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Making Medicines in Africa: An Historical Political Economy Overview

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Introduction

This chapter sets out to show that, contrary to widespread misperception, pharmaceutical manufacturing in Sub-Saharan Africa is an established industry with a long history dating back at least to the 1930s. Data for the industry on the subcontinent are fragmented and incomplete (Berger et al., 2009; UNIDO, 2010a; 2010b; 2011a; 2011b), and this chapter and this book contribute to building a coherent historical picture and evidence base. This chapter presents some illustrative historical evidence, drawn from secondary data, reports and fieldwork by the authors and colleagues, as well as academic and non-academic literature.[1] We show that neither industrial capabilities in pharmaceuticals nor policy frameworks to support local pharmaceutical manufacture are a new phenomenon on the subcontinent.

The chapter takes an historical political economy lens to the development of the pharmaceutical industry, providing an overview and then examining three countries' industrial history in more depth. By a 'political economy lens' we mean a view of the evolution of the industry that replaces it within its historical political and economic context. Pharmaceuticals share many elements of the broader African experiences of industrialization. The industry also has, however, some very specific characteristics concerning technology and markets.

This chapter briefly traces the pharmaceutical industry's genesis and development in the context of colonial political history, independence and post-independence industrialization. We trace the development of the industry during the era of import substitution policies in the 1960s to 1970s, the economic crises of the 1980s and early 1990s, and the industrial rebuilding from the 1990s onwards. Some key political economy

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themes that are developed throughout the book are introduced here: the current context of international market liberalization, initiated in the era of economic crisis and structural adjustments policies, and its implications for manufacturing investment; the varying role of multinational corporations' (MNCs) investment in local manufacturing in Africa; the co-evolution and integration of the pharmaceutical industry with other manufacturing and industrial sectors; and the insertion of this relatively high-technology sector into local and international innovation systems and policies.

The chapter begins with an initial historical overview, based on firm-level evidence from nine Sub-Saharan African countries. It then compares and contrasts the industrial history of pharmaceuticals in three case study countries, Tanzania, Kenya and Zimbabwe, for which we have field data. These three countries cannot represent the highly diverse industrial history of Sub-Saharan Africa (henceforth often referred to as just Africa). Rather, they provide support and background for some of the generalizations suggested by the overview, and identify some illustrative similarities and differences in the pharmaceutical sector's roots and evolutionary trajectories across African countries. The case studies also identify a number of themes explored in depth in the rest of the book.

Pharmaceutical manufacturing in Africa: an historical overview

There has been substantial academic and policy questioning of the feasibility and desirability of African local pharmaceutical production (Kaplan and Laing 2005 is one of the most widely cited sources). We begin by countering this perception with evidence that pharmaceutical manufacturing companies have been setting up production facilities and manufacturing medicines in Africa since the 1930s.

A sketch of a pharmaceutical investment timeline

Figure 1.1 shows a time line of the pattern of establishment of pharmaceutical firms across different political and economic geographies on the African continent. It is drawn from a data base of start-up dates for manufacturing by larger pharmaceutical firms in a number of the major manufacturing countries in Sub-Saharan Africa, including South Africa, Nigeria, Kenya and Zimbabwe, and also some countries with smaller manufacturing sectors: Tanzania, Botswana, Uganda, Ethiopia and Ghana.

