Pharmaceutical Manufacturing in Bangladesh – A Success Story. What can we learn?

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Executive Summary:
Pharmaceuticals as an engine of growth - lessons from Bangladesh

Establishing a local pharmaceutical sector requires policy vision, policy consistency and coherence, with matching resource allocations, innovation support and monitoring. Although the state is a big actor in this effort, the private sector is equally important, and fostering capabilities in the local firms in circumstances, where the general innovation environment has several shortcomings, is no easy task. Experiences of many developed and advanced developing countries (especially India and China) shows that it requires critical coordination and foresight on part of policy making to enable local firms to access technologies, create local capabilities, produce and export. If done correctly, local production can achieve several goals at once: it can become a source of steady employment, establish backward and forward linkages with the rest of the economy with related technology spill-overs and demand effects that facilitate broader economic development. It can also generate potential savings through manufacture of good quality local medicines and promote national health security. In the longer term, it can also become a source of foreign exchange and facilitate firms' forays into other high technology sectors.

Bangladesh's pharmaceutical sector today is one such success case. Having registered phenomenal growth rates over the past decade, the sector is thriving. Local firms cater to 97% of the local market estimated to be just above 2.5 billion USD in 2018 (IMS, 2018), and are seeking to gradually expand into more rigorous production segments including vaccines and API production. In the past decade, an expanding local consumer market, new governmental incentives and economic growth patterns of the country have all helped the sector. Thus, even critically, all the direct and indirect benefits of local production capacity seem to have materialized in the case of Bangladesh, thus posing a series of inevitable questions, such as: what makes its case different? Are there historical, context-specific reasons, or can we draw clear conclusions as to the kinds of policies that are required for local production?

A detailed review of the historical development of the sector and the underlying policy framework helps to identify a series of best practices and lessons that can inform other national efforts to promote local production, such as that of the East African community.

Table 1: Best Practices and Lessons from Bangladesh's Pharmaceutical Sector

Best practices	Lessons
• Integrate industrial and drug policy visions • Embed the sector into the local economy • Enable systemic capabilities for the emergence of the sector • Interpret policy (and use ambiguity) in favour of local firms • Co-invest and co-compete with the local firms • Enable technology transfer and entrepreneurial spin-offs • Involve the private sector in discussions on the sector • Establish a system of mandatory product pricing for drugs on the essential medicines list. • Set and control prices for all drugs to ensure that they are affordable.	• Take greater responsibility for health care expenditure • Establish a system of mandatory product pricing for drugs on the essential medicines list, with regular review and control these prices • For those drugs not on the essential medicines list, pricing should be based on public health (and not revenue) considerations • Create greater checks and balances against direct marketing and doctor-pharmacy-firm level collusions in the health sector. • Promote greater coordination between pharmaceutical production and health systems actors. • Increase accountable, rural penetration of pharmaceutical products.

But adopting best practices based on what has worked elsewhere calls for some degree of caution, not just because technological and entrepreneurial development is often shaped by context-specific factors, but also because the global geopolitical context for trade, intellectual property and industrial development has now changed. As a result, many of the policy options, such as that of completely restricting foreign firms from the local market, may no longer be possible.

Despite these caveats, given the political vision, commitment and the public health needs of the East Asian community, a number of recommendations can be drawn. A starting point is integrating and clearly embedding the ambition for pharmaceutical manufacturing in the national vision and development plans. A second priority will be to employ all forms of TRIPS flexibilities, and to not forego degrees of freedom (through grant of data exclusivity or other TRIPS-Plus requirements) that are relevant to maintain policy space for the development of pharmaceutical manufacturing. Apart from these two, a number of other policies need to be better coordinated and implemented to foster local firms in a systematic way. Provisions and incentives introduced in these policies can go a long way in supporting the local firms. A tool kit of recommendations for the East African Community is contained in Table 2.

Table 2: Tool kit for Local Pharmaceutical Production: Recommendations for the East African Sector

Policy	Objectives	Instruments	Actions
1. Create an enabling framework for local production	1. Coordinate policy across the spectrum	National Science and Technology Policy Investment Framework Technology transfer policy National Development Plan National Health Policy	- Create a forecast of firm level capabilities and their needs - Ensure coordinated promotion of local firms and their priorities for investment, technology transfer, industrial growth - Establish linkages with national health policies in terms of goals and actions - Provide incentives that allow firms to collaborate to create new products, processes and also enable contract manufacturing across the pharmaceutical value chain.
	2.Generate systemic enablers	National Science and Technology Policy	- Identify R&D priorities and financial incentives for public research. - Increase public R&D funding and ensure that it is spent with relevance for the industry. - Set out a public sector R&D map identifying priorities of relevance to pharmaceutical research and a plan to develop this capacity - Allocate public sector funding only subject to research plans that match the ambition in the newly specified public sector R&D map. - Promote skills and knowledge building for applied research in pharmacy and related disciplines of relevance to pharma, such as chemistry. - Ensure collaborative linkages between local firms and local R&D institutes through research grants, and other specific performance incentives. - Strengthen the role of national R&D institutes to perform drug related research and attract relevant technology transfer.
2. Create a local market for local production	1. Promote a gradual but definite share of local firms in the pharmaceutical supply chain	Industrial policy National Health Policy Drug Procurement Guidelines	- Recognize the pharmaceutical sector as a priority sector for industrial development. - Provide investment and importation incentives to local firms - Ensure imports of raw materials for key pharmaceutical products at zero tariffs - Streamline processes for permits, port storage and improve general infrastructure, with a view to offer one-stop license for port, storage and transport for local firms. - Provide SEZs or other economic benefits to local firms in the pharmaceutical sector. - Provide industrial production incentives such as tax holidays, formulation grants, etc. – to encourage local firms. - Engage and work closely with local firms to provide training and assistance on plant practices and production techniques. - Provide specific rules that mandate re-investment of profits earned through local tax and other incentives into the pharmaceutical sector.

Policy	Objectives	Instruments	Actions

	2. Create a fair playing field between foreign firms and local companies		- Set clear goals for the shares of the market that should be occupied by local firms over the short term, mid-term and long term.
			- Segment the market through policy such as the 1982 National Drug Policy and enable the local firms' exclusive access to certain production segments.
			- In therapeutic categories reserved for local firms, set out licensing requirements from foreign firms to local firms, with a view to promoting:
			  • Production capacity
			  • Technology transfer
			  • Better standards of local production
			- Ensure, through the national health policy and drug procurement guidelines that national producers are offered assistance and prioritized in local procurement.
			- Provide a dual drug registration system, specifying favorable registration rates to local firms.
			- Provide cGMP-related technical assistance to enable them to improve quality control and quality assurance processes.
			- Use all TRIPS flexibilities as much as possible in favor of local production.
			- Establish / mediate agreements between MNCs/ foreign firms and local companies for technology transfer and licensing of products.

	3. Promote forward and backward linkages between the pharmaceu-tical sector and the local economy	Industrial Policy Investment Policy Trade policy National Science and Technology Policy	- Promote the emergence of ancillary sectors for packaging, testing, API production and biotechnology in the country or at the regional level. - Increase regulatory harmonization in the region, to allow firms to easily sell and pool demand in neighboring markets. - Promote acceptance of locally manufactured drugs - Co-invest in firms/ or in the sector at the governmental level to signal confidence and legal certainty for the local firms and banks.

Policy	Objectives	Instruments	Actions
3. Support good quality medicines and affordable prices	1. Promote local production or local supply for greater access	Industrial policy National health policy	- Update the Essential Medicines List with provision for regular revisions based on the disease profile of the country. - Provide for a new differential pricing scheme with restricted pricing that needs to be provided by drugs that are imported/ locally produced. - Incentivize local production of those drugs in the essential medicines list. - Negotiate actively for other drugs that are not on the essential medicines list with the aim of ensuring drug supplies form the cheapest suppliers, amongst MNCs or other firms. - Generate more effective guidelines to control and actively monitor marketing practices and safeguard ethical behavior by doctors.
	2. Increase collaboration between the DRA and other health agencies and the local firms.	Health Policy National Procurement Guidelines	- Promote close collaboration and trust building between local firms and the DRA. - Promote the participation of local firms in boards of pharmacy, and drug committees formed by the DRA. - Allow for extensive interaction and training of local firms by DRA on a constant basis. - Create capacity in the DRA to advise companies on regular upgrading activities.

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1. Introduction

Bangladesh's pharmaceutical sector has defied overwhelming odds over the past three decades. Buoyed by local consumer demand, Bangladesh's pharmaceutical firms currently manufacture a range of drugs including insulin, hormones, anti-cancer products and vaccines and also produce nineteen kinds of active pharmaceutical ingredients (APIs). Sectoral annual growth rates have been estimated in the range of 11 to 15% per annum since 2011,[1] as a result of which total local pharmaceutical production reached USD 1.9 billion (BDT 151.5 billion) in 2017 and peaked at an all-time high of roughly 2.5 billion USD in 2018 (IMS, 2018). Increased investments in production capacity by local firms, and an expanding local market, which almost doubled between 2012 and 2017 (IMS, 2017), have provided the impetus for this expansion.

