

Indian generics producers, access to essential medicines and local production in Africa: an argument with reference to Tanzania

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Abstract

Much analysis of the supply chain for essential medicines to Africa assumes broad sustainability of low cost generics supply from Indian manufacturers. We use Indian data and interviews to question that assumption. In a case study of Tanzania we then argue for the necessity and feasibility of enhanced local production of essential medicines. We identify key industrial policy interventions, including industrial protection and active government purchasing; public goods including legislative and regulatory frameworks and training; and encouragement and facilitation of joint ventures. We show that a basis has been laid for these activities, and identify the urgency and difficulty of the policy challenge. There are lessons for the Tanzanian case from Indian industrial history, and policy space is provided by Tanzania's Least Developed Country status. Industrial and health policy can be further integrated to the benefit of Tanzania's citizens. The Tanzanian case has broader implications for African policymakers.

1. Introduction: access to medicines, Indian exporters and industrial policy in Africa

About half of the population in Africa lacks regular access to essential medicines, and about 90 % of medicines are imported (WHO, 2005: 1). Imported medicines are sourced largely from Indian generic manufacturers, and this situation is quite widely seen as sustainable by donors and by campaigners for medicines access¹, though warning voices are emerging (Shadlen, 2007). Much international donor and institutional opinion questions the viability and desirability of African pharmaceutical manufacturing development (Kaplan and Laing, 2005; Bate, 2008).

However, promoting local production of pharmaceuticals now figures more prominently among solutions being discussed internationally and within Africa to enhance medicine access. Initiatives include a UNIDO project to strengthen local production²; an African Union initiative for local pharmaceutical production³; and moves by some bilateral donors, notably the Germans, towards more active support for African pharmaceutical development (Losse *et al.*, 2007)⁴.

One justification for this change of heart is concern about the future market strategy of Indian manufacturers. India took advantage of the abolition of product patent protection in pharmaceuticals in 1972 and has achieved drug prices among the lowest in the world. Indian manufacturers are now the dominant low cost international supplier of quality drugs (Chaudhuri, 2005). However to implement the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), India re-introduced product patent protection in pharmaceuticals in 2005. Indian generic companies can no longer produce and export new patented drugs unless voluntary licences are obtained or compulsory licences granted. Patent protection has changed the market incentives and market strategies of Indian exporting firms (Shadlen, 2007; Chaudhuri, 2005, 2008).

African countries will thus be unable to import new essential drugs from India. Furthermore African countries face a reduction in reliable low cost Indian suppliers. We contribute new interview evidence that Indian manufacturers cannot be relied upon as the sole major source of essential medicines for African populations. Access to medicines

will be adversely affected, so a search for alternative sources of supply including developing local manufacturing capacity is of fundamental importance.

We argue here, in the Tanzanian case, for an active industrial policy to support local pharmaceutical production. Countries such as Korea have developed industries from scratch (Amsden, 1989). In Tanzania, we show that pharmaceutical manufacturing activity is already rising and there is evidence to suggest potential viability. By ‘industrial policy’ we mean government policies to encourage restructuring in favour of new industries and activities. We include ‘infant industry’ protection to allow achievement of static and dynamic scale economies and technological development; the provision by government of essential activities and public goods; and public-private interactions to support technology transfer and enhance discovery of potential production efficiencies and their benefits (Rodrik, 2004; UNCTAD, 2006 Chapter V; for a critique of active policies see Pack and Saggi, 2006).

We trace Tanzanian experience to date and then discuss the challenge of industrial development in pharmaceuticals. A key issue is government capability: we show that the Tanzanian government has had some success in identifying relevant policies and undertaking essential activities with donor support. We use market survey and interview evidence to show that local producers of generics have redeveloped as viable suppliers, and that there is technological upgrading underway. We also show that local production is currently a key contributor to access to essential medicines in rural Tanzania, and argue that improved supply of reliable locally produced medicines is an important route to improved access and security of supply. We thus argue for the necessity and possibility of improving local industrial capabilities, building on an emerging integration of medicines policy and industrial policies in Tanzania.