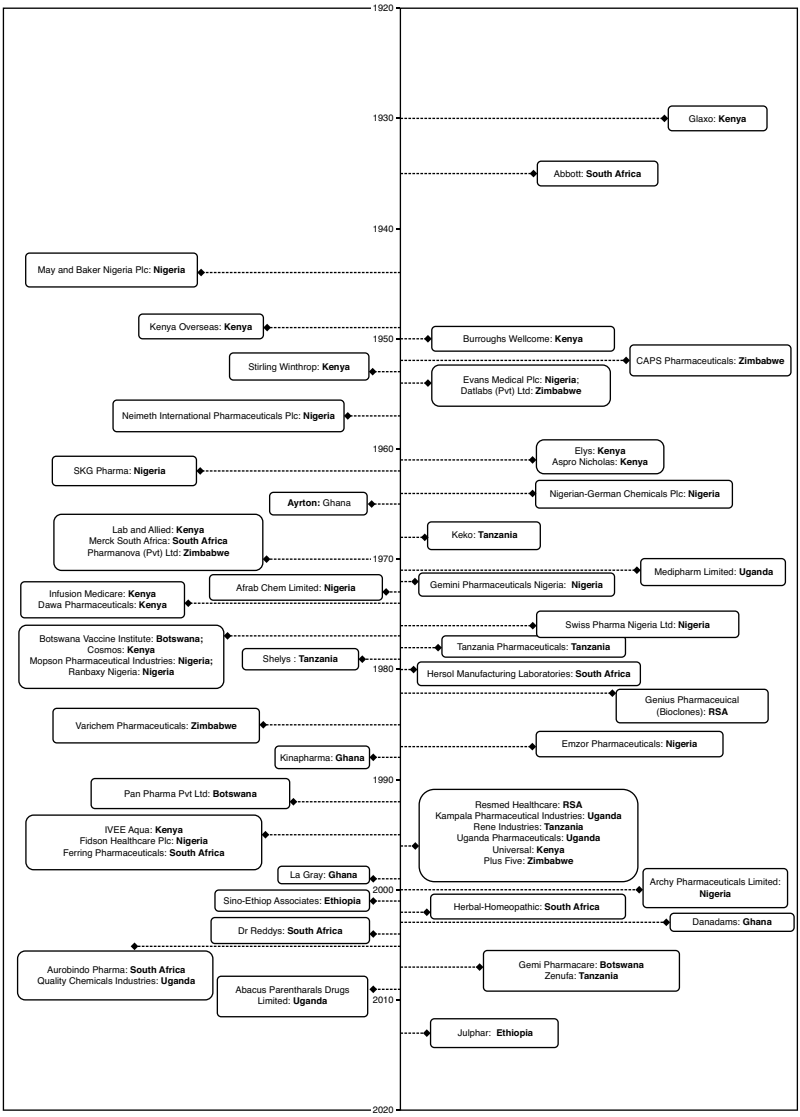

Figure 1.1 A timeline of selected pharmaceutical firm start-ups by country, 1930–2013

Source: drawn by author from created database.

The genesis of local pharmaceuticals manufacturing in South Africa, Nigeria and Kenya appears here as linked to multinational European companies setting up subsidiaries in colonies. In South Africa, Abbott was set up in 1935; in Nigeria, May and Baker was established in 1944; and in Kenya, Glaxo set up shop in 1930 (Figure 1.1). The whole period from 1930 to 1960 shows a slow take-off of local manufacturing in Kenya, Nigeria, South Africa and Zimbabwe. Historically these are the leading industrial countries in Sub-Saharan Africa. Local pharmaceutical industry set up did not occur in isolation, but was contemporary with the rise of other industrial sectors that supported mining and agricultural processing industries. Some of this industrialization was driven by pre-war supply chains with colonies and the disruptions of supplies during World War II.

Figure 1.1 suggests two major bursts of activity in setting up pharmaceutical firms. The first is the 1970s, starting in the 1960s and building up. Then there is a gap in the 1980s and early 1990s, when the rate of start-ups slows almost to zero. The second major burst of activity is from the mid-1990s and continuing into this century.

For most of the countries in Figure 1.1, the 1960s and 1970s were the early years of independence. Across the subcontinent, this post-independence era was characterized by efforts to tackle the challenge of industrialization and growth. Common approaches to industrial policy, promoted also in the development economics and planning literature, mixed public sector investment with import substitution policies, as briefly described in the case studies below. These were years of active developmental states in Africa (Mkandawire, 2001), which were also investing in public sector health and education provision to address the colonial legacies of inequality and discrimination. Domestic production of medicines, by public sector firms and locally owned private companies, found a market in expanding health sector demand.

By the late 1970s, however, this industrial development model was in trouble, and the impact of the economic crisis is reflected in Figure 1.1 by the dearth of new industrial investments in the 1980s. Key events included the oil crises of the 1970s, which severely inflated import bills, undermined balance of payments and fiscal balances and slowed down industrial activity through lack of foreign exchange. The early 1980s were years of severe economic crisis in many countries, exacerbated by severe drought.

The response across much of Africa took the form of structural adjustment programmes, linked to International Monetary Fund fiscal support and requiring extensive privatization and liberalization of trade. The

timing varied: Ghana, for example, embarked on structural adjustment as early as 1983, whereas Zimbabwe only started in 1991.

The 1980s and early 1990s were, as a result, a period of deindustrialization across much of Africa. Previous industrial gains were eroded in many countries, and economic growth turned to decline, while health and education also suffered severely (Cornia et al., 1987). This is the context for the pause in industrial investment evident in Figure 1.1: the case studies that follow add some detail on this period, including the fate of existing firms and the distinctive experience of Zimbabwe.

From the mid-1990s, Figure 1.1 shows industrial investment in new pharmaceutical plants restarting across many countries. Much of this investment was by local investors. In some countries after independence, local entrepreneurs with working experience gained in multinational companies set up their own production facilities, a phenomenon not dissimilar to the Indian pharmaceutical industry evolution.