The growth and expansion of this sector is unique for many reasons. At the outset, Bangladesh was the only developing country to successfully establish a local manufacturing sector since the onset of the Agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS Agreement). Secondly, it is the only least developed country (LDC) with significant capacity to produce, and thirdly, it represents a case where the pharmaceutical sector, having started out as a means to promote local access to medicines, has also become an engine of growth in the country, contributing to 1.2% of GDP in the financial year 2018 (Rahman and Farin, 2018). Bangladesh's pharmaceutical sector remains the largest employer of the country's skilled workforce, employing pharmacists, chemists, biochemists, microbiologists, engineers, business administration graduates, doctors and a variety of other professionals. Current forecasts suggest that these favorable trends will continue well into the next decade: the local pharmaceutical sector is expected to reach a market size of USD 5.11 billion by 2023 (Daily Star, 2018). To support this expansion, the government has declared the sector to be a thrust sector since 2006 (Mohiuddin, 2018) and the 'product of the year', i.e. a national priority sector, in the year 2018 (Farhin, 2017), and announced additional incentives to local firms.

However, when Bangladesh first decided to stop imports of drugs into the local market as part of the newly enacted National Drug Policy and the Drug Control Ordinance of 1982, these outcomes seemed highly unlikely. Not only because traditional theory warns against the inefficiencies of creating a closed, protected market with infant industry protection of the kind that the national Drug Policy of 1982 created for local pharmaceutical production, but also because, for much of the 1980s and the 1990s, the goals still seemed far-fetched. Even in the 2000s, studies continued to note that the industrial base for pharmaceutical production was poor (Amin and Sonobe, 2013); total factor productivity in the industry was low (Fernandes, 2008) and that the pharmaceutical sector was lacking in competition (World Bank, 2008).

This study aims to look at the policies that led to the historical development of local pharmaceutical production in Bangladesh. It analyzes the historical development of Bangladesh's pharmaceutical sector to identify the policy measures that supported this advancement. It assesses whether and how local production has helped to serve local access to medicines and provide favorable medicine prices locally. In both sets of inquiries, the focus is on identifying best practices, but the study also looks at lessons learnt. Finally, the study contains recommendations on how these best practices can be applied in the context of the East African Community.

[1] The DGDA estimates the local Growth at 15%. EBL (2018) estimates that from 2012 to 2017, historical five years CAGR was 15% and from 2014 to 2017, historical three years CAGR was 21%. Rahman and Farin (2018) the five years CAGR (Compound Annual Growth Rate) for the sector between 2012 and 2017 to be at 13.5%.

The study, draws extensively on primary research conducted specifically to inform the work. This includes meeting a number of stakeholders within the Bangladesh's pharmaceutical sector, and also actively soliciting their inputs during a workshop on best practices for local production and pharmaceutical pricing in the country (see Annexes 1, 2 and 3). Thus, unless otherwise stated, all information contained is the result of primary research and interviews. Section 2 begins by presenting a sector snapshot of the local pharmaceutical firms, focusing on the current strengths, market structure and shares, export capacity, and drivers of success. Section 3 provides a historical evolution of the policy framework that supported the emergence of this capacity. Section 4 discusses the best practices for fostering local production and Section 5 presents the lessons learnt for drug pricing. Section 6 concludes with policy recommendations for the East African region.

2. Bangladesh's Pharmaceutical Sector: A Sector Snapshot 2019

According to the Directorate General of Drug Administration (DGDA), there are approximately 257 licensed pharmaceutical manufacturers operating in the country currently, of which about 150 are actively producing allopathic and herbal medicines (BAPI 2018; DGD, 2019).[2] The sector has expanded in sales from 100 million USD in the mid-1980s, to 220 million USD in mid-1990s, to over 600 million USD in mid-2000s, to exceed 2.5 billion USD in 2018 (Amin and Sonobe, 2013; IMS, 2018).

2.1. Current Strengths

Local pharmaceutical firms produce mainly generic versions of drugs that are off-patent worldwide. The market is split between generics, which account for approximately 92% of total local production in 2017 and 8% of patented drugs (BMI, 2018).[3] Of the generics sold locally, it is further estimated that over the counter drugs account for 20.8% of local production.[4] Most of the local market is structured around branded generics competition between the local firms.[5] As a result, although the DGDA has registered 1530 generic products from the sector in total, these drugs are sold to the consumers through 29,508 brands.[6] All national estimates suggest that local companies meet around 97% of local demand and in recent years, have expanded their production to include specialized products like vaccines, anti-cancer products and hormone drugs are imported to meet the remaining 3% of national requirements.

Bangladesh's firms engage in secondary manufacturing of finished formulations of drugs across a wide variety of categories, which involves importing APIs and other raw materials and formulating them together in capsules, syrups or other dosage forms (Bennett et al, 1997).[7]

[2] The Bangladesh Association of Pharmaceutical Industries (BAPI) has around 144 registered companies, which is a slightly lower figure (BAPI, 2018).

[3] These figures are more or less consistent with those contained in the National Formulary of Bangladesh, which estimates that around 10% of the total drugs being sold in the country currently are patent protected (field interviews).

[4] In Bangladesh, over the counter (OTC) drugs comprise non-prescription products that can be sold in drug stores, grocery stores and convenience stories. They include pain relief medication, sleeping aids, cold and cough medication, weight reduction products or vitamin and other nutritional supplements. See for example, Babu (2007).

[5] *Branded generics* are simply drugs that are not under patent protection elsewhere but sold in the local market under a brand name, as opposed to branded drugs or innovator drugs.

[6] The DGDA also estimates that there are 459 registered ayurvedic products, 448 registered unani products, 483 registered homeopathic products and 84 registered herbal products in the market currently (see DGDA, 2019).

[7] Bennett et al (1997) define primary manufacturing to include the manufacturing of APIs, intermediaries and excipients. Generally, primary manufacturing countries have all three manufacturing processes vertically integrated within the company, although the manufacture may be spread over many locations.

The interviews conducted with the top 10 firms suggest that a wide variety of the packaging material is now sourced internally, including packaging material, product literature, white bottles, empty syringe/injectables, plastic containers, among others. Many other kinds of packaging materials (blister foils, seals, etc) are still imported along with most APIs and excipients. On the whole, interviews reveal that around 80-95% of raw materials are being imported for pharmaceutical production (LR Global, 2017; Azam, 2016) and this makes the sector susceptible to external shocks.

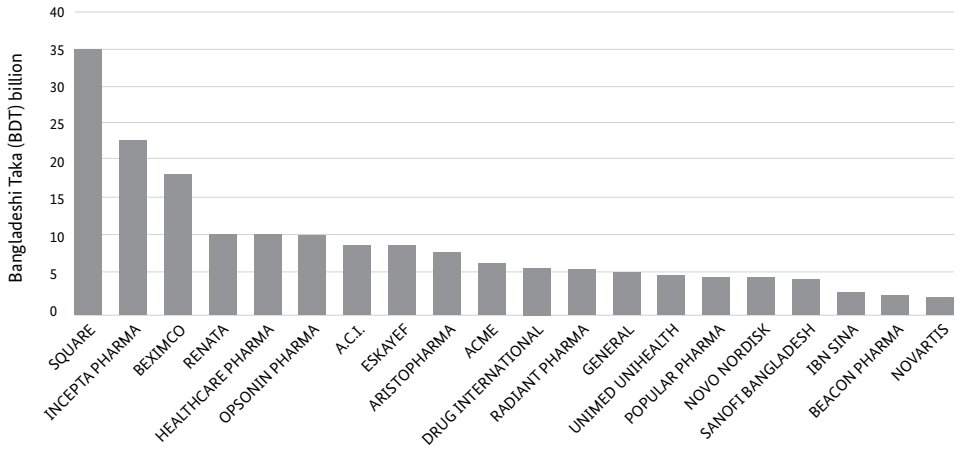
More recently, local firms have begun to produce APIs, which now amount to 19 APIs in total for the entire country. These include penicillin, cephalosporin, paracetamol, metformin, erythromycin, ciprofloxacin, diclofenac, azithromycin, omeprazole, esomeprazole and atorvastatin (DGDA, 2019). This production comprises the final production stage only, after importing the intermediates from abroad. A newly planned API park (see Section 3) is expected to help firms expand their capacity for API manufacturing.

2.2. Market Structure and Market Shares

The sector consists of three kinds of firms: private enterprises, state-owned (Essential Drug Company Limited) and civil-society based (Ganashastha Kendra, which is a civil society based public policy agency and also essential medicine producer). The Bangladesh Association of Pharmaceutical Industries (BAPI or Bangladesh Aushad Shilpa Samity in Bengali), established in 1972 with just 33 members, has now expanded to become a full-fledged player, actively representing and campaigning for the industry. There are two joint ventures in the sector - Roche Healthcare and Sun Pharma – that have local manufacturing plants and a handful of multinational companies.

