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Pharmaceutical Manufacturing Decline in Tanzania: How Possible Is a Turnaround to Growth?

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Introduction

“This sector [pharmaceuticals] is going to die...A hundred percent reliance on imports is dangerous.” (Tanzanian government official)¹

As Chapter 1 described, Tanzania has a decades-long history of pharmaceutical production, the sector mirroring fluctuations in Tanzania’s post-independence industrial history. By 2004–05, the sector was estimated to be producing pharmaceuticals worth US\$32.5 million, supplying around 30% of the local market and exporting about 10% of local production (MoHSW, 2006). The subsequent rise and decline of the sector is analysed in this chapter, locating firms’ sources of both market resilience and vulnerability in local patterns of ownership, finance and management, interacting with the internationalization of firms’ domestic and regional markets. Finally, the chapter examines the ‘turnaround’ challenge facing the local industry. Concerned policy makers are aware, as the above quotation shows, of the health sector insecurity inherent in complete reliance on medicines imports.

Methods and sources

The chapter draws on extensive interviewing in 2013–14, some earlier interviews, unpublished research findings and feedback from

involvement of the authors in policy debates in Tanzania.² Senior managers in all five pharmaceutical firms producing human medicines for the private and public market that were operating at the time of the research were interviewed. Interviews were conducted with CEOs and/or production managers, using a semi-structured interview schedule that focussed on firms' capabilities to supply the Tanzanian health sector. Interview data are not attributed to specific firms except by agreement; otherwise, firm-specific information is drawn from the public domain and referenced.

In addition, informants and stakeholders associated with the industry were interviewed, including policy makers, regulators, senior actors in business associations and wholesalers in public, non-profit and private sectors. Finally, seven firms producing non-pharmaceutical products relevant to the health sector were also interviewed.

Recent industrial rise and decline in pharmaceuticals

In 2004–05, seven pharmaceutical firms were producing medicines for human consumption in Tanzania (Chapter 1). There were no multinationals, and only one joint venture with an external partner. The years up to 2008–09 then saw substantial investment, upgrading and some consolidation and new entry in the industry: this was an optimistic period in the sector.

Investment and consolidation

The largest firm is Shelys Pharmaceuticals, a pioneering firm developed by the Sumaria group. Sumaria is a successful example of the large, diversified, family-owned conglomerates that dominate Tanzania's large industry sector (Sutton and Olomi, 2012). It is a regional multinational, producing plastics, cement and consumer goods, and moving into renewables. It built up Shelys as a wholly owned firm in Dar es Salaam; in 2003, Sumaria bought Beta Healthcare International, a Kenyan pharmaceutical company, with private equity funding from Aureos Capital, making Shelys Africa Group the largest East African pharmaceutical company at that time. Shelys built and commissioned a new plant for making penicillins in Tanzania in 2008, to international good manufacturing practice (GMP) standards, and at the time was planning diversification including parenterals and anti-retrovirals (ARVs) (Shelys, 2008). In 2008, Sumaria sold 60% of Shelys to Aspen, a South African multinational, allowing private equity to exit.³

Three other larger firms were developed by Tanzanian African capital. Interchem Pharmaceuticals, set up in 1989 in Moshi and part-owned by the IPP group of companies that includes large media interests, made substantial investments but closed in 2008. In 1995, the government sold 60% of the equity in two closed government pharmaceutical firms into Tanzanian private family ownership, and each reopened. Keko Pharmaceutical Industries then made substantial investments. Tanzania Pharmaceutical Industries (TPI) began production in 2008 of three first-line anti-retrovirals (ARVs) for HIV, the first such production in Tanzania. With European Union financial support and technical support from Krisana Krasintu of Thailand, TPI was upgrading its production and quality assurance and planning a new GMP-compliant plant for ARV production (Losse et al., 2007). In 2007, Zenufa, a firm with a family-owned parent company based in the Democratic Republic of Congo (DRC), invested in a new plant in Dar es Salaam, aiming for full GMP standards, with initial loan financing from the Belgian Investment Company for Developing Countries.

Also in this period, Tanzansino, a Chinese government–Tanzanian military collaboration, closed for planned major renovation,⁴ while two family firms owned and run by Tanzanian pharmacists, Mansoor Daya and AA Pharmaceuticals, were investing and expanding supplies to the local market. Mansoor Daya is the oldest Tanzanian local producer, while AA was started in 2003.

By 2009, Tanzania-based production was supplying an estimated 35% of a local medicines market worth about US\$140 million, and rising medicines exports had reached almost US\$8 million.⁵ A particular strength of the local firms was supply to the rural areas: rural availability relied quite heavily on local manufacturers, and interviews with rural medicines buyers in 2006–07 had found evidence of brand recognition and trust for locally produced medicines, especially those from Shelys (Chaudhuri et al., 2010; Mujinja et al., 2014). In 2009, Tanzanian pharmaceutical production looked like a relative success story.