Pharmaceutical manufacturing capabilities in Africa: an overview

In 2005, a survey found that 37 of 46 African countries possessed some pharmaceutical manufacturing capability (Berger et al., 2009). Since then, numbers and activity have continued to expand (Figure 1.1). Almost all this manufacturing capacity produces generic medicines. Generic medicines are copies of originator or innovator branded medicines; generics have the same dosage form, therapeutic effect, delivery route, known risks and side effects as the originator drug. Local manufacturers in Africa import active pharmaceutical ingredients (APIs) and excipients mainly from India and China (UNIDO, 2010a; 2010b; 2011a; 2011b). Active pharmaceutical ingredients are the therapeutic component of the drug, while excipients are pharmacologically inactive substances used as a carrier for the active ingredients of a medication or as lubricants during the manufacturing process. Local firms import plant, equipment and machinery from India and China, while analytical equipment is sourced mainly from high-income countries such as Germany. Only South Africa and Ghana had built some technological capabilities to manufacture APIs locally, according to the 2005 survey (Berger et al., 2009), though other countries are now seeking to do so as well (see Chapter 7).

The pharmaceutical technologies in use, and the range of pharmaceutical drugs manufactured in African countries, are extensive. Firms have progressed from producing basic tablets and capsules to more complex technologies such as layered and sustained-release tablets. Product portfolios include suspensions and creams, syrups for children, sprays

for inhalation and a range of sterile products such as injectables and ophthalmic preparations. The range of medicines includes anti-pain, anti-infectives including the penicillins, anti-worms and anti-virals, including anti-retrovirals for HIV/AIDS. There is a concerted effort to move into more products for chronic diseases such as hypertension and diabetes that are on the rise, implying a growing market.

Three indicative country case studies

The rest of this chapter briefly compares the industrial evolution of the pharmaceutical industry in three contrasting countries: Zimbabwe, Kenya and Tanzania. We show that their pharmaceutical sectors did not arise in isolation: in each case, the pharmaceutical industry co-evolved in important aspects with the broader industrial development. National patterns of industrial growth and periods of deindustrialization, along with shifts in industrial ownership and financing, are reflected in pharmaceutical firms' evolution. Broad industrial, macroeconomic and political economy influences are shared across industries in national industrial histories.

However, pharmaceuticals also display distinctive industrial characteristics that are observable across countries. The most striking are the technological challenges embodied in pharmaceutical production; the increasing regulatory impact on the African-based industry; and the implications of the health sector structure and funding, including the rise of donor funding, on the evolution of the local industrial structure. These issues are all explored in depth in the rest of the book. Here we present a comparative sketch of three pharmaceutical industrial histories, as an introduction to the analyses to come.

These historical sketches also employ some key concepts that will be used throughout the book, notably the concept of industrial capabilities. Given the high-skill, technologically demanding requirements of pharmaceutical production, as compared to widely produced consumer goods in these countries, the technological capabilities of the firms are key to their efforts to sustain competitiveness. By 'technological capabilities' we mean a set of skills and information the firm requires to operate a given technology and its associated organizational system efficiently (Wangwe, 1995). Firms' competitiveness in pharmaceuticals depends on their ability to obtain, absorb and use technological knowledge, capabilities which build on past skills and knowledge to cumulative effect. Successful firms' capabilities evolve from simpler to more complex activities in investment and process and product engineering (Lall, 1992).

Zimbabwe: the loss of early industrial advantage

There are elements of triumph and tragedy in the industrial history of Zimbabwe. As early as 1990, it was, after South Africa, touted as the next newly industrializing country (Pangeti et al., 2000; Phimister, 2000). The well-established and vibrant manufacturing sector was one of the most advanced and diversified in Africa (AfDB, 1994), contributing 30% to GDP and accounting for 35% of the country's gross export earnings. There were extensive linkages between manufacturing and key economic sectors such as mining, finance and agriculture. The manufacturing sector evolved to supply mining and agriculture, leveraging an extensive infrastructure (Mlambo, 2000; Phimister, 1988; 2000). Zimbabwe therefore provides a narrative of a pharmaceutical sector that arose in integration with other manufacturing and service sectors, illustrating the importance of linkages and support structures in an economy.

Early import substitution

The distinctive history of Zimbabwean manufacturing results from its political history and the related push towards industrial development through import substitution. The legacy begins from the Second World War era. Before then, the country was a destination for British and South African manufactures. During the war, the blockade of traditional trade routes from Britain and the resultant shortages prompted local industrial diversification and accelerated growth of local manufacturing. The average annual industrial growth from 1944 to 1948 was 24.4% (Pangeti et al., 2000). Later, the unilateral declaration of independence (UDI) from Britain in 1965, the trade with South Africa and the resulting UN sanctions (Pangeti et al., 2000; Phimister, 2000) reinforced the push towards industrial self-supply.