The sector is highly concentrated, with the top ten firms capturing 70% of the total market, the top 20% capturing 80% of the market and the top 3 firms (Square, Incepta and Beximco) accounting for 36.3% of the total market in the last quarter of 2018 (IMS Q3, 2018). BAPI's data shows that the share of sales and the share of growth of the top 10 firms in the sector correspond. For example, in 2012, the top 10 companies captured 66.26% of all sales, and accounted for 69.36% of the growth of the sector; whereas in 2015, the top 10 companies captured 68.31% of all sales and accounted for 68.45% of the total growth in the sector (BAPI, 2017).

Chart 1: Market Shares of Top 20 Firms, 2018-2019



Source: Author, based on data from IMS Q3 (2018).

These sector dynamics are a small improvement over how the sector looked like in 2007. A comparison of the nature of products, sector growth, total number of firms and supply potential of the sector is compared in table 1. Table 1 shows some significant improvements, namely the supply potential of the sector which now caters to 97% of the local economy, and an expansion of the product portfolio of local companies.

Table 1: Bangladesh Pharmaceutical Market Place: Then and Now

Feature	2007	2019
Nature of products	Predominantly branded generics - Final formulations based on imported APIs - All APIs were imported	Predominantly branded generics - A 'me too' market - Many local firms manufacture API (19 in total) (BAPI) - Manufacturing of packaging material - Production of new kinds of medicines – insulin, human hormones, etc. - Vaccine production
Sector growth	Pharmaceutical sector small, but growing rapidly - 500M USD market size - Growth: 10% per annum	Significant expansion of the market - 2.5 million USD market size (IMS, 2018) - Growth: over 10% for the past 5 years
No. of firms	235 registered firms with 85 active	257 registered firms with 150 active
Sector profile	Top 10 generate 70% of market Top 2 generate 25% of market	Top 10 generate 70% of market Top 2 generate 28% of market Top 20 generate 80% of the market

Source: Author's surveys, 2007 and 2019.

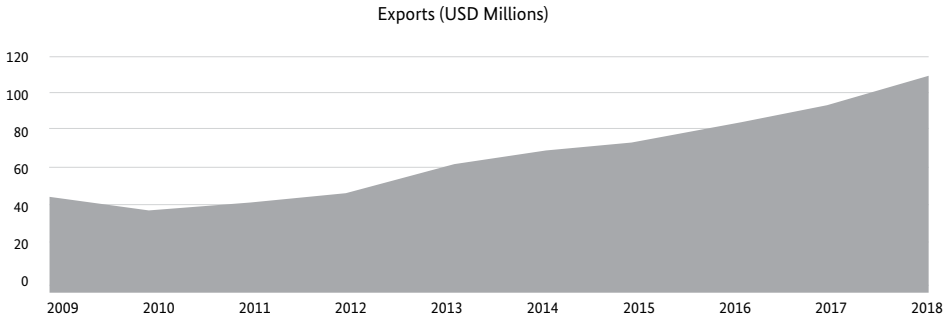
Field interviews with the top 10 local companies conducted for this study show that Incepta Pharmaceuticals is producing hepatis B, rabies, hepatitis A and typhoid vaccines and Renata Pharmaceuticals is in the course of setting up a vaccine production facility. A number of companies are venturing into the production of biogenerics, and several others are already producing anti-cancer medicines (see ACI Pharmaceuticals).

Square Pharmaceuticals, Beximco and ACI are already USFDA certified, whereas Incepta produces through its own US plant (Nevap) and Renata has a plant in the United Kingdom.
Several of the large firms boast global accreditations with the USFDA (USA), Therapeutic Goods Administration (Australia), ANVISA (Brazil), MHRA (UK), EMA (EU) Health Canada and TFDA (Taiwan). Many of the firms, such as Beximco, Square, and Renata have filed and received several ANDAs in the US market.

2.3. Export Markets

According to the DGDA, 54 pharmaceutical firms exported to 146 destinations as of 2018, including Europe, Australia, Africa and USA (DGDA, 2019).[8] The number of countries to which local firms export has expanded fast, from 113 countries in 2015 to 146 countries in 2018, of which 37 are in Africa, but exports remain a small part of the total production (see chart 2). In 2018 for instance, although the total value of local production was estimated to lie somewhat over 2.5 billion USD, the total exports of the sector were at USD 103.46 million (EPB statistics, 2018).

Chart 2: Evolution of Exports, 2009-2018



Source: Author, based on data from IMS Q3 (2018).

Bangladesh is currently an LDC, as a result of which it is not obliged to recognise patents on pharmaceutical products. This allows the local sector to produce generic versions of drugs patented elsewhere for domestic consumption. The local sector can also export such medicines to other countries that are LDCs exempt of such patent requirements or under compulsory license from countries that do not have sufficient production capacity (Correa, 2018; Roffe and Spennemann, 2006).[9]

Square and Beximco began manufacturing ARVs in 2006 and 2007. Beximco began producing Saquinavir with Roche, as part of an agreement that included technology transfer (field interview; Gay, 2018). Square Pharmaceuticals similarly began several ARV combinations in 2008 including Adiva (efavirenz), Hivarif (lamivudine), Avudin (lamivudine and zidovudine), Tivizid (abacavir, lamivudine and zidovudine) and Nelvir (nelfinavir) (field interviews). Beacon Pharmaceuticals is the first generic drug company globally to introduce a generic version of Gilead's Epclusa (sofosbuvir + velpatasvir), which is used to treat all types of hepatitis C infections.

Export portfolios of the top firms are increasingly diversified, ranging from HIV/AIDS to cancer medications, to HFA inhalers, CFC inhalers, suppositories, nasal sprays, injectables and IV infusions. Interviews conducted for this study showed that exports are less than 10% of the total volume of firm's production on average, although firms do have plans to expand in the coming years. Interviews revealed three major impediments for export. The first is the need for bioequivalence studies, which is an increasing part of the product registration process of many countries, including many in Africa.

[8] This is somewhat at odds with the data from the Export Processing Bureau, which reported in 2018 that the sector exported to 199 countries. See also Mahmud (2018).

[9] Bangladeshi firms can manufacture under compulsory license from any other country without pharmaceutical production capacity, as recognised by the the Doha Declaration on the TRIPS Agreement and Public Health (WTO, 20 November 2001). See also, WTO (2003) Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. Available: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

Bangladesh's national regulatory requirements do not require bioequivalence for product registration and the larger firms normally get this done in India, Malaysia or other destinations. A second impediment for export expansion is the lack of sales/distribution force in the export markets. A number of firms noted investment restrictions placed by the Bangladesh Government which prevents them from investing and setting up sales capacity in foreign countries. A third major issue being faced by Bangladesh firms is competition from Indian generic companies. Up until recently, the product portfolios of a number of top Bangladesh firms were overlapping with those of large Indian companies. This made it difficult for local companies to compete, given that Indian companies have greater economies of scale, more experience in penetrating foreign markets and cheaper access to APIs (field interviews).

2.4. Drivers of Success

Interactions with firms reveal three main drivers of market success in the past decade: expansion of markets into rural areas, the resulting expansion of local distribution networks, and new company strategies for expansion. In Bangladesh, most of the medicines are sold directly to the consumer through pharmacy sales or by doctor prescriptions. Firms rely exclusively on their own internal distribution networks, which comprise medical representatives who deal directly with doctors and provide a number of incentives to pharmacies to stock their products. The sector invests only around 1% of its total sales in R&D (BMI, 2018), and almost all firms interviewed admitted to spending around 15% of their total profits on marketing, including an expansion into rural areas.

Thanks to the expansion of medical services to rural areas, most notably as a result of a series of health system reforms in the country, firms are able to expand their consumer base and penetrate into regions of the country that were previously inaccessible. They are also employing a number of new kinds of marketing and production strategies to target domestic and export markets. Chief amongst these are:

(a) diversification into new product portfolios – which is being made possible by the government's import concessions that allow them to expand into new therapeutic categories (see discussion in section 3.2)
(b) penetration into smaller but more lucrative markets abroad
(c) setting up foreign production facilities: Beximco has set up additional factories in Saudi Arabia and is in the course of setting up a plant in Sri Lanka as part of an agreement with the government that stipulates the production of 36 different products in the plant with a buy-back guarantee for 15 years. Square pharmaceuticals has embarked upon the process of building a plant in Kenya (field interviews, 2019).

