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 Ghana

Empowered lives.
Resilient nations.

From the People of Japan

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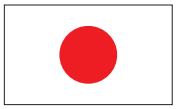

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About the Access and Delivery Partnership

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 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.

Contents


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List of abbreviations

Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
CIMS	Current Index of Medical Sciences
GMP	good manufacturing practice
HIV	Human
INR	Indian Rupee
IRP	international reference price
TB	Tuberculosis
UNDP	United Nations Development Programme
VAT	value-added tax
WHO	World Health Organization

List of tables

Executive summary

This paper assesses the key barriers to growth of the local pharmaceutical industry, and aims to highlight the opportunities to promote viable production of pharmaceuticals in Ghana.

Ghana has a population of 26 million and a per-capita gross national income (purchasing power parity) of US$ 3540 in 2012. Ghana is highly dependent on imported sources for the supply of essential medicines. In 2012, Ghana imported formulations worth US$ 125.7 million, which makes up 70% of the pharmaceutical market.

There are currently 38 pharmaceutical manufacturing units in Ghana, of which about 20 are actively involved in manufacturing formulations. These local manufacturers experience major challenges, including higher costs of production and absence of manufacturing facilities compliant with World Health Organization (WHO) good manufacturing practice (GMP). Factors resulting in the relatively higher cost of production in Ghana include the inflated costs of raw materials, utilities, transportation, equipment maintenance, financing and technical capacity.

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 Ghanaian government to be actively involved in addressing the barriers identified in this paper, by implementing industrial 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 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. In Ghana, the Export Trade, Agricultural & Industrial Development Fund has been established for majority-owned local enterprises to access loans from the government specifically for upgrading their manufacturing facilities to WHO GMP standards, 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 WHO prequalification, when procuring medicines; and many countries, including Ghana, are now starting to impose different variants of GMP compliance to ensure the manufactured product is effective and safe. The Ghanaian government 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. In fact, Ghana is the first country in which the African Union's Pharmaceutical Manufacturing Plan for Africa is being implemented, and has received technical support and capacity building from developed countries in upgrading local manufacturing to WHO GMP standards. A potential on-going source of 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 Food and Drugs Authority of Ghana is also playing an important role in strengthening bioequivalence facilities and testing and quality-control laboratories, and in incorporating best practices. However, the Ghanaian government will need to commit funds for this vital activity to stimulate the diversification into higher value-added products manufactured by local producers.

Market

In the import-dependent retail market in Ghana, local prices compared with IRP are very high, particularly for medicines sold by multinational pharmaceutical companies. 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.

To improve the competitiveness and improve the accessibility to market of local producers, Ghana has implemented a negative import list and enforced import duties and value-added tax on imported finished formulations, while providing a 15 percent price preference for local manufacturers in public procurement. The Ghanaian government may also establish a watchdog mechanism to monitor prices and, if necessary, introduce ceiling sale prices. It may also be possible to use the bargaining power of the National Health Insurance Agency 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.

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. It is critical to ensure adequate access to market for the viability of the local industry.

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.

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 Ghana's citizens.

The context

As in most countries in Africa, Ghana is dependent on foreign sources for the supply of essential medicines required for the Ghanaian people. Efforts to promote local production of pharmaceuticals are often questioned, particularly by health policymakers, 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] In this paper, we argue that it is possible to promote a viable local industry without sacrificing affordability and accessibility of medicines. We focus on Ghana, 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 26 million, Ghana is one of the smaller developing countries, with a gross national income (purchasing power parity) of US$ 89.8 billion and a per-capita gross national income of US$ 3540 in 2012, which ranks Ghana at 140 out of the 185 countries listed by the World Bank.[9]

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Pharmaceutical industry in Ghana

The pharmaceutical industry in Ghana has been in existence for some time. One of the largest manufacturers, Ayrton Drug Manufacturing, was set up in 1969. There are currently 38 pharmaceutical manufacturing units in Ghana, of which about 20 are actively involved in manufacturing formulations. The country remains dependent on imports, however. About 70% of the market is still supplied by foreign manufacturers.

In 2012 Ghana imported formulations worth US$ 125.7 million from 60 countries. Just 13 countries accounted for 92.1% of total imports. India is the largest source, with a share of 42.7% of total imports, followed by Belgium (10.7%), Switzerland (7.2%), the United Kingdom of Great Britain and Northern Ireland (6.8%), China (6.8%), Germany (4.5%) and Slovenia (4.2%). France, South Africa, Denmark, Sweden, the Netherlands and Egypt contribute between 1% and 4% each to total imports (Table 1).

