating to promoting local production of medicines with good quality. To circumvent this problem, we attempted a simulation exercise. India has revised Schedule M of its Drugs and Cosmetics Act (1940) to implement GMP. We started from India and simulated the situation in Africa by making necessary adjustments based on cost and other differences. We consider Ghana as the representative small import-dependent African country. The results are broadly valid for other African countries, including Tanzania, with similar cost structures. As a source of information and insights, the paper relied heavily on interviews conducted in India and Ghana. In India, we focused on a Mumbai-based formulations manufacturing company compliant with Schedule M, which was willing to share its cost and technical data (table 5).

Table 5: Viability and profitability of tablet manufacturing in India and Ghana, 2012^a

	India ^b	Ghana: scenario 1 ^c	Ghana: scenario 2 ^d
Total sales revenue (million rupees)	197	271	362
Total sales revenue (million Ghanaian cedi)	7	9	13
Total variable costs (million rupees)	124	161	238
Total fixed costs (million rupees)	42	68	68
Total quantity produced and sold (million tablets)	152	209	405
Breakeven quantity (million tablets)	89	130	224
Total profits (million rupees)	30	41	55
Profit margin (%)	15.3	15.2	15.3

a Source: Chaudhuri S. and A. West (2014). Can local producers compete with low-cost imports? A simulation study of pharmaceutical industry in low-income Africa. *Innovation and Development*, vol. 5, No. 1, pp. 1–16.

b Indian costs and Indian cheapest brand prices.

c Higher Ghanaian costs and Indian cheapest brand prices.

d Higher Ghanaian costs and median IRP and no sales promotion costs.

We assumed that the Indian facility manufactures five types of tablet with different active pharmaceutical ingredients, strengths and sales prices: amlodipine 2.5 mg, ofloxacin 200 mg, ciprofloxacin 500 mg, amlodipine 5 mg and metformin 500 mg. It is estimated that about 30 percent of the quantity manufactured is for the costliest products, ofloxacin and ciprofloxacin; 30 percent for the cheapest product, amlodipine 2.5 mg; and the remaining 40 percent for products priced in between. The prices

we used are the net sale value of the cheapest brand among the important brands in the domestic formulations market in India (those with market share of 1 percent or above). The analysis showed that with sales of 197 million rupees and a quantity manufactured of 152 million tablets, the Indian company earns a profit margin of 15.3 percent (table 5, column 2). Thus, it is assumed that a 15 percent profit margin is adequate to maintain operations of this company, but most companies in India operate on a lower profit margin.

Starting with an analysis of the Indian situation and basing our calculations on the cost and other differences, we simulated the cost structure in Ghana. The material costs are estimated to be 30 percent higher in Ghana, machinery costs 15 percent higher, factory building construction costs 35 percent higher, and power and fuel costs 50 percent higher. Given the cost disadvantages, profitability will be lower in Ghana if the volume of tablets manufactured is the same: the profit margin will be 5.7 percent compared with 15.3 percent in India. One of the ways to compensate for the cost disadvantage is to charge higher prices, but this would negatively impact on affordability and access to medicines, a concern highlighted by critics of local production in Africa. But prices do not need to be higher to ensure viability and profitability. As table 5 (column 3) illustrates, the Ghanaian facility can enjoy the same profit margin as that of the Indian company, not by charging higher prices, but by increasing the quantity manufactured to 209 million tablets and sales of 271 million rupees (9 million Ghanaian cedi).

If the Ghanaian manufacturer were to charge the IRP, then the market size would need to be even larger. In the market segments from where we have obtained IRPs, brand names do not play a critical role; and in procurement by government agencies through competitive bidding, brands do not play any role at all. If we exclude sales promotion expenses (but continue to include distribution and other marketing costs), and if Ghanaian manufacturers charge the IRP, the production level needs to reach 405 million tablets with sales of 362 million rupees (13 million Ghanaian cedi) for a 15 percent profit margin (table 5, column 4). It should be noted that this analysis assumes a 15 percent profit margin as adequate for the sustainable operations of the company, but most pharmaceutical companies in India operate on a lower profit margin. Therefore, it is possible that the minimum required volume of production for viable operation is lower than 405 million tablets.

Despite Ghana having much higher production costs than India, it is possible for Ghanaian companies to sell at lower prices (eg. IRP level) and still be viable and profitable if the required market is ensured. The production level of about 400 million tablets is a relatively low volume. In Tanzania, Mansoor Daya Chemicals already has the capacity. Keko Pharmaceuticals, Shelys and Zenufa Laboratories have much higher capacities. Manufacturing capacities are grossly underused, however, and local manufacturers are largely restricted to production of over-the-counter medicines. If access to finance and technology can be arranged to upgrade facilities and skills, and a market can be assured, then local production can be viable, and will contribute to better affordability and accessibility of medicines.