3. Policy Framework for Pharmaceutical Production in Bangladesh

Bangladesh has an elaborate institutional structure that acts to facilitate local production and access to medicines. The main agency responsible for registration, quality testing, control and marketing of all pharmaceutical products is the Directorate General of Drug Administration (DGDA). The DGDA usually acts on recommendations for registration of drugs that are made by the Drug Control Committee. The National Drug Advisory Council advises on implementation of the National Drug Policy and the promotion of local pharmaceutical industries. There is also a Pricing Committee (which approves pricing decisions on medicaments) and a Standing Committee for Procurement and Import of Raw Materials and Finished Drugs (GIZ, 2007). In addition to this, the National Research Ethics Committee is responsible for reviewing all clinical trials of medicinal substances and advises the DGDA to ensure that the drugs available in the country fulfil the necessary requirements for safety, quality and efficacy.

The seeds for this elaborate institutional set up were sown by the National Drug Policy and the Drug Policy Ordinance of 1982. Over time, the revisions to the National Drug Policy (2005 and 2016), along with the National Health Policy (2012), National Industrial Policy (2009) and the intellectual property framework have provided much needed impetus to local pharmaceutical production in Bangladesh.

3.1. Back to Where it all Started: The 1982 National Drug Policy and the Drug Policy Ordinance

The National Drug Policy and the Drug Policy Ordinance of 1982 are two policy milestones credited with creating a conducive policy framework for local production in the country. Enacted against much resistance from local medical experts, multinational companies (MNCs) and several industrialised countries, the National Drug Policy of 1982 succeeded in introducing new policy changes, setting out an enforcement framework and providing a drug pricing mechanism that changed the local sector entirely.

3.1.1. Policy changes

The National Drug Policy and the Drug Policy Ordinance of 1982 placed several bans on multinational companies with a view to limiting their supplies in the local market. In the main, it brought about the following changes:[10]

(a) A ban on MNCs manufacturing simple products such as common analgesics, vitamins and antacids. These products were targeted given that they were relatively easy to manufacture, and at the time of the ordinance, accounted for 16% of the total local market.[11]
(b) A requirement that only firms with production facilities in Bangladesh will be allowed to market their products in the country or produce for MNCs under license for those drugs for which there was inadequate domestic supply within Bangladesh. This provision secured two industrial aims:
  • Protection of local firms from undue import competition, and;
  • Linkage between manufacturing of medicines and local employment, investment and technological know-how effects in the sector, thus capturing all direct and indirect economic benefits.
(c) A ban on pharmaceutical product patents and grant of pharmaceutical process patents for only a limited period of protection provided that the pharmaceutical substance in question was manufactured in the country. This provision was stipulated to discourage MNC presence in the country, similar to India's Drug Price Control Order of 1970, which was the starting point of India's pharmaceutical sector.

3.1.2. Enforcement framework

The National Drug Policy of 1982 was flanked by a detailed enforcement framework contained in the Drug Control Ordinance of 1982, which for the first time, brought together all issues of manufacture, importation, quality control, sale, distribution and use of medicines under one umbrella (Azam, 2016). It recognized two main agencies as the key regulators of drugs and pharmacies in Bangladesh, namely: the Directorate General of Drug Administration (DGDA) and the Pharmacy Council of Bangladesh (PCB) (See also, Rachid, 2014).

[10] For a more extensive account of all the policy changes in general, see Azam (2016).
[11] Estimate provided by Dr. Zafrullah Choudhury (who was the architect of the National Drug Policy of Bangladesh), Personal Interview.

The DGDA was set up as the primary focal point for all registration and control of both imports of raw materials and the final finished products. The ordinance stipulated that no drugs could be manufactured or sold locally without formal registration, providing for a new drug control committee and a licensing authority that jointly would control:

(a) drugs that could be imported;
(b) drugs that could be registered for sale, distribution and use in the local market; and
(c) stipulate the prices of drugs sold locally.

DGDA was also vested with the right to suspend or cancel the registration of drugs or impose a fine for lack of compliance with the rules or if there were quality or other issues with the products sold in the local market. Dealing in substandard or unregistered drugs (including counterfeits) was identified as a serious issue with a punishment of five years of imprisonment and fines.

3.1.3. Price controls

The 1982 National Drug Policy also set up a detailed price control system to ensure access to medicines. The implementation of the price control system is conditional on the issuance of a regulatory order by the Ministry of Health, but the DGDA is vested with the mandate of controlling prices of those drugs that are deemed to be under price control. The price control system introduced by the 1982 Drug Policy is unique in the sense that it does not just set the prices of final products but does so on the basis of government control of the prices of all raw materials. The drug pricing system was thus enacted to ensure two essential goals:

- Government control of the price of all raw materials in use by the sector, ranging from APIs to excipients and packaging material. This was initially set up to ensure that the local firms had good and low-cost access to raw materials required for drug production.
- Determination of maximum retail prices (MRP) at which each and every drug introduced in the local market would be sold to ensure access to medicines.

A total of 150 drugs were placed under price control in 1982, which were brought down to 117 drugs as a result of the 1993 Price Control Order. A new update created in 2009 found that of these 117 drugs, an estimated 100 were obsolete and proposed 209 new drugs to be placed under price control in the interests of public health and greater access to medicines in Bangladesh.

For those drugs that are deemed to be essential on the Essential Medicines List, the prices are set on the basis of what the DGDA seems to be appropriate compensation.

3.2. Plugging the Holes: The Revised National Drug Policy of 2005

Although these incentives enabled the development of a number of local pharmaceutical firms (see section 3), by the end of the 1990s, two main sets of challenges remained. On the one side, it was clear that some of the systemic weaknesses in infrastructure and innovation capacity were impacting upon the local pharmaceutical sector. These were, in the main, shortcomings related to efficient manpower, good quality public research institutions, R&D capabilities and biotechnology capacity (Gehl Sampath, 2007; World Bank, 2008).

On the other side, three main impediments for health policy stood out. Firstly, a major shortcoming of the local health sector, glaringly evident by the end of the 1990s, was the lack of quality assurance of locally produced medicines, alongside an observed shift toward the production of those medicines that were outside of the essential medicines list by the local pharmaceutical firms (Islam et al, 2017).

Secondly, the Essential Drugs List was relatively outdated and called for a revision taking into account the rise of non-communicable diseases, such as cancer, diabetes and cardiovascular illnesses, which were becoming widely prevalent in the country. Thirdly, the weaknesses of the Directorate of Drug Administration, which had only two laboratory facilities (in Dhaka and Chittagong), with a testing capacity of 3,500 samples of medicines a year, was also becoming a large issue in ensuring medicines of a good quality of a local market. By the early 2000s, there were around 12,000 samples of different brands of medicines being introduced without tests every year (World Bank, 2008), despite the theoretical requirement in the regulatory framework that stipulated that medicines introduced in the local market should be tested for quality and efficacy twice every year. There were only three technical staff in the Chittagong laboratory and eight technical staff in Dhaka, and the entire country has only 28 post-surveillance personnel, of which 12 are active in Dhaka alone (UNCTAD, 2011).

These capacity constraints also limited the ability of the DGDA to control prices of drugs effectively. Not only did the prices of drugs vary enormously in the local market, calling into question the effectiveness of the local price-control mechanism (Choudhury et al, 2006), there was a broader question of how far the high prices reflected higher quality of medicines (Gehl Sampath, 2007; 2009).

3.2.1. National drug policy, 2005

In an effort to rectify this situation, a New Drug Policy (2005)[12] and a National Biotechnology Policy (2005) were both enacted, and the government also announced plans for establishing an API park. The New Drug Policy (2005) identified, in this regard, some key aims that were targeted to improving the technological base for local production (emphasis added):

(a) to provide, on a priority basis, required services and facilities to local drug manufacturing industries of all the recognized systems of drugs so that self-sufficiency is attained in the manufacture of both drugs and pharmaceutical raw materials;
(b) to encourage foreign manufacturers to invest, manufacture and sell drugs in Bangladesh with corresponding assurance of transfer of new technology and technical knowledge in the country;
(c) to ensure that no discrimination is made between the local and multinational companies, which have manufacturing plants in Bangladesh while applying the principles of this policy;
(d) to encourage both local and multinational manufacturers to establish full-fledged Research & Development (R & D) facilities in the country;
(e) to encourage investors to set up facilities for manufacturing pharmaceutical raw materials in the country; and
(f) to encourage collaboration between universities, research institutes and manufacturers for undertaking basic and applied research in medicine, pharmacy, biotechnology, genetic engineering and biomedical sciences.