Table 1: Formulations imports into Ghana, 2012[a]

	Imports (US$ million)	% of total
India	53.6	42.7
Belgium	13.4	10.7
Switzerland	9.0	7.2
United Kingdom	8.5	6.8
China	8.5	6.8
Germany	5.6	4.5
Slovenia	4.2	3.4
France	3.9	3.1
South Africa	3.8	3.0
Denmark	2.1	1.7
Sweden	1.8	1.4
Netherlands	1.8	1.4
Egypt	1.4	1.1
47 other countries	7.9	6.3
Total (60 countries)	125.50	100.1

a Calculated from the United Nations COMTRADE database.

Local pharmaceutical manufacturers in Ghana, as in most other African countries, experience major challenges, including higher costs of production and absence of manufacturing facilities compliant with World Health Organization (WHO) good manufacturing practice (GMP).

The following are among the major reasons why production costs are higher for pharmaceutical manufacturers in Ghana compared with foreign pharmaceutical manufacturers:

- lack of technically qualified people;
- higher unit costs of raw materials due to purchasing in smaller amounts and higher transportation costs;
- requirement for higher inventories of materials and spare parts due to difficulties arranging supplies at short notice;

- higher costs of imported machinery;
- higher interest charges on loans;
- higher electricity and other utility charges.

The small scale on which most African local producers operate means they have higher unit costs of production. Firms with large manufacturing plants and production runs that serve bigger markets are able to economize on costs and can afford dedicated facilities for particular formulations. A firm with a large plant can also buy materials at lower prices.

Some of the factors that have helped local manufacturers gain a foothold and remain competitive in the Ghanaian pharmaceutical industry include the following:

- restricted imports list;
- 10% import duty on finished formulations;
- 15% value-added tax (VAT) (including the National Health Insurance levy) on imported finished formulations, and VAT exemption for imported materials used for domestic production of formulations (although this has now been withdrawn);
- 15% price preference for local manufacturers in public procurement.

One of the most important steps taken by the Ghanaian Government to promote the local pharmaceutical industry was to ban the imports of finished formulations of 14 widely used products that could be produced locally, including ampicillin, tetracycline, chlordiazepoxide, indometacin, paracetamol, aspirin and diazepam. Domestically manufactured formulations also benefit from being exempt from the 10%import duty on finished formulations. Previously, manufacturers of domestic formulations benefited from a 15% VAT refund for all materials and machinery required for formulations production, but in 2013 the Ghanaian Government withdrew this exemption. The 15% price preference for domestic manufacturers via public procurement also offers an advantage to local firms, although this mechanism is experiencing some challenges in its implementation and may need to be improved in its consistency and transparency.

The major local manufacturers include Letap, Ayrton Drug Manufacturing, Phyto-Riker, Amponsah Efah, Kinapharma, Danadams and Pharmanova. None of these local manufacturing plants is compliant with WHO GMP, and all currently manufacture only simple products (see Table 2 for an illustrative list). Some local firms, for example Kama and Ernest Chemists, are involved in both manufacturing and importing. Only one company, LaGray, manufactures an active pharmaceutical ingredient (erythromycin) for captive consumption.

Table 2: Key products manufactured by local firms in Ghanaa

Company	Key products manufactured
Ernest Chemist	Antibiotics, antimalarials, anthelmintics, antihistamines, analgesics, diuretics, antidiabetics, gastrointestinal medicines, vitamins and supplements, cold and cough preparations
Kinapharma	Antihypertensives, hypolipidaemic agents, antibiotics, antimalarials, antihistamines, analgesics, vitamins and supplements, cold and flu preparations
Phyto-Riker	Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, psychotherapeutics
Ayrton Drug Manufacturing	Antibiotics, antimalarials, anthelmintics, antihistamines, antacids, analgesics, vitamins and supplements, cold and flu preparations
Kama	Antibiotics, antimalarials

a Source: Frost & Sullivan Research Service, *Pharmaceutical Industry in Ghana and Nigeria* (Mountain View, California, 2011).