Zimbabwe's industrial history illustrates the potential benefits of import-substituting industrialization for countries that later liberalize trade. After 1945, imports from overseas recommenced, increasing competition. Local industry responded by turning to regional markets as an outlet for industrial overcapacity. The expanded markets included the 1953 Central African Federation (CAF) of Zambia, Zimbabwe and Malawi (then Northern and Southern Rhodesia and Nyasaland) (Pangeti et al., 2000). During this era, foreign direct investment by South African and British companies flowed into local manufacturing industry (Phimister, 2000). Industrial protection and import substitution were then vigorously pursued after UDI.

During the early expansionary phase, two of the five major pharmaceutical companies were established: CAPS Pharmaceuticals and Datlabs. The pioneer company, CAPS Pharmaceuticals (then Central African Pharmaceuticals [Private] Limited), was founded in 1953, manufacturing formulations and wholesaling (UNIDO, 2011b). In 1958, CAPS stopped general wholesaling and focussed on manufacturing (CAPS website, 2012). Datlabs (Pvt) Ltd was set up in 1954 as a subsidiary of Ingrams, a South African company (UNIDO, 2007; 2011b). These companies focussed on serving the regional market in the Central African Federation countries. A third major pharmaceutical company, Pharmanova (Pvt) Ltd, was established later, in 1970 in the UDI era (UNIDO, 2007). This period created an industrial base second only to South Africa in the region, including established pharmaceutical producers, inherited in 1980 by the independent government.

Industry–health care integration

A country's domestic market for pharmaceuticals is dependent on its health care spending and health care structure. At independence the new Zimbabwean government targeted the narrowing of the inherited racial gap in living standards by introducing free health care and education for all as key elements of social transformation (Davies and Ratso, 2000). Zimbabwe became renowned for high growth in education, health and public administration to promote social equity in development (Helmsing, 1990). The country also continued its inherited historically high level of reliance on domestically produced medicines (Turshen, 2001).

Zimbabwe also made a pragmatic and early shift to cheaper generic prescription policies to reduce cost of medicines: in 1981, the Ministry of Health produced an essential drugs list (EDLIZ) (WHO, 1995), and this formed the basis for local medicines production strategies. Zimbabwean entrepreneurs established Varichem Pharmaceuticals (Pvt) Ltd in 1985 to serve this expanding market (UNIDO, 2007).

The government also took industrial policy steps to address some of the consequences of 15 years of political unrest, liberation war and sanctions. Industrial machinery had become obsolete due to scarcity of foreign exchange, which continued into the early years of independence (Bond, 1998; Phimister, 1988; Chifamba, 2003). Companies struggled to import capital equipment and upgrade their technologies. The government partially eased foreign-exchange restrictions for verified export orders through an Export Revolving Fund (ERF) in 1983, followed by an Export Retention Scheme (ERS) in 1989 and later

an Open General Import Licence (OGIL) in mid-1990s (Chifamba, 2003).

However, Zimbabwe was not spared the economic crises that swept across African countries from the mid-1980s. Expansion of social services without rising revenues led to budget deficits, forcing the government to abandon their initial resistance to economic structural adjustment programmes (AfDB, 1998). On the advice of the IMF and technocrats in the Ministry of Finance, the country embarked on a structural adjustment programme in 1991. Disastrous economic outcomes included deindustrialization, unemployment and deterioration of the health care system (AfDB, 1997; Brett, 2005; Richardson, 2005).

Despite the deteriorating industrial and economic conditions, however, Plus 5 Pharmaceuticals was established in 1996. The start-up used venture capital funding (UNIDO, 2007; 2011b), a testament to Zimbabwe's financial system's capability at the time, despite deindustrialization, and also to the continuing vibrancy of the pharmaceutical sector. The country continued to rely on locally manufactured medicines (Turshen, 2001), and Zimbabwe appears to have sustained some alignment of industrial and health policy goals through this tumultuous period.

Pharmaceuticals in an era of economic collapse

After 1997, however, economic collapse set in. The decade from 1997 to 2008 saw deindustrialization on a grand scale, as manufacturing decline was driven by hyperinflation (MTDP, 2010). Manufacturing real growth rates were negative every year from 1997 to 2008 except 2005, signifying declining manufacturing capacity as well as loss of skills and technological capabilities. Manufacturing share of GDP fell from 20% in 1997 to 11% in 2008 while GDP shrank annually. The manufacturing share of exports fell from 20% to slightly over 10%. The private sector declined to the point of operating at 10% capacity, faced with shortage of capital, foreign currency, and interrupted electricity supplies. Physical infrastructure crumbled, skilled people emigrated and incentives and institutions were severely debilitated (AfDB, 2009).