2. Sources and methods

This paper draws on a systematic review of data and documentation on Indian exports of generic medicines to East Africa, and on the East African pharmaceutical markets. Indian generics manufacturers⁵ were interviewed during 2006 and 2008 concerning export experience to Africa and future business strategies. In Tanzania⁶, four pharmaceutical manufacturers; seven private importers/distributors and wholesalers; two non-

governmental non-profit importer/wholesalers; and the large government importer/wholesaler were interviewed in Dar es Salaam and Arusha in 2006-7 with some follow up interviews in 2008. Government officials involved in regulation, and relevant faith-based and NGO organizations, were also interviewed.

In addition, this paper uses some results from a survey of medicines markets in four rural districts of Tanzania in late 2006, including pricing, availability, manufacturer of available drugs, and prescribing/dispensing practice. That survey used the WHO methodology for price data collection (WHO/HAI, 2003) and collected data on price, source and availability of a set of 31 tracer medicines drawn from the Tanzanian essential medicines list⁷.

3. Indian generic exporters and African pharmaceutical markets

The strategy of Indian generic companies towards African markets is influenced by those markets' importance for profitability. Profitability in turn reflects market size and segmentation, prevailing prices and competition, import barriers and regulatory processes.

African market size is very small in global terms. World pharmaceutical production, and consumption of pharmaceutical products, are highly concentrated in high income countries (WHO, 2004 pp. 5, 32). Of a global pharmaceutical market of \$744,008 million in 2006, the entire Middle East and Africa accounted for only \$14,824 million (about 2%). The largest pharmaceutical market in Africa, South Africa, with sales of \$1,761 million, is small compared to China (\$20,800 million) and India (\$9,423 million).⁸ Africa's total pharmaceutical imports (53 countries) amounted to only \$6.6 billion in 2006, of which 33 LDC African countries imported only \$1.6 billion (Tanzania \$87.3 million).⁹

India's pharmaceutical exports in 2006-7 went predominantly to Europe and America (57.8%), and Asia including the Middle East (26.9%). Africa constituted a relatively small but expanding market : up from 10.7% of total Indian exports in 1994-95 to 14.1% in 2006-7).¹⁰

However, the importance of the African market differs sharply by type of Indian exporter. Among the major Indian companies which dominate both the domestic and the export market, Africa is a substantial foreign market only for Cipla: a major supplier of antiretrovirals (ARVs) for treating HIV/AIDS. Africa accounted for 14.1 % of Cipla's sales in 2006-07, more than Europe (10.6 %) and comparable to the Americas (16.6 %). Ranbaxy's formulations sales in 2006 went predominantly to the USA and Europe (58%), and only 6.9% to Africa. For Ipca, Africa provided 7.7% of total income, compared to 46.7% from India itself and 23.3 % from Europe. For other major Indian companies such as Dr Reddy's, Wockhardt, Lupin, Glenmark, and Torrent, Africa is in the residual category.¹¹

Major Indian companies concentrate on North American and European markets because they are larger and prices are kept higher by stricter regulatory requirements that make market entry more difficult. The USA has the toughest regulatory standard: Indian companies exporting to the USA must file a Drug Master File (DMF) for APIs (active pharmaceutical ingredients) and Abbreviated New Drug Application (ANDA) for formulations, and set up dedicated plants. Lately Indian pharmaceutical companies have been acquiring companies abroad. But out of the 57 acquisitions between 2002 and 2008, only four were in Africa – all in South Africa. Target companies belonged primarily to developed countries – 14 in USA, 8 in UK, 4 each in France, Germany and Japan.¹²

Most Indian companies cannot afford the costly and time consuming requirements of the US market. The less strong companies therefore concentrate on unregulated markets (Chaudhuri, 2005). Most African countries have long had basically unregulated pharmaceutical markets, though some including Tanzania are now implementing higher standards. Table 1 ranks the major Indian exporters to Tanzania by number of products registered; as the final column shows, these include firms active in the USA (with ANDAs/DMFs filed) and others inactive.

Exporters to Tanzania inactive in the US include companies such as Intas, a significant player in India's retail formulations market (rank: 18). However others, including Lincoln, Simrone and Aurochem (Table 1), are small players in India's retail formulations market. Simrone is not in the listed top 468 domestic retail formulators.