Pharmaceutical market structure in Ghana

The size of the total formulations market in Ghana was estimated to be about US$ 329 million in 2012.[10] The imported and local formulations market in Ghana is primarily a retail market that includes patented drugs, prescription generic drugs and over-the-counter formulations, all of which are primarily sold under brand names. Part of the retail purchases are reimbursed under the National Health Insurance Scheme. About 64% of the drugs purchase is financed through out-of-pocket expenditure, 23% is reimbursed under the National Health Insurance Scheme and the remaining 13% is procured publicly, including from donor-fundedpurchases.[11] The share of insurance-funded medicine purchase has subsequently gone up.

Medicines procured and distributed by the Central Medical Stores, the Ghanaian Government agency under the Directorate of Procurement and Supply, fall under two categories: medicines funded by international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and medicines purchased by the Ghanaian Government from its own resources. Donor-funded purchases for medicines to treat human immunodeficiency virus (HIV), tuberculosis (TB), malaria, diarrhoea, influenza and neglected tropical diseases and for reproductive health are made through a process of competitive bidding restricted to manufacturers that have received WHO pre-qualification for the relevant pharmaceutical products. None of the products manufactured in Ghana, or in most other African countries, has received WHO pre-qualification. Thus, a significant segment of the medicines market in Africa is beyond the reach of local manufacturers. The pre-existing market for some manufacturers, for example for malaria in Ghana, was simply wiped out after the Ghanaian Government, under the Affordable Medicines Facility for Malaria programme, began to procure pre-qualified malaria medicines from foreign companies.

In Ghana, about 71% (US$ 235 million) of the total market of US$ 329 million is made up of prescription drugs; the remaining 29% comprises over-the-counter medicines. Local manufacturers cater primarily to the over-the-counter segment of the market and to some extent simple prescription formulations. Ghana has a substantial market for patented drugs, with sales of around US$ 109 million in 2012, accounting for about 46% of the prescription drug market in Ghana. The remaining 54% of the prescription segment of the market is made up of generic drugs.[12] Almost all patented drugs sold in Ghana are sourced from multinational pharmaceutical companies from European countries, mainly Belgium, Switzerland, the United Kingdom and Germany.[13]

Multinational pharmaceutical companies enjoy a monopoly for patented drugs, but these companies also participate, with limited competition, at the higher end of the market for patent-expired products and continue to charge high prices for their products. Generic manufacturers, particularly from India, have been able to exploit this strategy by charging lower prices for patent-expired products. Armed with lower prices and active brand promotion, Indian companies such as Cipla, Ranbaxy, Sun Pharmaceuticals, Cadila and Glenmark have been able to dominate the markets in many products. Traditionally, as a global strategy, multinational pharmaceutical companies focused on the large developed country markets; this has changed in recent years, however, and the multinationals have started to introduce lower-priced generic brands to compete in the generic market.

The larger, more reputed Indian companies active in the Ghana market primarily target the market where entry barriers are high and competition is lower. These companies promote their products through brands; their main competitors are the multinational pharmaceutical companies and generic companies from other countries. Companies often try to enter and grow in these markets by charging lower prices than those of the innovator companies. The smaller Indian companies are more active in the over-the-counter and simple formulations segments, where they compete mainly with local manufacturers. Indian companies have a network of local importers and distributors who play an important role in facilitating their entry and growth in Ghana.

Drug prices in Ghana

In the institutional market, purchases of drugs by the Ghanaian Government (through the Procurement Unit in the Directorate of Procurement and Supply) are done mainly through an international competitive bidding process among eligible suppliers. In this market, the quoted price is the determining factor, as suppliers cannot differentiate their products by branding or through other means to claim superiority and charge higher prices for their products. The retail market in Ghana, as a branded market, suffers from imperfections, as buyers have limited knowledge about the prices and quality of all the other products in the market. The larger, more reputed companies exploit, through branding, the perception that the safety and quality of medicines from different manufacturers are not equal. Consumers and health professionals are often unaware of the existence of lower-priced, less promoted products, or they have less confidence in these products and tend to trust branded products from reputed companies. This enables larger companies to charge higher prices and maintain dominant market shares.

A survey undertaken in 2004 for 50 medicines by the Ghanaian Ministry of Health, in collaboration with WHO and Health Action International, provides some interesting indirect evidence about the prices of drugs in the branded retail market in Ghana. The survey compared local prices with international reference prices (IRP) obtained from the price lists of large, non-profit-making generic medicine suppliers around the world. The survey showed that in private retail outlets, retail prices for innovator brands varied between 2.86 times the IRP (for co-amoxiclav) and 154.34 times the IRP (for fluconazole 150 mg), the median being 18.47 times the IRP. Generic products are much cheaper than innovator products but still cost significantly more than the IRP. In private pharmacies, the median lowest-priced generic product was found to cost 4.12 times the IRP. Prices varied between 0.99 times the IRP (for artemether) and 33.65 times the IRP (for fluconazole 150 mg).