Yet even in this era, aligned industry, health and social development policies did create some positive feedback mechanisms, enhancing local manufacturers' innovative capabilities. This environment was instrumental in the country being one of the first in Africa to locally manufacture anti-retroviral medicines (ARVs) to address the HIV/AIDS pandemic (Banda, 2013). As Chapter 15 describes, in 2002 Zimbabwe issued a compulsory licence allowing its local manufacturers to produce ARVs.

This demonstrated purposive application of political will and policy infrastructure, associated with sustained local manufacturing capabilities, to meet a pressing health and social need.

However, the economic crisis created a cumulative collapse in the public health system's capacity to procure drugs over the period from 2003 to 2009. The country shifted to high donor dependence for public health care funding and drug procurement (Banda, 2013). In addition there was international political isolation, acute shortage of foreign currency and dwindling foreign direct investment (FDI) coupled with skilled resources flight (AfDB, 1997; Brett, 2005). The greatest challenge for local pharmaceutical industry was the loss of public health procurement as an industry policy tool (NECF, 2010). The increased reliance on donor funding posed a demand-side constraint for local firms: drugs for HIV/AIDS, TB and malaria were procured externally because the national procurement agency NATPHARM was incapacitated through lack of funds.

Current pharmaceutical manufacture in Zimbabwe

When the government of national unity was formed in 2009, there were various initiatives to resuscitate and rehabilitate the economy. Key strategies in the Short Term Economic Recovery Programme (STERP, 2009) were social protection, including food and humanitarian assistance and education. For health care, the focus was on building capacity in human resources, drugs and medical equipment availability, and reduction of preventable diseases. The health delivery strategy included addressing drug shortages: drug stocks in 2008 were just 36% of requirements, and stock-outs of essential drugs, vaccines and medical supplies had become common. The strategy also included capacitating NATPHARM, the national drug procurement agency, to supply government health institutions. There was a gradual improvement in the sector in the 2011–14 period.

The pharmaceutical industry in Zimbabwe now consists of nine pharmaceutical manufacturing companies registered with the Medicines Control Authority of Zimbabwe (MCAZ). Of these, five are the major generic manufacturers accounting for 90% of the formulation businesses (UNIDO, 2011b). The companies operate in a competition-intensive, low-margin commodity-type business, where profitability and long-term viability depend on economies of scale, assured demand and large markets (Berger et al., 2009). Currently the country is capable of producing 50% of all drugs on the essential drugs list, and if all research and development (R&D) activities in formulations are taken

into account, the capability rises to supplying 75% (NECF, 2011). Firms used to export quite extensively in the East African region, and also to Namibia, Angola and South Africa (UNIDO, 2007; 2011b). In 2014, the local industry supplied medicines to the health sector valued at US$24 million compared to US$184.7 million of imported medicines and US$100.4 million of donated medicines (Zimstats, nd).

While Zimbabwe's experience shows that African countries can manufacture drugs for their local health system, and illustrates some ways in which health and industrial policies can be aligned, it is also a grim history of how economic crisis drives loss of industrial development opportunities in pharmaceuticals.

Kenya: creating the dominant East African producer

Kenya, like Zimbabwe, has a long history of pharmaceutical production. Local pharmaceutical manufacture can be traced back to the 1940s. The pioneer firm was the Kenya Overseas Company, established in 1947 and beginning local manufacturing activities in 1948. The next batch of firms included Sterling Winthrop (US), established in 1953; Burroughs Wellcome (East Africa) Ltd (UK) in 1955; and Aspro-Nicholas (EA) Ltd (Australia) in 1961 (Wamae and Kariuki Kungu, 2014). The early firms built up initial skills and experience in pharmaceutical manufacture in Kenya before independence in 1963.

After independence, Kenya also pursued policies of import-substituting industrialization (described and explained in Chapter 2). These policies supported manufacturing for the domestic market in the face of the 1970s balance-of-payments crises and rising oil prices. In this period pharmaceutical manufacturing expanded, benefitting from the industrial protection, and also from an active government policy to promote investment and technological upgrading. The government established the Industrial and Commercial Development Corporation (ICDC) to provide development finance, and supported a number of parastatal joint ventures, including Dawa and Infusion Medicare. The firms of Lab & Allied and Cosmos were also set up in this period.