Vital (rank 433), Medreich (rank 442) and Aurochem (rank 454) are insignificant players in the Indian market. MedoPharma and Lincoln are slightly larger, ranked 161 and 111 respectively.¹³

This pattern of local and international supply can also be seen in drug registration data from the Tanzanian Food and Drugs Authority (TFDA)¹⁴. Of 3388 drugs registered, 269 (8%) are from Tanzanian manufacturers. Registrations from forty other countries are dominated by India (1315 products) followed by Kenya (307), Egypt (199), and European countries including Cyprus. China is not a major supplier to date. Of 53 companies with 20 or more drugs registered, 41 are generics companies and 12 MNCs. The largest by number of registrations is the Indian generics company Cipla (165 products); then Ranbaxy (79) and Ipca (59).

The registration data also confirm the importance of local and regional suppliers: Shelys (99 products) and Interchem (70) are both Tanzanian; Elys (81) is Kenyan. Two Cyprus firms, Remedia and Medochimie, are also significant in both registrations and in our rural survey. MNCs, include GlaxoSmithKline, Pfizer/Pharmacia, Sanofi, Bristol Myers-Squibb, and Novartis, supply niche urban markets and specialist products; they barely feature in the rural survey. Our rural market survey confirmed that Indian suppliers to the mass market were predominantly second rank Indian firms. Indian manufacturers of five or more tracer medicines found in rural outlets were Intas (7), Simrone (6), and Aurochem, Lincoln, Medopharm and Emcure (5 each); the last supplied some of the ARVs.

African pharmaceutical production is historically weak. In the early 1990s, only one country in Africa, Egypt, could produce the bulk APIs that are the basis for formulations. Thirty two countries (including Ghana, Kenya, Tanzania, South Africa, and Uganda) produced only formulations; nineteen had no pharmaceutical industry (Balance *et al.*, 1992). Eight countries including middle-income Botswana still have no pharmaceutical manufacturing (WHO, 2004: 1-2).

Local manufacturing has recently been developing in Africa primarily through the initiatives of locally owned companies.¹⁵ Multinational companies have had little significant involvement in pharmaceutical manufacturing in Africa outside of South

Africa and Kenya. Indian companies have however now set up some manufacturing plants primarily through joint ventures with local companies: Cipla in South Africa, Uganda and Morocco; Cadila in Ethiopia; Ajanta Pharma in Mauritius; and Ranbaxy in Nigeria and South Africa.¹⁶

4. Local pharmaceuticals supply in the Tanzanian market : role and reconstruction

The size of the Tanzanian pharmaceutical market is poorly documented, with no regularly published data available. In 2004-05 the market was estimated at \$110 million (Ministry of Health and Social Welfare, 2006): \$78 million (71%) supplied from imported sources and the remaining 29 % from local production.¹⁷ Industry interviewees suggested that the proportion of local production has remained broadly the same in an estimated market of \$140 million in 2007.

Market structure and the role of local production

There are several interacting market segments. Government- and donor-funded medicines are largely procured by the semi-autonomous government buying agency, the Medical Stores Department (MSD), and sold to government and some faith-based and other NGO health facilities. Some NGO facilities also procure directly or through non-profit importers/wholesalers. The government wholesaler MSD procured medicines in 2004-05 worth \$43 million, about 40 % of the market.¹⁸ Currently MSD's share is estimated to be about half.¹⁹ MSD procures drugs through competitive bidding : in 2004-05, about 74 % of its drug purchases were imports (Ministry of Health & Social Welfare, 2006). India accounts for most of MSD's imports; Kenya for a small proportion.²⁰

There is a substantial private retail market in medicines, through registered pharmacies (of which there are only 400 country-wide, largely in the towns), drug shops mainly permitted in 2006 to sell only a narrow range of medicines including anti-malarials, and privately owned health facilities. Most medicines are obtained by consumers through out-of-pocket payment; government prices are generally lower than non-government prices.