The Indian generic companies operate in similar market structures in India and Ghana. Table 3 compares the retail prices of selected products sold in India and Ghana. The products include formulations that are currently manufactured in Ghana (ciprofloxacin, paracetamol, amlodipine, diazepam, metformin) and formulations that are not manufactured in Ghana (anastrozole, granisetron, losartan, rabeprazole, rosuvastatin). Median prices were calculated for India from retail price data available from a widely used prescribers' handbook, *Current Index of Medical Sciences* (CIMS).[14] Median retail prices for Ghana were obtained from the Medicines List (February 2011) of the Ghanaian National Health Insurance Scheme. This list specifies the maximum prices at which the medicines prescribed are reimbursable. Pricing data are collected from manufacturers, wholesale distributors, private pharmacies, the Ghanaian Government, and mission and private health care facilities; the median prices are set as the maximum price reimbursable under the insurance scheme. The National Health Insurance Scheme covers about half the population, and about 40% of the funds paid out by health insurance are for medicines. National Health Insurance Scheme-funded medicines comprise a major segment in Ghana, accounting for about 23% of the market.[11]

Table 3: Retail formulations prices in India and Ghana

	Median price (INR, 1 tablet)		Ghana/India price ratio (column 3/column 2)
	India, 2013[a]	Ghana, 2011[b]	
Tablets manufactured in Ghana			
Ciprofloxacin 500 mg	6.18	9.11	1.5
Amlodipine 5 mg	2.36	3.64	1.5
Metformin 500 mg	1.46	1.52	1.0
Diazepam 5 mg	2.90	0.30	0.1
Paracetamol 500 mg	1.14	0.30	0.3
Diclofenac 50 mg	1.43	1.82	1.3
Lisinopril 5 mg	4.58	6.07	1.3
Atorvastatin 10 mg	8.60	9.11	1.1

	Median price (INR, 1 tablet)		Ghana/India price ratio (column 3/column 2)
	India, 2013[a]	Ghana, 2011[b]	
Cetirizine 10 mg	3.10	3.04	1.0
Metronidazole 200 mg	0.39	0.61	1.6
Tablets not manufactured in Ghana			
Anastrozole 1 mg	48.50	182.10	3.8
Cepacitabine 500 mg	150.05	267.08	1.8
Granisetron 1 mg	14.05	409.73	29.2
Itraconazole 100 mg	47.50	182.10	3.8
Losartan 50 mg	5.65	12.14	2.1
Rabeprazole 20 mg	2.75	75.88	27.6
Risperidone 2 mg	3.80	75.88	20.0
Rosuvastatin 20 mg	20.36	69.81	3.4
Tinidazole 500 mg	5.52	69.81	12.7
Sertraline 100 mg	6.3	98.64	15.7

a For Indian prices, these are median prices of brands accounting for 1% or more of the market. Market share data were obtained from the sales audit data of AIOCD Pharmasofttech AWACS, a pharmaceutical market research company. Price data were obtained from *Current Index of Medical Sciences*.

b For Ghanaian prices, we used the Medicines List (February 2011) of the Ghanaian National Health Insurance Scheme. Prices in Ghanaian cedis were converted to Indian rupees using the annual average exchange rates for 2011.

Table 3 shows that the extent of price differentials between India and Ghana is quite large, a difference accentuated for by products not manufactured in Ghana. Granisetroncosts 30 times more, rabeprazole 28 times more and risperidone 20 times more in Ghana than in India. For products manufactured in Ghana, prices are almost the same in Ghana and India. For three products, prices in Ghana are lower than those in India; these products include diazepam and paracetamol, both of which enjoy an importation ban in Ghana and are stocked exclusively by local manufacturers. Thus, it is evident that local production in Ghana contributes to lower prices and affordability. It should be noted that the Ghana prices refer to 2011 but Indian prices refer to 2013. Depending on the extent to which Ghana prices have gone up since 2011, the current price differential may be larger than that shown in Table 3.