The Drug Policy of 2005 set out new objectives aimed at improving the quality of medicines in the local market by introducing the cGMP (WHO's standards for good-quality production of medicines in developing countries) and strengthened the mandate of the DGDA further by providing that the DGDA will strive (emphasis added):

(a) to ensure that the general population has easy access to useful, effective, safe and good quality essential and other drugs at affordable prices;
(b) to strengthen the Directorate of Drug Administration by raising its status to that of a Directorate General of Drug Administration with corresponding increase in its manpower and infra-structure facilities to make it more effective as a DRA;
(c) to update, from time to time, the criteria of registration for import of all systems of medicines in line with the quality guidelines followed in developed countries to ensure safety, efficacy and usefulness of such medicines;

[12] National Drug Policy, 2005 (Bangladesh), 14 July 2010, available at; www.clcbd.org/document/download/53.html

(d) to ban the manufacture, sale and distribution of counterfeit, adulterated and sub-standard drugs and to award exemplary punishment to persons guilty of such actions;
(e) to strengthen the system of procurement, storage and distribution of drugs and medicines so that these are accessible to people in all areas of the country; and
(f) to continue the current system of controlling prices of the commonly used essential drugs as listed and updated from time to time by the Government.

The new elevated status of 'Directorate General' was intended to support the DGDA by granting it full regulatory authority and mandate on matters of drug registration and control, in response to the severe resource constraints that the office had been facing. The Policy also proposed a revised Essential Medicines List, which was enacted in 2009. The policy also introduced toll manufacturing (contract manufacturing), which allows for companies to utilize their existing production capacity to produce drugs for other companies, both local and international.

3.2.2. Reinforcing health and industry objectives: The National Drug Policy, 2016

The National Drug Policy of 2016 introduces some new aspects to bring the policy in line with the National Health Policy 2011 and the National Population Policy 2012. It once again underscores the need to have effective, good quality drugs but also highlights other objectives that remain a major issue in the local health sector, namely:

(a) to ensure rational and safe use of drugs and proper dispensing;
(b) to achieve self-sufficiency in the manufacture of drugs and raw materials by providing services and facilities on a priority basis to all local drug manufacturing industries;
(c) to expand the export of drugs that are manufactured in the country; and
(d) to establish an effective surveillance system for medicines.

3.3. Other Industrial Policy Incentives for the Pharmaceutical Sector

The pharmaceutical sector in Bangladesh has received a number of incentives from the outset, particularly those related to tariff concessions, imports and fiscal incentives for investment, which were all structured through the National Drug Policy or in conjunction with it. Thus, although Bangladesh only enacted its first comprehensive industrial policy in 2009, the absence of such an express policy did not particularly affect the sector. After its recognition as a thrust sector (with priority for export) in 2006, local firms were also granted a number of export policy incentives, discussed at length in this section.

3.3.1. Import concessions

In 1997, the government introduced a 7.5% flat rate of importation on all raw materials (Azam, 2016). Under the Import Policy Ordinance of Bangladesh for 2015–2018, there is an emphasis on easing the imports of all raw materials that are in use in export-oriented industries. The importation of raw materials and packaging materials for the pharmaceutical industry takes place at tariff rates that are much lower than other sectors. The procedures for importation are further facilitated by creating a "block list" of imports for each recognized pharmaceutical company approved by the Directorate General of the DGDA. The block list provides the description of the raw material and packaging material, value and quantity according to the annual production plans of the pharmaceutical companies. The list is prepared as part of product registration, but also provides a basis for setting the final price of the drugs. Companies importing raw materials have to present an import invoice and analysis report of the quality, value and quantity for each import. The analysis report of the raw materials must be certified by the DGDA or be prepared by a government-approved pre-shipment inspection agent (Bangladesh Ministry of Commerce, 2007).

In keeping with the aspirations of the National Drug Policy 2005 and 2016, the government has sought to reduce customs duty on raw materials relevant to the sector. For instance, in the 2014-2015 budget, customs duties on 40 raw materials for use in pharmaceutical manufacturing were reduced to 5% from the prevalent rates of 10-25% (Mohiuddin, 2018). Similarly, the government also introduced custom duties on anti-cancer medications in the 2014-2015 budget which have been continued into the current 2018-2019 budget, which contains custom duty reductions for ninety-seven APIs (Rahman and Farin, 2018; DGDA Interview, 2019).

3.3.2. Investment incentives and tax holidays

Investment incentives were made available to local firms through favourable bank loans in the 1980s and the 1990s that helped them invest in machinery (Amin and Sonobe, 2013). Tax holidays have been provided for pharmaceutical firms ranging between 5 to 7 years, depending on their location (UNCTAD, 2011), on condition that the firms invest the profits back into the sector. Companies are required to invest their benefits from the tax holidays within 2 years from the end of the tax holiday in the same undertaking or in any new industrial undertaking, or in stocks and shares of listed companies, or in government bonds or securities, or for other purposes as required by the Income Tax Ordinance of 1984. Such tax holidays have really helped local firms expand. UNCTAD (2011) notes that large firms like Square and Beximco have benefited from these tax holidays thereby re-investing the profits into larger or newer facilities for pharmaceutical production.

3.3.3. Skills development

In the 1980s, despite the presence of pharmacy courses at the University of Dhaka, local manpower was an issue (UNCTAD, 2011) which was only addressed subsequently. By the 1990s, availability of graduates, trained in chemistry and pharmacy was a really important factor that helped local firms to expand. In fact, accounts show that as the sector expanded, human resources also expanded alongside. As of 2010, there were 12 public and 22 private universities offering Bachelors' and Masters' degrees in Pharmacy (Mazid and Rachid, 2011). Field interviews confirm that the greater demand for manpower in the sector is being met by university graduates in the disciplines of pharmacy, chemistry, biochemistry, biotechnology, microbiology, engineering, marketing and related disciplines, although many firms admitted to the fact that there is a need for more high technology, research intensive work in the sector in the coming years.

3.3.4. Technology transfer and export facilitation in the 2009 Industrial Policy

The 2009 industrial policy targets green field investments in the 2009 Industry Policy of Bangladesh: targets foreign investment to bring about technology transfer, management and marketing skills and to facilitate access to export markets (Ministry of Industries, 2008). An Indian pharmaceutical company, Sun Pharmaceuticals, began its operations in Bangladesh in a "green field" investment in 2007. Interviews revealed that there is not full agreement on opening the market for essential medicines to foreign companies.

3.3.5. Common industry infrastructure

The common API park, which has been in discussion since 2007, was recently commissioned in Munshigunj, 37 kms from Dhaka, with a total area of 200 acres and 44 industrial plots (DGDA, 2019). This is expected to significantly contribute to expanding the capacity of the local firms (Sultana, 2016). The government is also planning to give 10% cash incentives to boost the pharmaceutical sector. In years to come, the sector still needs other forms of common industry infrastructure to expand, particularly to upgrade its bioequivalence facilities, for clinical trials and new drug R&D.

3.3.6. Export concessions

In 1997, a new regulation introduced the notion of refunding value-added-tax when the products are exported. Most recently (January 2019), two new export incentives have been introduced by the Government: a 10% tax concession for export of finished pharmaceutical formulations and a 20% tax concession for export of APIs.

3.4. Bangladesh's Intellectual Property Framework

The Patent Law of 1911 which is in force in Bangladesh has a number of provisions that do not adhere to the Agreement on Trade Related Aspects of Intellectual Property Rights (see Tazin 2016; Royhan, 2013 and Chowdhury, 2014). As it stands currently, it provides patent protection for only 16 years, does not allow patents for plant and animal varieties; allows for compulsory licenses to be introduced by entities other than government; and states that foreign patents can be cancelled after four years if the product is not also manufactured domestically (Gay, 2018).

4. What Really Worked: Looking Beyond the Policy Framework

By all standards, the National Drug policy of 1982 and the Drug Control Ordinance of 1982 were the turning point, often termed by scholars as a "revolution" (Sarker, 2006). The two policies led to a dramatic reversal of the local supply chain. In 1981, there were 166 licensed pharmaceutical manufacturers in the country, but 65% of the products were imported and sold by 8 multinational companies and substandard medicines in the market were estimated to be as high as 36% (World Bank, 2008; p.50). By 1988, Reich (1994) estimates that local companies were producing 69% of all drugs sold locally, and as opposed to just 30% of the drugs on the EML being produced in 1981, 80% of the drugs on the List were being produced (Reich, 1994).

Therefore, not only did the share of the multinational companies fall continuously over the subsequent decades, to reach a low of 10% market share by 2017 (Rahman and Farin, 2018), local production went up from 35% of the local market to 90% by 2007 (Gehl Sampath, 2007; Azam 2016). Table 2 captures the reorganization of the top 10 firms in the market between 1985 and 2019. At the time of the survey for this study, GSK had just closed down its operations in Bangladesh (as of December 2018) and no MNC remained in the top 10 firms in the country.[13]

[13] IMS (2018) data confirms that four MNCs - Aventis, Novartis, Sandoz, Novo Nordisk – are in the top 20 firms in the country.