The mid-1980s and 1990s saw in Kenya, as across Sub-Saharan Africa, a process of market liberalization, associated with structural adjustment programmes, and a shift to export promotion. In Kenya, export promotion included a number of schemes to allow bonded production for exports using duty-free inputs, but this had little impact on pharmaceuticals (Chapter 2). The early 1990s in Kenya also saw a push to 'buy local', using local health section procurement to benefit industrial

development. There was industrial investment in pharmaceuticals production in this period, including Universal (Figure 1.1).

By the turn of the century, the Kenyan domestic medicines market was opening up in familiar ways to more global competition, notably from South Asia. Donors moved in to supply medicines for malaria, TB and especially HIV/AIDS, but this was later and more patchy in Kenya than in some neighbouring countries (Chapter 2). The relative strength of the production capabilities of the Kenyan industry by 2001 allowed the government to decide to permit compulsory licensing of generic production of HIV/AIDS medicines, and the subsequent issuing of voluntary licences (UNIDO, 2010a; see also Chapter 2). However import liberalization was by this date generating increasing competition from imports of finished formulations, and this seems to have been a factor in the departure of a number of multinational producers. In 2014, almost all pharmaceutical firms in Kenya were locally owned (Chapter 2).

A local industry with regional potential

In February 2014, Kenya had 39 pharmaceutical manufacturers registered with the Pharmacy and Poisons Board (PPB). Thirty-four were producing pharmaceuticals for human health, while the rest concentrated on veterinary products (Wamae and Kariuki Kungu, 2014). There were also 20 multinational firms with local representation for marketing purposes and /or involved in clinical trials.

Like the firms in Zimbabwe, Kenyan pharmaceutical activities are mainly production of finished formulations, with some reformulation and development activities. The industry mainly produces generic products, importing APIs, excipients and other raw materials from India, China and Germany. India dominates both raw materials and finished product imports, accounting for 40% of all pharmaceutical-related imports in 2008 (UNIDO, 2010a: 49). Few key inputs can be sourced locally; exceptions are maize starch, sugar and glucose syrup, rectified spirit and ethanol, as well as sodium chloride and quite a wide range of packaging materials.[2]

The Kenyan industry continues to suffer from relative low capacity utilization, and Chapter 2 explores the reasons for this in detail. They include limitations in the functioning state of machinery, delays in sourcing spare parts from abroad and human resource issues, in particular shortages of highly specialized skills in some critical areas such as product development.

Despite these constraints, Kenya's pharmaceutical sector is the strongest producer of pharmaceuticals in the East African region, and is

upgrading to more demanding technological capabilities. In addition to the standard generic products in the dosage forms of tablets, capsules, creams and syrups, the industry in Kenya includes three firms producing injectable infusions (small and large volume parenteral preparations) and ophthalmic formulations. One firm (Universal) has achieved WHO prequalification for one of its products, allowing the firm to tender for donor contracts and also providing an indicator of the firm's technical capabilities and standards.

A further measure of the strength of Kenya-based pharmaceutical production is its export success, which accelerated from about 2002. Kenyan pharmaceutical producers' main export destinations are in the COMESA region: the Common Market for Eastern and Southern Africa, which does not include South Africa or Tanzania.[3] However, the Kenyan industry still supplies a tiny fraction of COMESA's medicines market, while provisioning only around a quarter of its own domestic market. There is substantial room for expansion. With supportive government policies, Kenya should be able to exploit effectively the integration of East African and Southern African markets to expand its role as one of the medicines production 'hubs' in Sub-Saharan Africa. Chapter 2 discusses the industrial challenges in depth.

Tanzania: a latecomer under stress

Tanzania has a shorter history of pharmaceutical manufacturing than the two countries just discussed. In the colonial period during World War II, facilities for manufacturing simple medicines were established to counter the risk of blockade. However, after the war, these closed, and the country reverted to imports. The mainland, then called Tanganyika, did not, unlike Zimbabwe and Kenya, have a large colonial settler population in the pre-independence period, and the level of industrialization at independence was correspondingly small.

Pioneering firms and public sector investment

The earliest pharmaceutical manufacturing firm in Tanzania seems to have been Mansoor Daya Chemicals Ltd., a privately owned firm. Mr. Daya, a pharmacist, began with a retail pharmacy in Dar es Salaam in 1959. He set up his own firm in 1962, originally in a small godown, later moving to his current production site.[4]

In the 1960s and early 1970s, the Nyerere government in Tanzania turned to the promotion of industrial development through public investment. In contrast to Kenya, the industrial policies were driven by

a more explicitly socialist agenda, although, as the case studies in this chapter illustrate, the use of public investment to promote industrial development was a broadly implemented approach in these post-independence years (Lall and Wangwe, 1998). Manufacturing output rose from 4% of GDP at independence to about 8% or 9% in the 1970s. The production was mainly oriented to the domestic market, although there was a slow growth of manufacturing exports to East Africa, until these markets were lost with the break-up of the East African Community in 1977 (Bagachwa and Mbelle, 1995).