India is the single largest source of Ghana's formulations imports. If medicines are sold in the retail market in Ghana at significantly higher prices than in the Indian retail market, this suggests Indian companies are exporting medicines to Ghana at inflated prices compared with their domestic market. Depending on the market structure and the nature of competition, Indian exporters can and do enjoy substantial profit margins. This means that Ghanaian consumers are not reaping the benefits of the lower pharmaceutical production costs in India.

The high prices and profit margins of imported products provide an opportunity for Ghanaian manufacturers to start producing these drugs and enter the market at lower prices, despite cost disadvantages. One Ghanaian firm stated their strategy is to target such products for market entry. They also gave an example: AstraZeneca used to be the market leader for lisinopril (under the brand Zestril). The Ghanaian firm manufactured this off-patent medicine and introduced it at an eighth of the imported price and was able to generate a substantial profit. Such instances are rare, however. The biggest challenge remains the unequal competition exerted by large importers. Another major constraint is the lack of adequate bioequivalence facilities for getting products approved for marketing.

Appropriate government policies can facilitate market entry and ensure a larger market share for local manufacturers.

Changes in the global pharmaceutical environment and their implications

Major pharmaceutical markets are located in developed countries, the largest of which is the United States of America, 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% 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.[10]

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% compound annual growth rate between 2012 and 2018, whereas major developed country markets will remain stagnant (Japan, United Kingdom), increase only marginally (United States) or decline marginally (Germany, 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.[8,15]

Response of multinational pharmaceutical companies to the changing global pharmaceutical environment

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 focusing 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 drug products under the same brand 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 generic 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, the 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 generic 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% 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. The Ghanaian company LaGray has entered into an agreement with Sandoz, the generic arm of Novartis, to manufacture products marketed under the Sandoz brand. 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 100 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 plants. The Indian companies also benefit from this arrangement as they have access to the formidable marketing resources of the multinationals.[16]All evidence suggests, however, that the multinationals are unlikely to start manufacturing in Africa on 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 environment

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 operate there. More prominent Indian companies are focusing more attention and investment on growing their presence in the African generics market. Such attention is driven largely by the potential market growth in the region, but also partly by the disappointing returns from the patent-expired sector in large markets such as the United States, which have turned out to be very competitive. 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 plants 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 there.

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 plants. Even though Ghana has put in place a 10% import duty and banned selected pharmaceutical products that local manufacturers are capable of producing, this is not enough to convince foreign companies to invest in local production. Indian companies still prefer to export from India into the Ghanaian market. 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 firms to the domestic market, Indian companies would lose out unless they undertake investments in Africa to cater to the market. 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 sort of guarantee for the safety of investments will increase the likelihood of Indian companies undertaking investments abroad.

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Industrial policy to promote local production

The situation that Ghana currently faces is not unusual for a country trying to develop an industry. The challenges typically faced by countries such as Ghana include relatively high costs of production, insufficient technical knowledge, competition with resource-rich foreign companies, and current dependence on imports. Another critical issue is the scarce availability of funding. Commercial sources often neglect industries and firms 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 throughout history, the roles of government and foreign enterprises are critical to industrial development.

Industrial policy in the Indian pharmaceutical industry

A comparison with India is appropriate at this stage, given the fact that India is the largest source of drug imports into Ghana and Ghana's 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 Ghana 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. The response of multinational pharmaceutical companies was poor. They were reluctant to invest in building manufacturing capacities and structures in India and preferred imports to serve the market. Similarly, multinational pharmaceutical companies and Indian companies are reluctant to invest in Africa today. It was primarily because of the reluctance of multinational pharmaceutical companies to start production from basic stages 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.[17]

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 plant 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 of financial institutes: term loans were provided to budding entrepreneurs at low rates of interest, and no separate collaterals were insisted – the plant that the loan helped to set up was treated as a collateral. Most of the Indian companies that are now global enterprises started as small-scale units. For example, the promoter of the Indian company Dr. Reddy's learned the technical skills while working at the public-sector plant; when he set up his own company, funds were provided by the public-sector financial institute at a low rate of interest.[17]

Industrial policy in the Ghanaian pharmaceutical industry

The Ghanaian Government initiated a number of policies to help local manufacturers gain a foothold in the local pharmaceutical industry. However, the VAT exemption for imported materials for local pharmaceutical manufacturing was withdrawn, probably due to revenue-generation considerations. Stakeholders involved directly in promoting local industry, including local manufacturers and the Ministry of Trade and Industry, have indicated their desire for VAT to be rolled back for locally produced medicines. The potential loss in revenue generation from the 10% import duty as a result of a reduced need for imported products may dampen the support for local manufacturing – this perception will need to be addressed.