Table 2: Top ten firms in Bangladesh: 1985 versus 2019

1985		2019	
Firm	**Ownership**	**Firm**	**Ownership**
Square	Local	**Square**	Local
BPI	MNC	**Incepta**	Local
GSK	MNC	**Beximco**	Local
Opsonin	Local	**Renata**	Local
Pfizer	MNC	**Healthcare**	Local
Fisons	MNC	**Opsonin**	Local
Gonoshasthya Kendra	Local	**ACI**	Local
MSD	MNC	**Eskayef**	Local
Ciba Geigy	MNC	**Aristopharma**	Local
Hoechst	MNC	**Acme**	Local

Source: Compiled by author using Amin and Sonobe, 2013 (for 1985) and IMS Q3 Estimates, 2018 (for 2019).

Normally, there are fixed costs associated with setting up production capacity in the pharmaceutical sector, where economies of scale and scope are the primary factors that lead to longer term reduction in price for drugs. A major criticism levied against large-scale investments into the pharmaceutical sector in developing countries has been that in the absence of clear markets and firm-level capabilities to reap those economies of scale and scope (which often cannot be guaranteed), local production may simply end up transferring the costs of producing these drugs locally to the consumer. This would imply that local production does not result in access to good quality medicines affordably (Kaplan and Laing, 2005) or alternatively, setting up local production may result in flooding the local market with products of *dubious or secondary quality.*

Setting up production capacity might result in greater costs of drugs in the short-term or mid-term if there is no critical governmental support by way of: (a) providing a conducive environment; (b) coordinating the industrial development of the sector with access to medicines. Many developing countries have not managed to create a link between the industrial development of the pharmaceutical sector (which has profit goals) and access to medicines (WHO, 2011).

In these cases, well-meaning policies were unable to achieve the goals of promoting pharmaceutical production or of balancing local production with access to medicines. Has Bangladesh's experience been different? What sets it apart? This section offers a summary of the factors that made the policies a success, then follows it up with the challenges that remain and the best practices that can be drawn from it.

4.1. Best Practice 1: Integrate Industrial and Drug Policy Visions

Economic development is as much a political as it an economic process. In Bangladesh's case, pharmaceutical self-sufficiency was made possible through a visionary policy-making process that integrated industrial and drug policy goals from the start. As Section 3 shows, Bangladesh chose the unusual policy path of providing industrial incentives either within or in conjunction with the national drug policy. This, on the one hand, helped give local production a boost since it was guaranteed a stable access to domestic market. On the other, it enabled the government to exercise control on pricing and availability of drugs.

Thus, although the impulse for local production stemmed from the need to promote access to medicines, the sector has been prioritized as an industrial sector continuously since 1982. Review of national debates and documentation shows that it has been high on the agenda, as part of a sovereign economic development vision of the country and remains a discussion point within national debates on a number of issues, ranging from production capacity, employment, skills building, drug prices, vaccine production and most recently, export revenues.

4.2. Best Practice 2: Embed the Sector in the Local Economy

A second success factor is that Bangladesh's pharmaceutical sector is embedded in the local economy in two ways, both of which have played a critical role in its performance. The sector was primarily responsible for the healthcare needs of the country, and this ensured that the domestic consumer base was guaranteed to local firms seeking to make investments. Secondly, the success of the sector is firmly rooted in the country's economic performance, which over time, has provided the sector opportunities for investment, expansion and export, enabling a synergetic relationship between the sector's expansion and economic growth; constantly guaranteeing a longer-term outlook for the firms.

Guaranteeing the domestic market and promulgating incentives for the firms over a longer period of time is important from many perspectives. First, it enables firms to make longer term decisions when governmental action is lax or too bureaucratic. A good instance is the case of the API park, which has been in the works since 2007. In light of several delays in making this a reality, large local firms moved to raise bank loans to invest themselves in API production facilities given the generally positive economic climate for the sector within the country. Second, it helps firms recover from macroeconomic (currency related) shocks that negatively affect their operations given their extensive reliance on imported raw materials. For instance, field interviews revealed that firms face extreme pressures in API sourcing, where prices can fluctuate widely depending on the number of producers and global demand.

4.3. Best Practice 3: Enable Systemic Capabilities for the Emergence of the Sector

Securing the local market alone does not help create local production capacity. A number of other parameters work hand-in-hand in enabling production capacity. In the case of Bangladesh, this conducive environment, as discussed at length in Section 3, included the gradual availability of man power, investment incentives, a favourable importation regime, domestic market access, access to other industrial inputs (land, electricity, etc.) and a favourable policy environment. This allowed the firms to build backward (for supply of raw materials, some of which are now being produced locally) and forward linkages (through exports and domestic sales).

4.4. Best Practice 4: Interpret Policy (and Use Ambiguity) in Favour of Local Firms

Another best practice that worked in favour of national firms is the consistent interpretation of policy in favour of the local pharmaceutical sector. For example, the term 'enough local supply' that was a pre-requisite to ban foreign importation in the context of the 1982 National Drug Policy was taken to mean: three or more local firms producing nationally. As a result, the moment there were three national firms producing a particular product, imports were automatically banned. This policy remains in force, and sometimes risks being interpreted too much in favour of national companies in certain instances (field interviews). For example, the recent closure of the GSK plant in December 2018 has resulted in a short supply of Rabipur (a rabies vaccine) and Varilrix (chicken pox vaccine). Rabipur is currently being manufactured by Incepta but there remain concerns regarding its quality and widespread availability in the country (See Azad el al, 2018).

The IPRs regime has also been interpreted in favour of local production. Furthermore, when the sector came under heavy criticism in the early 2000s and later, for reasons of not complying with stringent production requirements (see World Bank, 2008), the policy response was to try and strengthen the collaboration between the DGDA and the local firms to help implement cGMP practices.

4.5. Best Practice 5: Co-investment and Co-competition by the Government

Similar to the case of India in the 1960s, Bangladesh's Government set up national pharmaceutical companies for the production of medicines. In the initial years, these companies worked side-by-side with local companies. Currently, only one of these companies, Essential Drug Company Limited, continues to manufacture, but it still supplies medication or procurement by the Central Medical Stores as part of the publicly funded health care system.

4.6. Best Practice 6: Enable Technology Transfer and Entrepreneurial Spin-offs

A highly important, but under-appreciated, aspect of Bangladesh's success is the role of technology transfer and tacit know-how that helped local firms build capacity in the initial stages. In the 1980s, a number of local firms began producing pharmaceutical products through licensing arrangements for MNCs. Square, for example, attributes its success to licensing arrangements with Jansen Pharmaceuticals. Companies also employed managers or high-ranking employees of large MNCs who suddenly found themselves unemployed thanks to the New Drug Policy, and thus benefited from tacit know-how. Table 3 shows how several of the top 10 companies today benefited from licensing arrangements and takeovers of large MNCs.

Azam (2016, p. 94) notes how local firms conduct a number of R&D activities related to reverse engineering. Field interviews show also that local pharmaceutical firms continuously engage foreign firms in their private capacity as consultants, or also recruit a number of expats to increase their R&D capacity currently.

Table 3: Technological Acquisitions in the Bangladesh Pharmaceutical Sector

Square	Square entered into a third-party licensing arrangement with Jansen Pharmaceuticals of Belgium (a subsidiary of Johnson and Johnson, USA) in 1974, which went on well into the 1980s.
Beximco	Beximco had licenses for two major foreign multinational corporations – Bayer AG (Germany) and Pharmacia & Upjohn Inc. (United States) in the 1980s.
Healthcare Pharmaceuticals	Healthcare began in 1988 as a distribution company in association with Roche (Bangladesh) Ltd, and until 2001 was only importing and distributing products for Roche.
Eskayef Bangladesh Limited	Eskayef was the successor of Smith, Kline and French in Bangladesh, until it was acquired by Transcom in 1990.
ACI	ACI emerged through a management buyout from SC Johnson and Son, when it sold its insecticide business and merged with AstraZeneca in 1982.
Renata	Acquired Pfizer more recently in 2006.

Source: Compiled by author through field interviews.

4.7. Best practice 7: Ensure the Co-evolution of Policy Incentives

Promoting the emergence of a local pharmaceutical sector is a long-term policy goal; one that calls for constant policy monitoring, revision, and updates. Co-evolution of policy is required to set the direction, and to continuously calibrate the sector's performance with the broader needs for access. An overall review of the sector in Bangladesh shows that there remain persistent shortcomings relating to quality control and monitoring of pharmaceuticals and vaccines, which in the current context, stem from an extremely dynamic and fast-paced private sector that often rent-seeks, i.e., lobbies with the government to protect its revenues and profits with the government through grants, subsidies or other forms of measures that can affect the relative positions of the firms in the sector. The DGDA is still relatively under-funded for the task that it is expected to accomplish, and there still remain failures of co-ordination between health system issues and pharmaceutical production (see discussion in Section 5). Despite all this, policy continues to co-evolve with the sector in a continuous fashion. Some of them, such as the provision of toll manufacturing (contract manufacturing) in the 2005 National Drug Policy were clearly intended to allow companies to engage in achieving total factor productivity by using their plants to produce on demand for competitors in country. Such practices also enable cooperation amongst firms and other stakeholders in the local pharmaceutical innovation system.