Recent industrial decline

Yet between 2009 and 2013, this success story turned into rapid decline (Wangwe et al., 2014a). By 2013, just five pharmaceutical firms were operating. The rising trend of medicines exports to 2009 had reversed (Figure 3.1). By 2013, imports of pharmaceuticals had risen to US\$286 million on the back of rising donor spending, while medicines exports had fallen to US\$1.7 million. Informed local estimates⁶ put the local producers' share of the domestic medicines market at under 20%.

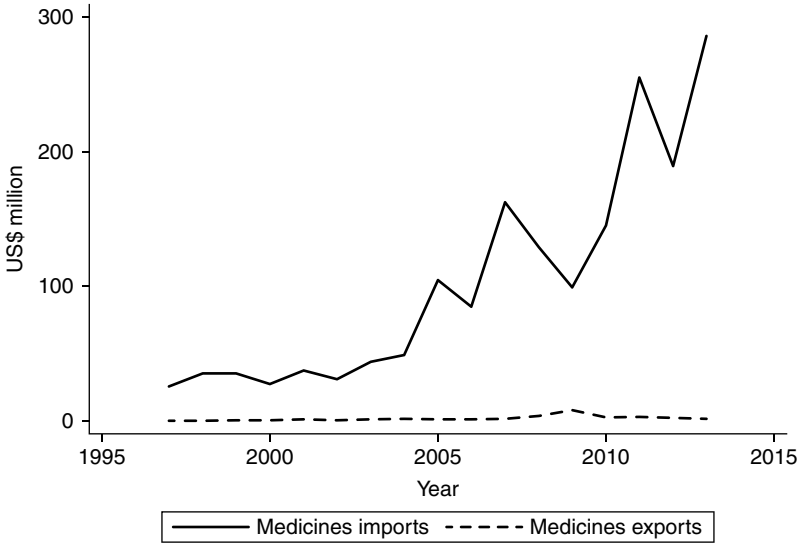


Figure 3.1 The expanding local supply gap: total imports and exports of medicines and blood products (US\$ millions)

Source: Drawn from Comtrade data, <http://comtrade.un.org/data/>, downloaded 5 August 2014.

As the market has expanded, the local firms’ share had fallen. Figure 3.1 shows the yawning trade gap.

Data on availability and sources of medicines in the Tanzanian public and private markets confirm this declining trend in local producers’ market shares, for a matched sample of medicines and health facilities and shops (Table 3.1).

As the number of producers dropped, the product range narrowed. The only local producer of anti-retrovirals (ARVs) had been closed. All but one of the remaining firms had by 2013 largely ceased to produce basic antibiotics, and the largest firm was moving out of production of many other basic medicines. Local producers’ share of public procurement had been falling, and only one local firm was tendering for public sector procurement contracts in 2013–14. A non-profit wholesaler estimated buying locally ‘far less than half’ than four years previously. A private wholesaler, who in 2010–11 had bought local medicines worth Tshs 1.5–2 billion, was, he said, now buying ‘almost nothing, a few syrups’. The resultant decline in the local market share of a number of key essential medicines shows up in the survey data (Table 3.2). A

Table 3.1 Decline in domestic market share of medicines made in Tanzania, 2006–12

Percent of sample medicines available on day of visit, by country of origin				
Year	Tanzania	Kenya	Other	Total
2006	33	14	53	100
2009	21	13	66	100
2012	12	11	78	100

Source: Authors' analysis of WHO/HAI survey data 2006, 2009, 2012.⁷

Table 3.2 Share of local manufactures among specified tracer medicines available in sample outlets, 2006–12

Local share of available:					
Year	Amoxicillin capsules	Folic acid tablets	Albendazole tablets	Ciprofloxacin tablets	Diclofenac tablets
2006	79%	79%	81%	40%	45%
2009	74%	27%	33%	32%	26%
2012	13%	51%	43%	24%	4%

Source: Authors' analysis of WHO/HAI survey data 2006, 2009, 2012.

domestic medicines market, worth around US\$250 million, had become supplied overwhelmingly from imports paid in dollars.

Industrial strengths and vulnerabilities: explaining sudden decline

The predominance of family ownership with diversified business activity, described above for the pharmaceutical firms, is characteristic of the Tanzanian industrial sector more broadly (Sutton and Olomi, 2012). Diversified family-run businesses have a number of competitive advantages in Tanzania's challenging business environment. Where bank finance is expensive and hard to access, diversified family firms can spread risk and provide access to financing which is both 'patient' (Goodluck, 2014) and also relatively low-cost and flexible. The business structure also reduces transparency and helps to weather crises. Tanzania has a shallow industrial structure: other than agro-processing, manufacturing relies heavily on imported inputs, so firms may integrate

backwards to produce inputs such as packaging. Large diversified firms can gain competitive advantage by addressing in-house some 'institutional voids' (Khanna and Palepu, 1997) in their environment, such as market information sources, skilled labour pools or institutionalized working relations with government.