Ensuring a larger market for local manufacturers

The pharmaceutical market is distributed almost equally between the institutional market (51 percent) and the retail market (49 percent).

Retail market

In the Tanzanian retail market, the local companies mainly market over-the-counter and simple formulations. The branded prescription market is dominated by multinational pharmaceutical companies and generic companies from India. Competing against the more resource-rich foreign companies is difficult. Even if the local companies were to charge lower prices, the foreign companies may continue to dominate in these branded markets. Thus, it is not enough to provide financial and technical assistance in production; strategies also need to be put in place to improve the certainty and accessibility of the market. Without this, the necessary private investment to promote the local industry may not be forthcoming.

Countries traditionally use import protection to ensure a larger market for local manufacturers. Import protection usually takes two forms – indirect (reduce the volume of imports by imposing import duties, thus increasing the cost of importation) and direct (import bans of selected products). In several countries in Africa, the local pharmaceutical industry is protected, at least to some extent. Ghana, for example, has an import duty of 10 percent on finished formulations. Tanzania introduced such an import duty, but this

has been rolled back. Ghana also bans the importation of 14 widely used products (including ampicillin, tetracycline, chlorthalidone, indometacin, paracetamol, aspirin and diazepam). Several other African countries, such as Nigeria, have similar negative import lists. A Tanzanian Government report proposed such a list of regulated imported products as part of the strategy to promote local production,¹³ but this has never been implemented. Apart from a 15 percent price preference for MSD purchases, the local Tanzanian industry enjoys no other advantage. Discussions among policymakers, local manufacturers and other stakeholders are needed to confront this issue and take action to promote the market share of local manufacturers.

Typical arguments against implementing import duties or bans on pharmaceuticals include the concern that if local production capacity cannot replace imports or meet local demand, shortages will develop, resulting in increased prices of and reduced access to medicines. These are legitimate concerns, but they are not insurmountable. Simply banning imports may not have the desired effect. Ensuring a larger market for local manufacturers must be part of a coordinated strategy to avoid the pitfalls.

The Tanzanian Government may need to identify a list of imported products which will be banned if capacities for domestic production are adequately developed. The products may be chosen carefully to reflect not only the essentiality of medicines but also the current capacities of local companies in developing these products. As part of a coordinated plan of action, the Tanzanian Government may provide support to allow manufacturing facilities to upgrade to GMP standards and also to help develop the products to qualify for regulatory approvals. Once adequate local capacities are developed, the Tanzanian Government may consider imposing a ban on the relevant imports because, by this stage, the likelihood of supply shortages will be reduced. Moreover, as is currently the case in the over-the-counter market, competition among local companies has kept prices low. Therefore, it is important to generate a good level of competition among local manufacturers before banning imports to ensure prices are kept low. The Tanzanian Government may establish a watchdog mechanism to monitor prices and, if necessary, introduce ceiling prices.

The bargaining power of insurance agencies can be used to enlarge the market for local manufacturers. Several insurance schemes currently exist in Tanzania – the National Health Insurance Fund, the National Social Security Fund, the Community Health Fund and the Private Insurance Scheme. However, coverage of these schemes is still very low.²⁴ The National Health Insurance Fund is potentially the most important of these: Tanzanian Government organizations have to provide coverage for all their staff, and the Fund also aims to widen the membership base by bringing in private members.

About 50 percent of the current National Health Insurance Fund is spent on reimbursement of medicines purchased mainly from retail outlets. The Fund conducts market surveys and adds a 30 percent retail margin on the median wholesale price that is fixed for reimbursement. The Fund may also assess the capacities of local manufacturers and, where adequate capacities exist, reimbursement may be restricted to locally manufactured products. In this way, shortages will not develop and prices will not increase, since the prices to be reimbursed are fixed by the Fund.

Institutional market

About 71 percent of MSD purchases come from abroad. The only advantage offered to local manufacturers is the 15 percent price preference, which does not provide much of an advantage as foreign manufacturers are still able to remain price-competitive. As specified in the Public Procurement Act (2011) and the Procurement Regulations (2013), MSD is able to procure medicines through international competitive tendering and national competitive tendering.

When the tender value is 1000 million TSH or less, the payment is made in TSH, and if some conditions such as “the goods, works or services are available locally at prices below the international market” are satisfied, national tendering is applicable. Such tendering, however, is not restricted to local manufacturers or suppliers – anyone can respond to tenders advertised in Tanzania.

To promote the growth of the pharmaceutical industry, the MSD may consider imposing a two-stage tendering process – technical evaluation followed by a financial bid. At the first stage of technical evaluation, only local manufacturers compliant with WHO GMP and has the manufacturing capacity to satisfy the procurement requirements may be eligible. Manufacturers that pass the technical evaluation are then invited to submit a financial bid. Based on IRP, the maximum purchase price may be specified. This will ensure a larger market for local manufacturers without compromising on price. If no local manufacturer passes the technical evaluation stage, then MSD may opt for international tendering.

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