This was a period of import-substituting policies, paralleling those in Zimbabwe and Kenya, with an overvalued exchange rate, import controls, protective tariffs and administrative allocation of foreign exchange. It was also a period of state-led industrialization, including public sector investments in manufacturing plants. Two public sector pharmaceutical firms were established to provide essential medicines to a rapidly expanding public health sector. Keko Pharmaceuticals was opened as a production unit within the Ministry of Health in 1968 to supply tablets, capsules and large-volume parenterals for distribution to public sector health care facilities. Tanzania Pharmaceutical Industries Ltd (TPI) began as a public enterprise in 1978 with assistance from the Finnish government.

This was thus a period when the government was placing priority on expanding health care to serve a basic need, and the pharmaceutical industry responded to an alignment of industrial and health policies. The industrial strategy prioritized production to meet basic needs, including health care, creating a conducive environment for investment in pharmaceuticals. Private clinical practice was banned in 1977, except for some religious providers, and the main market for medicines was the public sector, plus retail pharmacies. However, the domestic market expansion was sufficiently attractive for a second private start-up, Shelys Pharmaceuticals, which began production in 1979. In 1984, Shelys was bought by the Tanzanian Sumaria Group of companies and built up into the largest pharmaceutical firm in the country.

Economic crisis and liberalization

Like our other other case-study countries in this chapter, Tanzania was hit by a major economic crisis in the 1980s. However, the impact in Tanzania was particularly severe, a result of a confluence of circumstances including a small and particularly internationally uncompetitive manufacturing sector focussing on consumer goods for the domestic market, and a liberalization process that was rapid and relatively

unconstrained by transitional policy safeguards. The late 1970s and early 1980s were marked by severe shortages of goods, as foreign exchange constraints reduced inputs to local production and export manufacturing declined. Capacity utilization dropped dramatically, and manufacturing output fell back to 7% of GDP by 1985 (Bagachwa and Mbelle, 1995). Pharmaceutical manufacturers were badly affected by foreign exchange shortages that constrained their ability to import APIs and other key inputs.

The major policy framework reversal was signalled by the adoption of the Economic Recovery Programme (ERP) in 1986. This shifted policy sharply away from import substitution, liberalizing imports of final goods and providing export incentives for manufacturers. While there was some export recovery, production of consumer goods for the domestic market suffered badly as cheaper imports flowed in. Given the prior levels of industrial protection in Tanzania, the liberalization constituted a much more severe shock than in Kenya or Zimbabwe, where protection had been lower and transition was better managed. Firms in Tanzania had little time for adjustment (Lall and Wangwe, 1998: 93). The result in Tanzania was a swathe of deindustrialization, and firms serving the domestic market failed.

Pharmaceuticals faced a second challenge also: the 'battering' taken by public sector health care funding and other government provided social services as the government budget went into severe crisis (Kaijage and Tibaijuka, 1996). As a result, the two government firms, Keko and TPI, ceased to be able to compete with imported medicines, lost their markets, and closed in the early 1990s. However, the two private pharmaceutical producers, Mansoor Daya Chemicals and Shelys, survived the economic crisis years. Shelys in particular was built up into a successful business as the largest pharmaceutical firm in Tanzania and expanded exports to the region. Another privately owned local firm, Interchem Pharmaceuticals was set up in 1989 in Moshi, part-owned by the IPP group of companies.

The challenges of competitiveness and upgrading

Industrial research in the 1990s emphasized the importance of firms' technological capabilities for survival and competitiveness in a more open economy (Wangwe, 1995). In the late 1990s and early 2000s, some of these technological capabilities were rebuilt in Tanzania, in pharmaceuticals as in other industries. The challenge was particularly great in pharmaceuticals given its reliance on skills and ability to manage technological upgrading effectively.