Some of these competitive strengths can be identified in Tanzanian family-run pharmaceuticals. Where market information is poor and consumers cannot judge quality directly, as in poorly regulated retail medicines markets, local brand trust and recognition is a powerful marketing tool (Khanna and Palepu, 1997). Where the domestic generics market is a firm's core business, investment in building a reliable generics brand benefits both consumers and manufacturer. All the pharmaceutical manufacturers interviewed had relied on capital from other parts of diversified family business, including property and trading. One firm was producing its own bottles, while two relied on overseas companies within a business group for quality assurance of inputs and access to technological information.

However, the vulnerabilities of family-based industrial organization, and of the shallow industrial structure, were also evident in the interviews. Reliance on imported inputs lengthens production schedules and increases quality risks. All firms had problems sourcing good packaging locally, and poor packaging of local products was a common complaint by Tanzanian health sector buyers. The financial and reputational risk associated with quality problems implied reliance on imported blister strips from India. Some firms had found locally bought bottles to be of unreliable quality and had switched to imports. While plastic containers for bulk tablets (sealed first into clean plastic bags) were made locally, the shallow industrial sector constrained improvements in local upstream supply. For example, a shift by pharmaceutical firms from glass to plastic bottles – desirable for safety and supply reasons – required substantial related investments by both pharmaceutical and plastics firms. At root of the problem was the small number of firms and a lack of mutual trust and coordination, posing a major hurdle to mutually beneficial industrial upgrading.

Access to technology and information was also generally constrained. Some firms relied on hard-pressed CEO's visits to trade fairs, and on established suppliers, for technical information, for training and upgrading support, and sometimes for trade credit. Ensuring quality of inputs from Asian suppliers was a constant challenge. Machinery suppliers – predominantly Indian or Chinese – installed, trained and provided spare parts and advice. Two firms had gained external donor support for

technical upgrading and capacity expansion. All trained their own staff and complained of the difficulties of finding and retaining pharmacists and pharmaceutical technicians. This small cluster of Tanzanian pharmaceutical firms apparently collaborated rather little, and benefitted from few spill-overs or linkages between firms.

Changing context and responses

The Tanzania-based industry is operating in a very open market context, where shifts in the relevant international market segments are immediately experienced within Tanzanian domestic and regional markets. Structurally and technologically, several worsening pressures appear to be producing a tipping point. The first relates to size and market positioning. Pharmaceutical firms in Tanzania mainly produce basic essential generic medicines and over-the-counter items such as cough syrups. Economies of scale are limited in basic formulations (Chaudhuri and West, 2014) but are large in active pharmaceutical ingredient (API) production. While small firms can compete, therefore, in formulations, they are at a structural disadvantage to large Indian exporters since they buy small API lots from Asian suppliers, some of whom also produce formulations. As one manufacturer put it, the 'key constraint in this market is demand'. If firms cannot sell sustainably, they cannot grow, and they need their home market as a basis for expansion.

The second pressure is technological and regulatory: firms are forced into a cycle of constant upgrading, both to meet rising international standards that are requirements for different levels of market entry, and to meet competitors' quality standards. Constant upgrading of firms' technological capabilities (Bell and Pavitt, 1993; Lall, 1992) is central to firms' competitive survival in pharmaceuticals, to sustain quality at a competitive price and to retain market access. For all the firms, the technological challenge was framed by Good Manufacturing Practice (GMP) standards.

GMP constitutes a production *culture* to be attained (see also Chapter 12). GMP Guidelines⁸ emphasize documentation and validation of the production flow, including effective quality control (independent of production management); high standards of hygiene and preventions of cross-contamination; effective and documented staff training and qualifications; and well-maintained equipment and premises. Our interviewees noted the extent of professional judgement in GMP implementation of, for example, 'adequate' ventilation, 'high' levels of hygiene, risk evaluation drawing on 'experience' and 'well-designed' documentation.

The Tanzania Food and Drug Authority (TFDA) presses for GMP adherence. Tanzanian firms either have attained locally acceptable GMP standards or are working towards them with TFDA support. Manufacturers agreed that TFDA required standards rise over time, just as do the standards achieved by international competitors and the expectations of international buyers. None, when interviewed, had WHO prequalification of individual products to allow them to tender for donor-funded contracts.

All firms reported recent and current substantial investment – relative to their capacity – in technological upgrading. Major investments included new machinery for expanding capacity or for automating processes to improve quality control and lower costs. Other investments included expensive improvements in air handling and plant standards (e.g. door seals and room separation) and production flow reorganization. One firm had just put in a new product line, and another was engaged in an expensive upgrade of tablet quality to produce higher compression. This last firm was aiming, with donor financial and technical support, for WHO product pre-qualification for a combination therapy. Most firms experienced financial stress in achieving these investments, which they saw as essential to stay in business.