Local production thus supplies around 30% of private and public markets. However this figure underestimates the importance of local manufacturing for sustaining access to

medicines in Tanzanian rural areas. Seven of the tracer medicines included in our survey in four rural districts were licensed for sale in private drug shops. These were widely available in shops and non-government facilities: median availability was 68%, and only one had less than 55% availability. Of these medicines, 66% on average²¹ were from Tanzanian manufacturers (18% from Kenya and 11% from India). In rural health facilities, paediatric suspensions, basic antibiotics, anti-malarials and analgesics from Tanzanian suppliers were all widely stocked. Only injectables, some chronic illness medicines and one antibiotic were available solely as imports. First-line combination ARVs had just begun to be locally produced in 2006. Many Tanzanian products had wide familiarity and labels that included information in Kiswahili.

Industrial reconstruction: a brief history

The rebuilding of local pharmaceutical production since the mid-1990s has had some demonstrable success. There are eight pharmaceutical manufacturers in Tanzania.²² The industry began in 1962 with a private company, Mansoor Daya Chemicals. During the socialist Nyerere government, two public sector plants were established. Keko Pharmaceuticals was opened in 1968 to supply tablets, capsules and large volume parenterals for distribution through public healthcare facilities. Tanzania Pharmaceutical Industries (TPI) began in 1978 with assistance from the Finnish government. Both government firms suffered financial stress in the economic crisis of the 1980s and were closed in the early 1990s.

In 1995, Keko and TPI were privatized, by sale of 60 % of equity to local private investors. Table 2 shows data for production volume and exports by company 2004-5. Much the largest producer is Shelys Pharmaceuticals, established in 1979 and acquired by the Sumaria group in 1984. Sumaria is one of the largest private sector business groups in East Africa, with interests in diverse sectors such as plastics, dairy, agro-processing. In 2008, Shelys was taken over by Aspen of South Africa.²³ The latest entrant is Zenufa Laboratories. Zenufa initially functioned as an importer and distributor of MNC products but diversified to manufacturing in 2007 with the aim of setting up a WHO Good Manufacturing Practice (GMP) compliant plant through a strategic collaboration with the Belgian Investment Company for Developing Countries.²⁴

None of the older plants met GMP standards. In 2000, an inspection by the Tanzanian Pharmacy Board closed 3 registered plants (Center for Pharmaceutical Management 2003). Since then production facilities have been upgraded. Substantial investments have been made by Shelys, TPI, Keko and Interchem aiming to expand, diversify and attain GMP status. Shelys has commissioned a new WHO GMP-compliant plant which the company claims is the first of its kind in East Africa (Shelys Pharmaceuticals, 2008). However no Tanzanian manufacturer has yet applied for approval under the stringent requirements of the WHO Prequalification project, which evaluates HIV/AIDS, malaria and tuberculosis medicines production for quality, safety and efficacy; approval is the gateway to the large international procurement of these medicines by United Nations organizations and others such as the Global Fund.

The production activities of Tanzanian manufacturers are relatively simple. They do not produce the APIs, importing them mainly from India and China. In formulations, they do not produce IV fluids or injectables, which are technologically more sophisticated. Only four companies – Shelys, TPI, Keko and Zenufa - produce antibiotics: the simpler ones such as amoxicillin, ampicillin, chloramphenicol, not the more advanced ones such as cephalosporins. Shelys' product range comprises mainly simple antibiotics, cough and cold preparations, analgesics and antipyretics, sedatives, nutraceuticals, anthelmintics and antimalarials. Just six Shelys products, for coughs and colds, fever and pain, plus an antimalarial, account for 50 % of its sales. It does not yet produce antidiabetics, antihypertensives, ophthalmic preparations.²⁵

TPI has started producing fixed-dose combinations of three ARVs. With financial assistance from Action Medeor, a German NGO and technical assistance from Krisana Krasintu of Thailand, TPI is implementing a programme for production and quality assurance and setting up a GMP compliant plant for ARVs. According to Shelys Pharmaceuticals (2008), Shelys plans to diversify to ARVs, large volume parenterals and anti-tuberculosis drugs. Roche has announced that it will provide technical expertise to Shelys Pharmaceuticals to produce the second-line ARV saquinavir.²⁶

TPI supply mainly the government wholesaler; Shelys is also a major supplier of the local private market. In 2004-5, TPI exported about 3 % of its production, while Shelys

exported about 18% of its production to neighbouring countries in East Africa. In 2003, Shelys acquired Beta Health care, a leading healthcare manufacturing company in Kenya. Shelys and Beta's products are available in about 22 countries in Sub-Saharan Africa (Shelys Pharmaceuticals, 2008). Other Tanzanian manufacturers sell only in the domestic market.