Another barrier to strengthening local manufacturing is the resistance posed by local importers and distributors, who possess significant resources and wield significant influence in a pharmaceutical market dominated by imported products. In Ghana, the situation is complex because some of the importers are also manufacturers, which has fractured the collective voice of local manufacturers and compromised the effectiveness of their lobbying.

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 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 for expanding the growth of firms. Under the current conditions in which they operate, local firms are not able to generate large enough profits to be adequately reinvested in the firm. Foreign investment has not been a feasible option, as multinational pharmaceutical companies and Indian generic companies are currently not ready for it. The local company LaGray tried another avenue to access capital: two private equity funds (one based in Tunisia, another in Ghana) became involved through investing in convertible debentures. The local and foreign entities soon clashed over differing objectives: the local partners wanted to develop manufacturing capacities and capabilities, while the foreign equity funds wanted to focus on marketing imported products and were not willing to invest in the establishment of a WHO GMP-compliant manufacturing plant, an initiative that had begun before their involvement.

Thus, domestic sources of funding provide the only plausible solution, but banks in Ghana charge interest rates which are not a viable option for most companies. A significant amount of capital is needed to set up GMP-compliant manufacturing plants, develop products that meet regulatory standards, and market products. The companies interviewed for this document have highlighted the significant challenge in accessing investment funding and affordable credit. The companies do not want subsidy but require equitable access to finances at rates of interest comparable to the rates paid by their main competitors in India. It should be noted that in India at the time of writing, the rate of interest on loans is less than half of that in Ghana.

The Ghanaian Government has implemented some good initiatives. The Export Trade, Agricultural & Industrial Development Fund in Ghana has been extended to pharmaceutical companies that are majority-owned by a local entity, to which US$ 25 million has been earmarked for loans at a low 12.5% interest rate. These loans are specifically for upgrading manufacturing facilities to WHO GMP standards. So far, the companies that have benefited from this scheme are Ernest Chemists, Danadams, Danex, Kinapharma and Amponsah Efah. Two active companies, LaGray and Pharmanova, have been excluded because of foreign ownership, but this is being challenged on the basis of their significant investment and activities in Ghana and integration into the local economy, unlike the multinationals and Indian generic companies.

Technology

When pharmaceutical manufacturing started in Ghana, technical requirements were simpler and the transfer of technology was often arranged through informal channels. The founders of local companies such as Amponsah Efah, LaGray and Pharmanova were technologists and used their knowledge and contacts to set up small-scale manufacturing plants. Technological requirements and production standards have changed fundamentally and become more difficult in recent years. If local manufacturing in Ghana is to be increased, the availability of, and access to, technical knowledge and expertise needs to improve substantially.

Manufacturing plants need to be compliant with WHO GMP, which comprises a set of safeguards and procedures at each stage of the production process to ensure the manufactured product is effective and safe. All aspects of the production process are covered by GMP, including 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, every time the product is manufactured. 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 plant, significant additional costs, particularly fixed costs, will be incurred. Costs include maintaining hygiene in the factory building and premises and avoiding risks of contamination and cross-contamination; installing a proper heating, ventilation and air-conditioning system to maintain the necessary conditions, including temperature, humidity and filtered air; 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 the procedures specified; and strictly following cleaning procedures when equipment is used for more than one material.

Previously, most developing countries, including Ghana, 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 the drug control administration. Companies are required to undertake various studies (e.g. bioequivalence studies) and to generate data and submit dossiers to the drug control administration. Marketing approval is granted after various types of review by the drug control administration, including chemistry review, bioequivalence review and plant 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 plants and to develop products that meet regulatory requirements for marketing are almost non-existent in Ghana and other African countries. It is vital that such a resource is made accessible if the indigenous industry is to develop.