A third interconnected pressure comes from donors' tendering processes. Donors such as the Global Fund⁹ procure a large share of medicines used in Tanzania (see also Chapter 8). Their large-scale tenders and the market entry requirement of product-by-product WHO prequalification¹⁰ shuts out local firms from markets for HIV, TB and malaria drugs. The effect has been most damaging in anti-malarials. In 2006, about 90% of the then first-line treatment for malaria (sulphadoxine-pyrimethamine [SP]) was sourced locally. From 2007, Tanzania shifted to the more expensive combination artemisinin-lumefantrine (AL) first-line medication. Subsidized supply by the Global Fund and other donors shut out local firms. Two firms developed AL formulations but concluded that pre-qualification (costing an estimated US\$150,000) was unlikely to provide market access given the scale and pricing power of Asian competitors. One local firm lost an estimated third of turnover; others also suffered substantial losses.¹¹

The final major contextual pressure reported by firms was a recent sharp increase in price competition from imports. This was particularly felt for 'beta lactam' antibiotics such as amoxicillin. These are produced in a separate plant from other medicines to prevent cross-contamination, and all the larger pharmaceutical firms interviewed had such production capability. All confirmed they were becoming increasingly unprofitable.

One has closed its beta lactams plant; another said it would do so 'in a couple of years, unless policy changes'. International tender prices for amoxicillin appear to have flat-lined since 2010 (MSH, 2010, 2013).¹² A local NGO wholesaler was buying at a landed import price well below a local firm's factory gate price. One informant stated some importers' landed prices were below his firm's full materials costs. Since about 78% of materials costs were calculated to be APIs in 2012–13, the latter allegation suggests dumping may be occurring. Local producers who up to 2009 were successfully competing to supply amoxicillin for domestic use had by 2012 largely left the market, as Table 3.2 also confirms.

At the national level, this move up-market leaves the domestic supply of basic essential medicines reliant on imports, which may not be sustainable at current low prices, and which may not reach rural areas as effectively as local supplies (Mujinja et al., 2014). The government official quoted at the beginning of this chapter saw this. Price pressure was also transmitted through private market competition. Around half of the Tanzanian medicines market is private (Chapter 8), and the number of competing wholesalers has been rising.¹³ Interviewees contended that margins on private sales and public contracts had been severely squeezed. The financial risk attached to supplying the public sector had also increased, since payment delays by the public procurement agency (Medical Stores Department [MSD]) were increasing, driven partly by 'erratic disbursement' of treasury funding (MSD, 2013: 8; see also MoHSW, 2013). These pressures discouraged local firms from tendering, and MSD officials confirmed that the local share of their procurement was falling.¹⁴

The larger manufacturers were responding by moving up-market, towards more technologically sophisticated, higher-value products with export potential. All continued to supply some over-the-counter medicines, and some higher-value items such as ciprofloxacin, an anti-infective (Table 3.2). Firms were refocusing on the domestic and regional private market, narrowing their product range and investing in new products for export. Overseas partners could support moves into higher-value products.

This business strategy carries two kinds of risk. At firm level it abandons what one firm called the 'cash cows': the cash-generating basic commodities; this reduced their turnover and liquidity and hence capability to invest. Family firms may find this reduces their survival chances in the medium term. The largest firm, Shelys, had been sold 100% in 2012 to Aspen, the South African multinational firm now part-owned by GSK (Aspen Holdings, 2013). The Aspen annual report

confirms the subsequent change in Shelys' business strategy: pursuit of higher margins by largely moving out of public sector supply (down to 5% of turnover in 2013), refocusing on the private market and dropping low-margin products. Shelys' recent investment has been largely in Kenya (*ibid*).

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Turnaround strategies: can the pharmaceutical industrial cluster be revived?

Government policy is totally unfriendly to pharmaceutical manufacturing. (Experienced Tanzanian manufacturer)

Where industrial problems vary by activity, policy must vary too: selective intervention is an essential element of industrial policy. Lall and Wangwe (1997) argued this point nearly 20 years ago; it remains true today that distinct sectoral problems require distinctive sectoral solutions. Pharmaceuticals share characteristics with Tanzania-based industry generally but also face characteristic challenges (see also Chapter 1). Furthermore, some of the firms' problems, as the manufacturer quoted above implies, are policy-based and distinctive to the pharmaceutical and medical supplies sectors. Furthermore, clusters of firms create mutual benefits in terms of knowledge flows and spill-overs (Nadvi and Halder, 2007; Page, 2012; see also Chapter 2), and Tanzania risks losing these benefits as the number of firms falls. Turnaround for this sector needs to be policy-led.

However, a shift to active sector-specific support requires change in the current policy approach, which, as government officials confirmed, currently focuses on policies to influence the general business environment and does not address specific sectoral needs (Wangwe et al., 2014b). The two broad policy challenges are to reverse policies that have the largely unintended consequence of incentivizing imports over local manufacture, and to generate active policy support for the continuous upgrading of technological capabilities essential for local firms to compete in these highly globalized markets.