4.8. Best Practice 8: Involve the Private Sector in Discussions on the Future of the Sector

Interactions between the pharmaceutical firms and the Government have often been criticized in Bangladesh on the grounds of rent-seeking and favour mongering (see discussion in 4.7 above). Currently, for example, the BAPI president is a Member of Parliament in Bangladesh and is an advisor to the Prime Minister. The tendency to curry favours notwithstanding, this is an essential element of good policy making for any sector, especially one that is as resource and technology intensive as the pharmaceutical sector. Strengthened interactions between the private sector and policy making have worked well in recent years on many fronts, such as on issues of training and requirements for regulatory approvals, which the DGDA remains committed to enable.

5. Impact on Drug Pricing and Access to Medicines

There has been a primary reliance on developing a local pharmaceutical sector to ensure access to medicines. The government of Bangladesh invests a very small percentage of its GDP in public health (0.36 UD per person according to WHO estimates). It has the largest out-of-pocket expenditure in all of South Asia on medicines, currently estimated at 64.3% of the total health expenditure of the country. This accounts for several shortcomings that the sector is facing today with regard to being able to liaise with the health sector today.

There are two systems of drug pricing in Bangladesh. First, for those drugs contained in the essential medicines list, a maximum retail price is set by the DGDA. For the other products sold on the market, there is an indicative pricing system. This section discusses the main issues in the development of these pricing systems, their effectiveness, observed retail margins, and presents some key lessons.

5.1. Pricing Instruments

All drug pricing works through the 'block list', which is a meticulous record of imports maintained by the DGDA recording the prices of raw materials procured by the local firms. For those drugs on the essential medicines list, the DGDA sets the maximum retail price (MRP), which takes the prices of the raw materials and simply provides a mark-up to the firms as profits for producing those medicines. For imported finished products, the price is calculated by the DGDA by allowing a markup on the costs and freight price to calculate the maximum retail price. The breakdown for the imported products includes trade price (88.89%) and retail commission (11.11%) (DGDA, 2019; Rahman and Farin, 2018).

For the medicines that are not on the essential medicines list, an indicative price is fixed by the DGDA. This indicative pricing does not have health or access to medicines considerations, but rather, derives its significance from a national revenue requirement that states that all products must pay value-added-tax at source (when leaving the factory premises). In the case of pharmaceutical products, this implies that an indicative price needs to be set out at the start of the process. Thus, when firms apply for registration, the Drug Approval Committee of the DGDA sets the indicative price.

A best practice in this context is to closely monitor the prices of the raw materials to set the prices of the medicines. The system of monitoring the prices of the raw materials for the final product prices for those drugs on the essential medicines list has definitely had some success in Bangladesh, especially up until the end of the 1990s. There are at least two reasons why these effects have not been sustained over time. One reason, as WHO (2015, p.27) notes, is that Bangladesh's essential medicines list has some "…. surprising inconsistencies". While the country has seen a steady rise in non-communicable diseases, only 37 of the total of 209 drugs that are currently on the list are for non-communicable diseases (Islam et al, 2017). A second reason for the relative ineffectiveness over time is that the prices of a number of drugs on the essential medicines list have not been revised by the Government. Their prices have remained unchanged for over two decades, despite significant rises in the importation costs of raw materials and fixed costs of production. This has forced several pharmaceutical companies to cease manufacturing, and there are other cases where companies have continued to manufacture while they cross-subsidize the production of these drugs by charging higher indicative prices for products that are not on the essential medicines list.

Lessons: Essential medicines and their prices need regular monitoring.
Firms need to be accountable for the production of these drugs.

5.2. Issues with Drug Pricing and Quality

Regulatory requirements in Bangladesh do not necessitate bioequivalence and a number of new requirements such as cGMP practices and clinical trials for vaccines are only now being introduced.

Thus, although Bangladesh's pharmaceutical firms produce generic versions that are much cheaper than the prices of drugs elsewhere, two caveats need to be exercised while discussing drug prices. Firstly, the local firms cannot compete, in pricing terms, with large companies in India and China due to the fact that these companies produce their own APIs, while Bangladesh's firms must buy APIs from external sources in order to formulate their drugs. Therefore, studies show that India and China are the lowest-cost producers of several drugs, including those that are on WHO's essential medicines list (Hill et al, 2018). Secondly, the issue of price comparison is valid only when products of similar quality are being compared.

Interviews show that a large number of firms have continuously increased capacity over the last few years and many are in the process of doubling their current production capacity. Despite the growing demand for medicines, due to general economic growth in the country, it is this expanding capacity that has kept the prices relatively low (Sonobe et al, 2018).

In an effort to control prices, the DGDA has also introduced a more stringent interpretation of the indicative pricing system, whereby the indicative price for the past two years is set on the basis of the first firm that introduces a new product to the market. Thus, the other firms who enter the market in these new segments undercut the price and this keeps prices from becoming too high. This system, however, is not without its own flaws. One disadvantage of this system is that it creates a race amongst the firms to become the first to introduce a generic version of a medicine that is not available locally, based not on quality, but based on the incentive of being able to negotiate the price with the DGDA. A second disadvantage is that firms that subsequently enter the market do not get to charge a higher price than the first firm, even if they use higher quality raw materials and/or produce the product at a higher standard, since quality is currently not the determining aspect of the price. A recent study by BRAC notes two instances where the medicines, when tested by third parties, exhibited poor quality. Out of 20 tested zinc syrup formulations, only 2 were found to conform to specifications, whereas a third-party testing (by UNICEF) of 11 drugs in Australia, revealed 2 were fakes (Rashid, 2016).

Despite these reservations, existing pricing data shows that firms are selling the generic sofosbuvir at USD 6 as opposed to USD 1000 for the original brand (12-week dose). Similarly, Harvoni is available for USD 12 as opposed to USD 1130 for the original brand (12-week dose) (BAPI, 2017). Similarly, the anti-cholesterol drug Crestor is available at 0.25 USD as opposed to 7.25 USD (BAPI, 2017). Additionally, what does not seem to be working well for drug pricing and access is the system of direct marketing that the firms engage in, as discussed in the next section.

Lessons: A more sophisticated drug pricing system with effective monitoring is required for those drugs that are not on the essential medicines list if access to medicines is the goal.

5.3. Problems of Drug Distribution and the Ills of Direct Marketing

Firms sell their medicines directly to pharmacies or through doctors' prescriptions (as outlined earlier in Section 2.4). This leads to a large, wasteful expenditure on the part of the firms for marketing: most firms interviewed suggested they spend around 15% of their investment on marketing their products.

In general, the production of all drugs follows a "me too" style, meaning, primary drivers of a product's success in the Bangladesh market are price competitiveness and distribution efforts. The shortened supply-chain from the firm directly to the pharmacy/ doctor and then to the consumer means that the gap between factory price and consumer price can often be over 1/3 of the total cost at which it is sold, enabling firms to recover huge profit margins, especially in the absence of stringent regulatory requirements. Rahman and Farin (2018) similarly compare the pricing of products on indicative prices and find that for all products on indicative pricing, the retail price can be broken up into trade price (75.5%), wholesale commission (2.3%), retail commission (12.0%) and value-added tax (VAT; 12.5%). The retail commission is almost the same in the case of imported products (see Section 5.1).

Thus, there are two things at work. On the one hand, for those products that are on the essential medicines list, there is a fixed price that remains the same (often since the 1990s), despite rising costs of firms (see Dey et al 2013). But at the same time, there are other product categories where firms can earn huge margins as discussed above.

Firms, consequently, engage in soliciting doctors and pharmacies through lumpsum payments, direct cuts in prescriptions and gifts. These are unregulated and impact upon the efficacy of the essential medicines list. Rashid (2016) notes in this regard that Beximco Pharmaceuticals has 1,200 people visiting pharmacies daily to take orders for drugs. Because doctors work for pharmaceutical companies, gaining from the prescriptions often to the detriment of the patient, many of these medicines are not widely prescribed by doctors since pharmaceutical companies do not have wide margins in these product categories. Physicians instead, prescribe more expensive drugs (Islam et al, 2017). WHO (2015) estimates in this context that at least half of all the drugs prescribed in public sector hospitals are not those contained in the essential medicines list despite policy mandating that the majority of drugs prescribed should belong in the essential medicines list. It also leads to over-prescription of drugs and testing services where firms have high profit margins at the expense of consumer benefits or needs.

The DGDA, despite its strengthened capacity, needs further reinforcements to tackle these ills. A closer coordination between the pharmaceutical and health systems is also needed to eventually curb these malpractices, so that checks and balances exist for how drug prescription and patient care interact with a thriving private sector that can produce medicines locally. Ethical practices of doctors and pharmacies and how they tie in with marketing of firms will need to be curbed, especially in light of Bangladesh's impending graduation from the LDC category, which will lead to a partial or total opening up of the markets (Razzaque, 2018).