A potential source of such technical capacity is India, where the pharmaceutical technical knowledge is highly diffused. India has numerous individuals with the requisite knowledge and skills, most of whom are currently employed by pharmaceutical companies or consultancy firms, 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 is the exportation of finished formulations to highly regulated countries such as the United States. India has developed significant expertise in setting up plants 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. China has 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; instead, Chinese companies recruited technically skilled Indians with the relevant qualifications and experience to provide this support. As shown by the Chinese companies, it is possible to use such a resource in India by exploiting 'pull factors' (opportunity to work in a foreign country, higher salary) and 'push factors' (dissatisfaction with the present job, personal reasons) 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. It is not easy to identify qualified experts who can provide the necessary technical support. This issue is confronting a particular local importer and distributor in Ghana. This company has been considering manufacturing products locally since 2000, and it had imported equipment, appointed a United Kingdom-based technical consultant to prepare a project report, and purchased land to build a factory. It is currently looking for additional funding and technical support, and for collaboration with international partners, for example from Germany, which has been active in some African countries in funding the services of technical experts. Another option that it is contemplating is a joint venture with an Indian generic company, which may fill the necessary technical and financial gaps. As explained by the promoter of the company, however, reputed and larger Indian companies such as Cipla are unlikely to enter into a joint venture with a small importer, and the company may be more likely to be successful by establishing a partnership with a smaller Indian company, but it does not know how to proceed. The Ghanaian 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.

The Ghanaian Government has made significant inroads in improving manufacturing quality and standards. Ghana is the first country in which the African Union's Pharmaceutical Manufacturing Plan for Africa is being implemented. As part of this plan, the United Nations Industrial Development Organization has arranged for visits of technical experts from developed countries to provide advice and training for upgrading local manufacturing to WHO GMP standards. Use of foreign technical services will be cheaper and can be made available more extensively if the import channel from India is opened up.

The Food and Drugs Authority of Ghana is also prioritizing the technical upgrade of local manufacturers. An industrial support department has been established to liaise with firms and provide necessary technical inputs. Local manufacturers have been told that they will be closed down if facilities are not upgraded to WHO GMP standards by January 2019. Permits will not be issued for any new manufacturing units unless they are compliant with WHO GMP.

In addition, the Ghanaian 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. The Ghanaian Government plans to set up a bioequivalence centre, although no international funding has been committed for this. If progress is to be made within a suitable time-frame, there is no option but for the Ghanaian Government to commit funds for this vital activity. This will go a long way in stimulating the diversification into higher value-added products manufactured by local producers. Additional fixed capital investment may be required for infrastructure, equipment, furniture and fixtures, staff expenses and so on for the 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 people will not benefit and nor will the local industry be able to sustain itself. This argument against local production is based on two questionable assumptions: that higher 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 Ghana, local prices compared with IRP are very high, 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 Ghana, 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 Ghana's citizens.

If the sale price of a product is so low that the cost of production is not covered, then local production will not be viable. But to find out whether this indeed is the case, we need to know the actual production cost and price structure. The imported price may not be low – it could even be higher than the cost of production.

If local producers are to compete with foreign manufacturers that can produce at lower costs, the local producers must first sell at a lower price and ensure the lower profit margin per unit of production can be compensated by a larger volume of sales to generate high enough returns to make local production worthwhile. The size of the market required to make local production viable and sustainable depends on the size of the cost disadvantages and the import prices. Such empirical analysis is conspicuous by its absence in the literature. In the absence of empirical investigations, the general assumption has been that the size of the market required to ensure local production viability may be beyond the reach of small developing countries.

An attempt has been made to fill this gap in the literature.[18] In African countries with underdeveloped pharmaceutical industries, it is very difficult to obtain relevant data and proper cost data are not available at all. What is important is not only to 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 plants cannot be used for the purpose of analysing issues relating to promoting local production of good-quality medicines. To circumvent this problem, we attempted a simulation exercise. India has revised Schedule M of its Drugs and Cosmetics Act to implement GMP. We started from India and simulated the situation in Ghana by making necessary adjustments based on cost and other differences. As a source of information and insights, the paper relied heavily on interviews conducted in India and in 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 4).

Table 4: 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 cedis)	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
Break-even quantity (million tablets)	89	130	224
Total profits (million rupees)	30	41	55
Profit margin (%)	15.3	15.2	15.3

a Source: S.Chaudhuri and A. West, "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 (2014), pp. 1–16.

b Indian costs and Indian cheapest brand prices.

c Higher Ghanaian costs and Indian cheapest brand prices.

d Higher Ghanaian costs, median international reference prices and no sales promotion costs.