Sector-specific policy issues

Around half of essential medicines used in Tanzania are obtained via public and non-profit procurement. MSD's public sector procurement gives local firms a 15% price preference in competition with importers when both meet the quality hurdles. The effective preference rate is somewhat lower (one interviewee suggested around 9%), because importers' prices are landed prices at the port, while local firms' price includes delivery to MSD's zonal warehouses.

Manufacturers and other interviewees argued, however, that the procurement and tax regimes in Tanzania specifically disadvantage local firms in pharmaceuticals, as compared to other industrial sectors. The key decision that has generated these disadvantages is the removal of the import duty on all finished formulations. The decision to remove the 10% import duty on pharmaceuticals, applying the East African Community (EAC) Common External Tariff (CET) rate of zero per cent, was announced in the 2009 budget speech.¹⁵ Since then, manufacturers supplying the private domestic market have no protection against finished imports.

Taxes and duties on imported inputs therefore specifically disadvantage local pharmaceutical manufacturers by raising their materials costs of production. The Customs Act 2008, recognizing this disadvantage, stated that where finished goods such as essential medicines are zero-rated for import duties, so are their inputs such as APIs, in order to ensure fair competition for local producers. However, as officials acknowledged, this commitment has proved 'complex' to administer in practice. While APIs are zero-rated, problems arise in identifying other inputs such as additives and excipients; manufacturers complained that highly refined sugar for syrups, for example, paid a high duty but could not be sourced locally. Manufacturers stated that efforts to put together a consolidated list of imported inputs to be zero-rated had not met with a positive response. Requests for zero rating could also be met by harassment and accusations of corruption and favour seeking.

Manufacturers also complained of uncertainty and instability in the tax and duty regime. VAT was payable on many imported inputs, and reimbursement was reported to be slow and often incomplete. Tax rules changed unpredictably. Proposals to impose duty on packaging were reported to have been raised, then withdrawn. 'Uplift', whereby customs officials increased the taxable value where under-invoicing was suspected, was unpredictable and sometimes punitive. Machinery, though exempt from duties in principle, required an import licence which could create

delay, leaving a choice between paying duty or losing cash flow. One interviewee who was considering investing in manufacturing stated that in Tanzania the rules are not as clear as in Kenya, ‘where it is clear’ what taxes are to be paid.

Pharmaceutical manufacturers identified ways in which contracts to supply the public sector disadvantaged local suppliers. Trade credit rules were an example: an overseas supplier winning a public sector tender would be given a letter of credit. This meant the firm was paid as soon as the goods were delivered to the port, and it could also be used to raise working capital (see Chapter 15). By contrast, local manufacturers were paid only 30 days – or more – in arrears once goods were delivered, leaving working capital to be raised by the firm. If the order is large relative to a firm’s capacity, that imposes a large financial burden. Smaller firms said the risk attached to public sector tendering had become unmanageable. One now preferred to supply the public sector via private wholesalers. A wholesaler who won a tender ordered from the manufacturer, who supplied and was paid, thus shifting the tender costs and some other financial costs and risks to the wholesaler.

This last strategy illustrates a more general trend. There appeared, anecdotally, to be a shift in public sector tendering practice towards buying from importers who would ‘bundle’ imports with (perhaps) some local supplies. Pharmaceutical wholesalers/importers in Tanzania are generally representatives of external, mainly Indian manufacturers. Tanzanian industry, however, has historically strong links to trading capital (Sutton and Olomi, 2012), and some local pharmaceutical manufacturers also import and distribute, with or without repacking. It follows that a policy tilt towards favouring importing over manufacturing may quite rapidly result in a shift towards much higher reliance on imported commodities as traders expand and manufacturers become more ‘hybrid’ in their activities, expanding more into importing.

Increasing sophistication: the capabilities squeeze

Tanzania has a low level of sophistication in manufacturing, that is, a low share of medium- and high-technology manufacturing within total manufacturing value added (UNIDO/GoT, 2012: 35–36). Its pharmaceutical sector produces products that are relatively unsophisticated by industry standards. However, within Tanzania, pharmaceuticals nevertheless represent a relatively high-technology, skill-intensive industrial activity as compared to much other Tanzanian manufacturing. The recent decline in this sector therefore threatens to reinforce a declining share of sophisticated manufacturing in total manufacturing

value added. Tanzania may be losing technological capabilities at firm level, retreating to a lower level of manufacturing capabilities (Warren-Rodríguez, 2010). In this sense, the apparent crisis in pharmaceuticals identifies a more general problem.