Some firms have struggled financially and in growth terms. TPI reported losses until 2002, and then turned profitable, though accumulated losses are yet to be wiped out (Losse *et al.*, 2007). Shelys is believed to be a profitable concern but like the other manufacturers, suffers from gross under-utilization of capacity.²⁷ Interchem used only 50 % of its overall production capacity in 2004-05.²⁸ Shelys used, in 2005, only 36 % of capacity in tablets, 30 % in capsules, 57 % in liquid orals and 30 % in dry syrups (including penicillin products). Similarly for Keko and Tanzansino, the capacity utilization has been low. The manufacturers attribute underutilization of capacities mainly to stiff import competition.

The problems faced by local manufacturers also include:

- Finance: access to both working capital and long term credit has been limited, and the cost of finance is very high, preventing most companies from undertaking improvements for operations and expansion;
- Utilities: the cost of electricity is very high and water supply is erratic;
- Technical expertise: the country lacks local expertise in pharmaceutical manufacturing; two pharmaceutical training institutes require major renovation (Ministry of Health and Social Welfare, 2006).

Managers of Shelys Pharmaceuticals argued that, while wage rates for unskilled workers were lower in Tanzania than in India, the cost advantages were undermined by lower productivity²⁹. Imported technicians and senior managers, for example in Shelys and Zenufa, were paid more than their salaries within Indian competitors.

5. Industrial policy and local pharmaceutical production: experience to date

Private initiatives to rebuild local pharmaceutical production have gained support from government policy initiatives, though substantial problems remain. Policies include improved regulation, government purchasing with a price premium for local production, and recently, import duties.

Improved regulation

Reputable suppliers rely on competent market regulation to exclude substandard products from the market. Regulation thus has public good characteristics. Tanzania has recently made a major effort to strengthen its regulatory capacity in pharmaceuticals.

Local products, like imports, must be registered. The registration system was weak before 1999, with hardly any quality control of drugs (Center for Pharmaceutical Management, 2003). Some manufacturers, including some from India, are believed to have taken advantage of the lax quality control administration and supplied substandard drugs to the market. In 2003, the Tanzania Food, Drugs & Cosmetics Act established the TFDA. The TFDA approves products on the basis of (i) product dossiers submitted by the manufacturers; (ii) plant inspection in Tanzania and abroad and (iii) laboratory tests, to ensure that the manufacturing plants follow GMP safeguards and procedures. Registration is for 5 years after which products must be re-registered.³⁰

The TFDA's strengthening of the registration system based on plant inspection has substantially improved quality of privately marketed drugs³¹. Some of the international traders who used to get products manufactured from India on contract basis disappeared. Both local and foreign manufacturers have been forced to upgrade. Some Indian companies initially failed to satisfy the inspectors, and some have improved and now have products registered. Problems do persist, as Bate *et al.* (2008) found for example for anti-malarial drugs in private urban and peri-urban retail markets in six African countries including Tanzania. There is active public scrutiny of the issue: newspapers continue to report sales of fake drugs.³²

The TFDA's resources are limited and its GMP standards are not as elaborate as in the United States and Europe. Unlike USFDA, TDFA inspections are plant-specific not product-specific. TFDA primarily checks whether the procedures mentioned in the product dossiers submitted by the manufacturers are followed. It does not check each product manufactured in the formulation plant, nor the raw materials sources: unlike the US market, manufacturers catering to the Tanzanian market can change API manufacturer without seeking TFDA permission.

The critical issue is not just specification of standards, but capacity to monitor whether the manufacturers are following the procedures and abiding by the safeguards, to produce drugs which are safe and effective, and if not to take corrective action. Here Tanzania lags behind, as does India itself. There are manufacturers in both countries who knowingly or unknowingly produce drugs which do not satisfy the quality requirements, and the drug control authorities in neither country have yet been able to prevent this.