We assumed the Indian plant 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. We assume that about 30% of the quantity manufactured is for the costliest products, ofloxacin and ciprofloxacin; 30% for the cheapest product, amlodipine 2.5 mg; and the remaining 40% 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% or above). We found that with sales of 197 million rupees and a quantity manufactured of 152 million tablets, the Indian firm earns a profit margin of 15.3% (Table 4, column 2). We assume a 15% profit margin to be adequate for the operations of the firm, but most of the companies in India earn less than this.

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. We assumed that material costs are 30% higher in Ghana, machinery costs 15% higher, factory building construction costs 35% higher, and power and fuel costs 50% 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% compared with 15.3% for India. One of the ways of compensating for the cost disadvantage is to charge higher prices. This impacts negatively on access to medicines, highlighted by critics of local production in Africa. But prices do not need to be higher for viability and profitability. As Table 4 (column 3) shows, if the quantity manufactured is higher at 209 million tablets, with sales of 271 million rupees (9 million Ghanaian cedi), the Ghanaian plant can enjoy the same profit margin as that in India without charging higher prices.

If the Ghanaian manufacturer charged the IRP, then the market size would need to be larger. In the market types from where we have taken IRPs, brand names do not play a critical role; and in purchases 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, then to earn a profit margin of 15% the production level needs to be 405 million tablets with sales of 362 million rupees (13 million Ghanaian cedi) (Table 4, column 4). We assume a 15% profit margin to be adequate for the sustainable operations of the firm, but most pharmaceutical companies in India earn less that this; the required volume of production for viable operation will be less than 405 million tablets if we assume a lower level of profitability.

Despite Ghana having much higher production costs than India, Ghanaian firms can sell at a low IRP 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. Larger firms in Ghana such as Ayrton Drug Manufacturing have capacities exceeding 1.5 billion tablets per year with sales of more than 15 million Ghanaian cedi. Even smaller firms such as Pharmanova have capacities of around 500 million tablets per year. Manufacturing capacities are grossly underused, however, and local manufacturers are largely restricted to production of over-the-counter medicines. If finance and technology can be arranged to upgrade facilities, and a market can be assured, then local production can be viable, contributing to affordability and accessibility.

Ensuring a larger market for local manufacturers

Countries have traditionally used import duty to ensure a larger market for local manufacturers. Ghana has also implemented a negative import list and provided a price preference in public procurement to benefit local manufacturers over foreign suppliers. Even though the negative import list has worked quite well in Ghana, these measures to strengthen the local pharmaceutical industry have had limited impact, as evidenced by the high proportion of imported products in Ghana.

In light of this, the Ghanaian Government may include additional products in the negative import list, but only if adequate local capacity exists to produce these medicines to mitigate against any risk of shortages. These products will need to be chosen carefully to reflect not only the essentiality of medicines but also the current status and the prospects of local firms developing such capacity.

As part of a coordinated plan of action, the Ghanaian Government may provide support to manufacturing plants in upgrading to GMP standards. It may also help in developing products to qualify for regulatory approvals. Once adequate local capacity is developed, the Ghanaian 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 medicines market, competition among local firms 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 Ghanaian Government may also establish a watchdog mechanism to monitor prices and, if necessary, introduce ceiling sale prices.

The bargaining power of the National Health Insurance Agency can also be used to enlarge the market for local manufacturers. The National Health Insurance Scheme currently does not differentiate between whether medicines are manufactured locally or imported. Under the scheme, the capacity of local firms may be assessed and, where adequate capacity is available, reimbursements to patients may be restricted to locally manufactured products. In this way, shortages will not develop and prices will not be higher, since the prices to be reimbursed are fixed by the National Health Insurance Scheme.

As far as the institutional market is concerned, the only advantage offered to local manufacturers is a 15% price preference, but this has not achieved the desired effect. Public procurement remains a matter of national discretion, since the World Trade Organization Government Procurement Agreement is a plurilateral agreement applicable only to the Member Countries that have signed it. Only 40 countries have signed this agreement, and Ghana is not one of them. Public procurement of medicines (and other goods) in Ghana is guided by the provisions of the Public Procurement Act, which provides for three types of competitive tendering:

- international, for procurement of more than 15 billion Ghanaian cedi;
- national, for procurement of between 200 million and 2 billion Ghanaian cedi;
- restricted, up to 200 million Ghanaian cedi.

International tendering means organizations located outside of Ghana are eligible. National tendering means that only organizations located in Ghana are eligible, but they need not be manufacturers and can be importers located in Ghana.

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

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