Firms' technological capabilities (Lall, 1992) are core determinants of their ability to compete. Many of the challenges described above concern product and process capabilities: the ability to manage and document the work processes following GMP guidelines, to ensure and be able to demonstrate quality and safety of the final product. For pharmaceutical firms, these capabilities determine their market access, both locally (achieving product registration and sustaining quality when products are tested) and for access to the regional and international markets. All the firms interviewed reflected technological conditions in the international industry, in that they were chasing a moving target, facing constant pressure to upgrade. They also found it hard to sustain technological capabilities over time.

Lall (1992) distinguishes between production capabilities, investment capabilities and linkage capabilities at the firm level (see also Chapter 2). Most pharmaceutical firms interviewed in Tanzania were struggling with all three.

One of the most serious constraints on firms' capabilities in Tanzania is the low level of general and technical education in the country, implying shockingly high levels of innumeracy and illiteracy among production line staff (UNIDO/GoT, 2012: 68). Firms argued that they have more machine downtime than would be true elsewhere, given operators' limited capabilities. Lack of command of English was also a problem as compared, for example, to Kenya, especially when trying to promote people internally. The rigorous rule-following, documentation-centred culture required by GMP is unfamiliar for staff: one CEO wanted to send supervisors abroad so they could get a feel for a GMP factory. The firms all train internally the laboratory pharmacists and chemists they hire, in the equipment and techniques for the factory; they all lose these trained staff both to other firms and especially to NGOs and government, where work conditions are easier. Training is expensive and there is no local pool of skilled labour, constraining a firm, for example, from quickly adding an additional shift. Finally, there is a repeatedly reported problem in obtaining work permits for essential expatriates.

'Access to skilled labour is also a problem.... in Tanzania, which is compounded by refusal to grant work permits and where granted, they are expensive'. (Manufacturer)

Investment capabilities, including finance, technological information and management of investment projects, also become more demanding over time, as firms upgrade to meet rising required standards for exports. The large jump in production capabilities required to move from local market standards to international requirements imposed by donors involves investment financing, improvements in internal process operations, replanning factory layouts, retraining, improving factory infrastructure and changing marketing capabilities. This kind of investment can amount to a substantial proportion of a local firm's annual turnover and generally required funding support from outside the business and from non-bank sources. Examples cited in the interviews included financial transfers from other family businesses; external grant funding; a low-cost loan; and a joint venture partner with 'financial muscle', as one firm described it. The joint venture and grant routes to improvement can combine finance and access to technology.

Development of capabilities in production of combination therapies for anti-malarial medication, in the form of two-layer tablets, provides an example. One firm¹⁶ was upgrading, with financial and technical support from Drugs for Neglected Diseases (DNDi), to produce a fixed dose artesunate/amodiaquine combination tablet, primarily for regional export through donor-funded procurement. The formulation was initially produced by Sanofi, in collaboration with DNDi, which then set out to transfer the technology to firms in Africa.¹⁷ To achieve this, the firm must meet WHO-prequalification standards at competitive cost, requiring changes across the production process. DNDi support includes the formulation, technological support and training, new machinery, laboratory upgrading, raw materials for the batches and technical and training support right through to pre-qualification. The firm itself is also investing substantially in quality improvements and cost reductions across the plant. The upgrading therefore benefits the entire plant, with spin-offs in improved tablet production for the local market also.

A second example also relates to combination anti-malarials. Another firm was benefitting from a new formulation available from its parent company, alongside support from its international network to, for example, assure quality of APIs at source. A third firm (currently closed) had benefitted from an EU grant to fund a new turnkey plant to produce anti-retrovirals plant for HIV/AIDS treatment. Without this type of substantial external input, it is hard for the firms in Tanzania to enhance their capabilities sufficiently rapidly to regain access to the regional market for anti-malarials and other medication widely purchased by donors.

External networks and support are thus essential to survival in the race to upgrade and retain or regain market access. The Tanzanian pharmaceutical firms are caught in a capabilities 'squeeze': as process and product standards rise, and as the standards become more binding as requirements for market access, the constraints imposed by the firms' working conditions at home become more severe. Lack of a local skills pool, high and rising energy prices, lack of economies of scale for buying inputs and marketing output, poor transport and business infrastructure and a lack of local linkages – all these constraints have long existed, but have become increasingly binding in the new technological and market environment.

**Policy to sustain upgrading and market access in pharmaceuticals:
Can it be done?**

It requires a change of mind-set for policy makers in Tanzania to turn to prioritizing and actively engaging in selective support of particular industrial sectors. The arguments for prioritizing pharmaceuticals include the national security issues raised at the beginning of this chapter. Loss of national ability to supply one of its population's basic needs increases reliance on exporters, notably from India, who may not be committed to production for this market medium term (Chaudhuri et al., 2010; see also Chapter 6). It may reduce availability and reliable supply especially in rural areas. The decline in the industry is also an element of deindustrialization and cumulative industrial decline, losing valuable skilled and semi-skilled employment opportunities, both in these firms and in upstream suppliers, for example in plastics and packaging firms. Tanzania is also losing opportunities to exploit synergies between health needs and financing and industrial development benefits, as compared to competing countries (see also Chapter 8).