However, from the late 1990s, the pharmaceutical industry in Tanzania was renewed and grew substantially, entirely through the efforts of local investors and managers. The government sold 60% of the equity in each of the inactive government firms, Keko and TPI, to private Tanzanian investors in 1995. Both reopened in the late 1990s. In 2003, Shelys bought Beta Healthcare International, a Kenyan pharmaceutical company (previously Boots), with private equity funding from Aureos Capital. This was the first cross-border merger whereby a Tanzanian firm purchased a Kenyan company, and it made Shelys Africa Group the largest East African pharmaceutical company at that time.[5]

By 2009, the high point of Tanzanian pharmaceutical production, there were eight firms producing for the local market and also exporting regionally. The new firms were started by a mix of local and international investment. Tanzansino started production in 2000 as a joint venture between the Tanzanian military and a Chinese provincial government body. In 2007, the ownership changed when the Chinese provincial government shares were bought by Holley Industrial Group Ltd., a Chinese industrial group including a firm producing and exporting one of the new artemisinin-based combination therapies for malaria.[6] AA Pharmaceuticals, a smaller firm established by a Tanzanian private investor who is a pharmacist, began production in 2002. And in 2007, a new plant, Zenufa Laboratories, was built and opened. Owned by a DRC (Congo)-based diversified family firm, Zenufa aimed for Good Manufacturing Practice status from the start. These new start-ups reflected the changed economic circumstances in Tanzania: faced with sharp external competition, they aimed for efficient manufacturing and regional export capability from the beginning.

Data are not easy to assemble, but Table 1.1 provides a summary overview of the pharmaceutical industry in Tanzania just before the start-up of Zenufa. Seven firms were then active. Shelys at that time was responsible for about half of local production by value (Table 1.1). Much of the rest of the output was supplied by TPI, Interchem and Keko. The main suppliers to the public wholesaler (MSD) were Shelys, TPI and Keko, while Shelys was also the main exporter. Chapter 3 analyses the Tanzanian industry after this date.

Conclusion: shifting the debate

This chapter aimed to dispel the persistent myth that pharmaceutical production is not an African industry, tracing the long industrial history of the production of medicines on the Sub-Saharan subcontinent. This

Table 1.1. Pharmaceutical production and exports, Tanzania, 2004–05

Producer	Value of production (US$ million)	Share of total production (%)	Sales to the public sector (US$ million)	Sales to private market (US$ million)	Exports (US$ million)
Shelys Pharmaceuticals	16.0	49.2	5.7	7.4	2.9
Tanzania Pharmaceutical Industries	6.7	20.4	4.0	2.5	0.2
Other firms	9.9	15.0	1.3	8.5	0.0
Total	32.6	100.0	11.0	18.4	3.1

Source: Compiled by the authors from data in MoHSW (2006). Data in Tanzanian shillings in that source converted to US$ using the average exchange rate of 0.00095 for the year July 2004–June 2005 obtained from www.oanda.com.

book aims to contribute to shifting the whole debate on *making medicines in Africa* definitively away from 'Should it be done?' to 'How can it be done well to the benefit of public health?' Despite the successes to date, local manufacturers serve only a small proportion of African domestic demand, let alone population need (Berger et al., 2009; UNCTAD, 2011; WHO, 2005; 2011). The bulk of medicines consumed are imported from India and China, and there is heavy reliance on disease-specific donor-funded imports. That situation is not sustainable. African countries need to grow their capabilities to address the health needs of their populations, and pharmaceutical manufacturing and its associated technical and scientific bases are needed for that effort.

Nationally and across the African subcontinent, efforts to expand local manufacturing and innovation are extensive. The business case for local drug manufacture – and its potential to enhance security of medicines supply – has gained ground within African Union (AU) and New Partnership for Africa's Economic Development (NEPAD) circles. Not all countries have the capacity and capability to embark on the full spectrum of pharmaceutical production, innovation and R&D. The *Strengthening Pharmaceutical Innovation in Africa* strategy report (Berger et al., 2009) and the UNIDO-AU-sponsored African Pharmaceutical Manufacturing Plan of Action (AU-UNIDO, 2013) propose a phased approach of working up the technological ladder (see Chapter 15). Given the current rates of investment and industrial development in pharmaceuticals, the debate

now concerns the policy and business determinants of cost-effective manufacture of safe and efficacious medicines, and the conditions for aligning industry, finance and public health needs. The mechanics of achieving this become a matter of strategic intent at national, regional and continental levels. This is the terrain this book explores.

Notes

1. Part of this chapter draws on research undertaken for the project *Industrial productivity and health sector performance*. The findings, interpretations, conclusions and opinions expressed here are those of the authors and do not necessarily reflect the views or policies of DFID or the UK ESRC, whose financial support is gratefully acknowledged (project ES/J008737/1). Some of the evidence is drawn from fieldwork by Watu Wamae and Joan Kariuki Kungu for this project.
2. Source: UNIDO (2010a) and interviews.
3. Source: http://about.comesa.int/, accessed 12 April 2015.
4. Source: interviews.
5. Source: Sumaria Group website: http://www.sumaria.biz/our-businesses/, accessed 6 March 2014.
6. Source: interview with Tanzansino manager, 2010.