A number of other evils in the health systems area worsen these effects. The drug distribution network comprises small independent pharmacies, but interviews revealed large gaps in pharmacist training, a propensity to dispense medications directly to consumers especially in rural pharmacies and a lack of accountability of rural doctors. Pharmacies often only stock those medicines where they can make large personal gains, while none of the pharmacies restock medicines that they consider a slow item (Rashid, 2016), and this extends the issues of corruption in drug prescription and drug distribution. Another large problem in this regard is the existence of unlicensed pharmacies – interviews with the Pharmacy Council of Bangladesh revealed that while there are a total of 120,000 licenses for pharmacies issued in the country, it is estimated that there are over 250,000 pharmacies in the country.[14] The government is seeking to address this through the new Model Pharmacy Initiative that aims to equip 500 pharmacies with graduate pharmacists in the country. There is also a System for Improved Access to Pharmaceuticals and Services (SIAPS) project being implemented by the DGDA in conjunction with the Ministry of Health and USAID to improve pharmacy infrastructure, administration and training.

Lessons: Direct marketing of drugs results in several serious malpractices that undo the benefits of local production and commercialize the health system in undesirable ways. Pharmacies and doctors need stringent guidelines, and the government needs a series of checks and balances to ensure that firms do not undermine access goals.

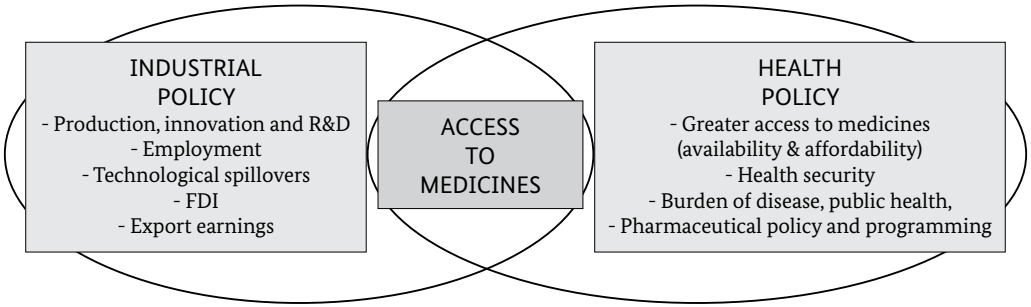
[14] Rashid (2016, p. 28) similarly notes that although there are approximately 300,000 private pharmacies in Bangladesh, the government has only 26,000 pharmacies officially listed.

6. A Toolkit for Local Pharmaceutical Production: Recommendations for the East African Region

Policy-makers around the world continually struggle to balance health policy objectives (that is, access to affordable and essential medicines of a good quality) with industrial policy objectives (e.g., promoting local production, innovation and technical change) in the pharmaceutical sector. As in Bangladesh, the tensions are numerous, and largely centre on promoting a domestic pharmaceutical sector and achieving the right kind of pricing mechanisms to ensure affordable access.

For countries seeking to embark now with ambitious strategies for local production, or for others who are working to expand on their relatively small production capacity, the case of Bangladesh is illustrative for several reasons. Bangladesh was ranked the second poorest country at the time it embarked on this strategic policy aimed at greater health access (Reich, 1984). However, the Government did not resolve the tradeoff between higher product prices in the short- or mid-term and greater access to medicines by promoting the lowest cost medicines from existing generic global suppliers. Rather, it sought to focus on creating a critical capacity in the local pharmaceutical sector through a series of coordinated policy incentives.

Figure 1: Industrial and Health Policy Balance



Source: Author

The best practices in this regard, which led Bangladesh to build local production capacity, have been identified in Section 4. However, a number of those possibilities, ranging from the possibility of entirely restricting foreign participation in the local market and the assurance of a large, in-country, domestic market is not available to East African countries. But at the same time, a number of other trade and technological parameters have changed, calling for reinforced and a more coordinated focus on policies that can form part of a tool kit for promotion of local production capacity as set out in Table 5.

This tool kit draws on the best practices identified in the study to suggest a number of policy interventions that can be tailored through specific policies (also identified in the tool kit) to promote three key goals:

(a) creating an enabling environment for local production
(b) ensuring local markets to domestic firms
(c) promoting local production/ local imports for greater access to medicines.

Table 5: Policy Toolkit to Promote Pharmaceutical Production in the East African Region

Policy	Objectives	Instruments	Actions
1. Create an enabling framework for local production	1. Coordinate policy across the spectrum	National Science and Technology Policy Investment Framework Technology transfer policy National Development Plan National Health Policy	- Create a forecast of firm level capabilities and their needs - Ensure coordinated promotion of local firms and their priorities for investment, technology transfer, industrial growth - Establish linkages with national health policies in terms of goals and actions - Provide incentives that allow firms to collaborate to create new products, processes and also enable contract manufacturing across the pharmaceutical value chain.
	2.Generate systemic enablers	National Science and Technology Policy	- Identify R&D priorities and financial incentives for public research. - Increase public R&D funding and ensure that it is spent with relevance for the industry. - Set out a public sector R&D map identifying priorities of relevance to pharmaceutical research and a plan to develop this capacity - Allocate public sector funding only subject to research plans that match the ambition in the newly specified public sector R&D map. - Promote skills and knowledge building for applied research in pharmacy and related disciplines of relevance to pharma, such as chemistry. - Ensure collaborative linkages between local firms and local R&D institutes through research grants, and other specific performance incentives. - Strengthen the role of national R&D institutes to perform drug related research and attract relevant technology transfer.

Policy	Objectives	Instruments	Actions
2. Create a local market for local production	1. Promote a gradual but definite share of local firms in the pharmaceutical supply chain	Industrial policy National Health Policy Drug Procurement Guidelines	- Recognize the pharmaceutical sector as a priority sector for industrial development. - Provide investment and importation incentives to local firms - Ensure imports of raw materials for key pharmaceutical products at zero tariffs - Streamline processes for permits, port storage and improve general infrastructure, with a view to offer one-stop license for port, storage and transport for local firms. - Provide SEZs or other economic benefits to local firms in the pharmaceutical sector. - Provide industrial production incentives such as tax holidays, formulation grants, etc. – to encourage local firms. - Engage and work closely with local firms to provide training and assistance on plant practices and production techniques. - Provide specific rules that mandate re-investment of profits earned through local tax and other incentives into the pharmaceutical sector.

Policy	Objectives	Instruments	Actions

	2. Create a fair playing field between foreign firms and local companies		- Set clear goals for the shares of the market that should be occupied by local firms over the short term, mid-term and long term.
			- Segment the market through policy such as the 1982 National Drug Policy and enable the local firms' exclusive access to certain production segments.
			- In therapeutic categories reserved for local firms, set out licensing requirements from foreign firms to local firms, with a view to promoting:
			  ○ Production capacity
			  ○ Technology transfer
			  ○ Better standards of local production
			- Ensure, through the national health policy and drug procurement guidelines that national producers are offered assistance and prioritized in local procurement.
			- Provide a dual drug registration system, specifying favourable registration rates to local firms.
			- Provide cGMP-related technical assistance to enable them to improve quality control and quality assurance processes.
			- Use all TRIPS flexibilities as much as possible in favour of local production.
			- Establish / mediate agreements between MNCs/ foreign firms and local companies for technology transfer and licensing of products.

Policy	Objectives	Instruments	Actions
	3. Promote forward and backward linkages between the pharmaceutical sector and the local economy	Industrial Policy Investment Policy Trade policy National Science and Technology Policy	- Promote the emergence of ancillary sectors for packaging, testing, API production and biotechnology in the country or at the regional level. - Increase regulatory harmonization in the region, to allow firms to easily sell and pool demand in neighboring markets. - Promote acceptance of locally manufactured drugs - Co-invest in firms/ or in the sector at the governmental level to signal confidence and legal certainty for the local firms and banks.
3. Support good quality medicines and affordable prices	1. Promote local production or local supply for greater access	Industrial policy National health policy	- Update the Essential Medicines List with provision for regular revisions based on the disease profile of the country. - Provide for a new differential pricing scheme with restricted pricing that needs to be provided by drugs that are imported/ locally produced. - Incentivise local production of those drugs in the essential medicines list. - Negotiate actively for other drugs that are not on the essential medicines list with the aim of ensuring drug supplies form the cheapest suppliers, amongst MNCs or other firms. - Generate more effective guidelines to control and actively monitor marketing practices, and safeguard ethical behavior by doctors.
	2. Increase collaboration between the DRA and other health agencies and the local firms.	Health Policy National Procurement Guidelines	- Promote close collaboration and trust building between local firms and the DRA. - Promote the participation of local firms in boards of pharmacy, and drug committees formed by the DRA. - Allow for extensive interaction and training of local firms by DRA on a constant basis. - Create capacity in the DRA to advise companies on regular upgrading activities.

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