Can this sector be turned around? A turnaround requires two key changes in mind-set and policy behaviour:

- an acceptance of the need for well-designed industrial protection mechanisms, and their effective implementation in stable and clearly explained rules;
- an active and sustained engagement with existing firms and their suppliers, in a determined effort to deepen and strengthen the local pharmaceutical production system.

There is principled opposition by some Tanzanian officials to protection of the market in essential medicines. Duties, argued one official, would

raise prices, so 'people would die'. This echoes emotive WHO and international NGO characterizations of tariffs on medicines imports as taxes that 'target the sick' (Olcay and Laing, 2005), or a 'sick tax'.¹⁸ In practice, however, there appear to be no studies of the tax incidence of import duties on medicines in comparable contexts, though the most important influences on retail prices are likely to be the extent of domestic market competition, the purchasing power of out-of-pocket purchasers and the extent of competition between public or non-profit and private vendors¹⁹ (see also Chapter 6).

It is, however, well established that 'infant industry' protection, to allow local firms to access markets, invest and grow *may* support both industrial growth and increasing industrial competitiveness, so long it is selective and temporary, and associated with incentives for domestic competition and export growth (Lall, 1992: 172). In the East African Community, of which Tanzania is a member, the common external tariff is set at zero for most essential medicines.²⁰ Tanzania could, without challenging the tariff agreement, institute a 'negative products' list of items that cannot be imported unless local manufacturers are unable to supply reliable quality at an acceptable price.

The key benefit of this change would be to allow local manufacturers to retain and grow their share of the basic essential medicines market. Without this market, the firms lose scale, cost efficiency and cash flow. The negative list would also be a relatively straightforward policy, in contrast to the complex efforts that would be required to identify and effectively exempt all essential inputs to local pharmaceutical production. Reducing or removing VAT on inputs to pharmaceuticals, or at least rapidly reimbursing the tax paid, would also shift the balance of incentives back towards manufacturers, as would raising the preference level above 15% for local suppliers in public procurement of medicines.

Additional practical changes that would shift the balance back towards local production include effective implementation by TFDA of their formal commitment to fast tracking of tests and registrations for local products (which may require additional TFDA resources). Providing trade credit for local suppliers to public procurement, as well as to overseas importers, would also rebalance the incentive structure, as would more timely funding by the Ministry of Finance for procurement by MSD of locally contracted supplies.

All of these policy changes are feasible, and many are implemented by other African countries including Ethiopia and Ghana (see Chapters 4 and 6). However, they would quite sharply shift incentives against the wholesaler/importers who currently manage the bulk of private sector

and substantial elements of public sector medicine supply. The changes would set manufacturing and importing interests against each other to some extent, posing challenges for policy makers.

Active engagement with existing firms in supporting upgrading of technological capabilities, local input sourcing and market access would also assist a shift in policy direction from trading to manufacturing, by engaging government officials more closely in manufacturing affairs. There are examples in Tanzania, outside pharmaceuticals, of success along these lines, such as the sustained consultations with manufacturers that led to the successful initiation of production of long-lasting insecticide treated bed nets. Manufacturing associations could strengthen their engagement with government. Current Tanzanian initiatives to create an active Task Force on Promotion of Local Pharmaceutical Production, including manufacturers, to improve policy and implementation in support of pharmaceutical manufacturing, could greatly enhance government-private sector collaboration.

Supporting continuous industrial upgrading requires a combination of types of support. Government policy can improve external constraints, for example by moderating utility cost increases, and streamlining slow, overlapping and expensive industrial licensing. Government can directly support areas where firms lack incentives and capability to invest themselves, such as industrial and vocation training schemes tailored to the needs of specific sectors, and funding for in-house training. Governments can work with donors to identify and tackle barriers to international market access for local firms. The large government shareholdings in pharmaceuticals, at present managed as passive holdings, could be actively used to support manufacturing improvement, or otherwise sold to support new joint ventures. Government could provide some direct financial support for investment.

The lack of industrial depth in this sector in Tanzania at present implies that government has a role in supplying missing 'public goods' of the type that larger clusters may generate locally: technological and market information; networks and introductions to help to generate joint ventures; active support for upgrading that would be available from consultants in more developed industrial contexts; and timely facilitation of external expertise when required. At present, in the small cluster of pharmaceutical firms, each was creating its own linkages; the mix of competition and beneficial externalities and collaboration characteristic of successful industrial clusters is missing here.

Two government bodies in Tanzania do provide some effective advice appreciated by manufacturers interviewed: the Japanese-supported

Kaizen unit in the Ministry of Industry and the TFDA. The manufacturers interviewed broadly appreciated the TFDA's practical and informed approach. TFDA officials are among the few in government who spend substantial time considering the requirements – and the point of view – of manufacturers. TFDA expertise could be brought into industrial policy implementation, perhaps through secondments, to help in changing the policy culture in support for pharmaceuticals.

Restructuring public procurement to support local firms' domestic market access can also help to stimulate and fund expansion and upgrading. This restructuring may include a policy already under development, to allow longer term contracts where procurement supports new local investment. This was being considered in relation to new investors, but could equally be applied to existing firms requiring longer contracts in order to fund upgrading. Manufacturers of medicines with longer public contracts could then be encouraged to use that stability to support their local suppliers' investments, for example in packaging. Given the shallow industrial structure of pharmaceuticals at present, industrial turnaround will need to address the local supply chain for pharmaceuticals, including local suppliers. Tanzania currently imports large quantities of glass, air, paper and water (bottles, packaging and intravenous fluids) in the pharmaceutical sector; even without any move into producing APIs, upstream improvement of input suppliers, and selective increases in sophistication of technological capabilities could cut industrial and import costs.

Conclusion: staying in the 'moving window'

Sutton (2012) argues that as markets integrate internationally, price competition intensifies and firms respond by investing in quality, producing better quality for a given cost. The net effect is to shift the market 'window' that firms must access upwards over time, dropping out of the window firms that can no longer meet the minimum quality/price ratio required for market entry. Tanzanian firms, facing a combination of a shallow industrial structure with few supportive linkages, a highly liberalized market, a policy 'tilt' towards incentivizing imports, and a largely passive industrial policy approach, have been vulnerable to these rising barriers to domestic and international market entry. The observed industrial fragility – the vulnerability to sudden decline – is not a new industrial phenomenon in Tanzania: for example, a number of the exporting firms that were the subject of an earlier industrial study (Wangwe, 2003) are no longer operating.

This conjuncture urgently requires a more engaged industrial policy. However, the industrial policy literature remains thin on how to sustain continuous engagement between government and manufacturers to support constant upgrading.²¹ The small, strategic, but currently shrinking pharmaceutical sector offers a good ground for experimentation in policy renewal, given its perceived strategic importance. Chapter 4, on Ethiopia, provides a comparative case study of an effective set of turnaround policies.

Notes

1. All quotations are from authors' fieldwork in 2012–14, unless otherwise stated.
2. This chapter is based on the research project entitled *Industrial productivity and health sector performance*. The findings, interpretations, conclusions and opinions expressed 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). Particular thanks also to all our interviewees who gave time within very pressured schedules to talk to us at considerable length. Thanks also to Martin Bell, Paul Nightingale and other participants in a SPRU seminar in February 2014, and to participants in a Policy Dialogue workshop in Dar es Salaam in November 2014. The same disclaimer applies.
3. Source: Sumaria Group website: <http://www.sumaria.biz/our-businesses/>, accessed 6 March 2014.
4. Interview, 2010.
5. Sources: Comtrade data for imports and exports, <http://comtrade.un.org/data/>, accessed 5 August 2014; NBS (2009) manufacturing survey for pharmaceutical production data.
6. There was no available manufacturing survey later than 2009 at the time of writing.
7. Thanks to Mary Justin-Temu for access to these data; Table 3.1 uses the 2006 sample of facilities and medicines only, for comparability.
8. East African Community Secretariat (nd) *Guidelines on Good Manufacturing Practice for Medicinal Products within the EAC*, Arusha: late draft kindly made available in near-final form by a TFDA official, in 2014.
9. The Global Fund to Fight AIDS, Tuberculosis and Malaria, www.theglobal-fund.org, henceforth 'the Global Fund' in this chapter.
10. See <http://apps.who.int/prequal/>, also Chapter 12.
11. Source: interviewing of firms previously supplying anti-malarials, 2010
12. Median selling prices USD/tablet 0.0171 2010, 0.0173 2013 (MSH 2010, 2013).
13. Sources: TFDA figures for wholesaler numbers cited in Mhamba and Mbirigenda (2010), and interviews.
14. An MSD accountant estimated for us that just 11% by value of MSD's new two-year framework contracts had gone to local firms in 2012–13.
15. Source: URT (2009: 67).

16. This example is reported with permission from the company's CEO.
17. <http://www.dndi.org/diseases-projects/portfolio/asaq.html?highlight=Wyj0YW56YW5pYSJd>, accessed 23 February 2015.
18. http://www.haiweb.org/medicineprices/29012010/MPM_6.pdf, accessed 23 February 2015.
19. See Waning et al. (2010) for an interesting investigation of non-profit supply and its impact on competition. We have found no studies of import duties' incidence on medicines prices in low- and middle-income countries.
20. The currently available EAC tariff schedule, available from http://www.eac.int/customs/index.php?option=com_content&id=41:common-external-tariff-handbook&Itemid=141, sets antibiotics' import duties at 10%, but this does not appear to be implemented at present in Tanzania.
21. We owe that observation to Martin Bell.



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