In the Tanzanian private sector, the drug import trade is dominated by a few large firms combining importing, distributing and wholesaling. Some have retail outlets in the cities. They are the main source of supply of drugs for the private retail drug shops, with local semi-monopolies in some rural districts surveyed. Indian manufacturers export directly to the Tanzanian private market through local logistics partners, generally these local importers/distributors. The market segmentation allocates expensive patented and originator brand imports to urban areas, especially Dar es Salaam.

The Tanzanian generics market also segments into branded generics and generic-generics (that is, those sold under brand or under generic names). The rural market is primarily generic-generics, and is highly competitive and price sensitive. Incomes and purchasing power are low, and our rural retail market survey showed few significant price differentials by country of origin for the most widely distributed medicines among our tracer drugs.

Low incomes and price competitiveness compound quality problems in this generic-generic market. Pharmaceutical companies supplying this market include some who follow proper quality standards and some who do not. The larger and more reputable Indian companies with larger overheads and larger investments in GMP plants are finding

it very difficult to compete in the generic-generics markets with suppliers, including those from India, who are less quality conscious. In some products, these larger companies have become non-competitive. Zydus Cadila, an Indian company, has decided to withdraw from Tanzania. It has not renewed its product registrations, and cited the inability of the Tanzanian regulatory authorities to prevent the sale of sub-standard drugs by unscrupulous suppliers as a major reason for their withdrawal.³³ Other larger Indian companies such as Ranbaxy, Cipla, Sun, Glenmark have not withdrawn; they are however targeting urban niche markets where there are entry barriers and branding is possible.

Public purchasing and industrial protection

Efficient public purchasing is an important element of both industrial and health policy in pharmaceuticals. MSD is internationally recognised as relatively effective among African public purchasing organisations³⁴, despite continuing problems of stock-outs and logistics. MSD has a good reputation domestically for quality control of medicines. Clinicians interviewed who were doubtful about the quality of Indian medicines on the local private market would use them when purchased by MSD:

It is difficult to comment on Indian drugs ...since we mostly rely on MSD so we are sure of the quality [Doctor NGO hospital]

MSD implements a 15 % price preference for local manufacturers in its tenders, representing about 9% effective protection since the price comparisons are between at-warehouse delivery for local manufacturers and at the border for imports³⁵. Until 2008 there was no private market protection; a 10 % import duty was then imposed on pharmaceuticals formulations other than ARVs, anti-malarials, anti-TB drugs and MSD imports. Among other official initiatives providing some benefit to local formulators are: no import duty on raw materials, components and machinery, and no value added tax or excise for domestic formulations.

The most widely recognised justification for such initiatives is ‘infant industry’ protection, aimed at permitting potentially competitive activities to engage in learning-by-doing and attain international competitiveness. Such protection can also break down barriers to entry facing local firms that are created by large overseas suppliers with

market power engaging in limit pricing (Bhattacharjea, 2002). There is evidence that local manufacturers face this problem in both public procurement and the private market, in the form of marginal cost pricing by some large Indian firms, not all of whom are regarded internationally as wholly reputable. Since Africa is not the main market for the large Indian generic companies, these companies can win tenders, or gain market share, by quoting a price below their full cost of production. Given their installed capacities, they still earn additional profits provided variable costs are covered.

Marginal cost pricing by major international manufacturers is considered a major issue by Tanzanian industry. The problem cannot be combated by regulation of dumping. The WTO defines dumping as charging a price lower than the price normally charged on the home market, and empowers member countries to impose countervailing duties. However there is no Tanzanian government machinery for investigating dumping activities by importers and hence international suppliers can continue to supply below home market prices and below production costs.

Local manufacturers argued that they are not afraid of competition from quality conscious Indian companies; their problem rather is with those Indian companies who sell substandard drugs at lower prices without incurring the necessary costs to achieve good quality.³⁶ Unscrupulous manufacturers can easily enter the market from abroad without fixed investments: they merely need a tie-up with importers who have a marketing infrastructure. The importer/distributors can push the sales of these substandard products together with products from more reputable companies. Profits can be shared between the manufacturer and the wholesaler to the detriment of the consumers. Retailers have no independent check on quality of medicines purchased, and are faced with immense pressure from consumers for lower prices³⁷. In this context, modest industrial protection can support development of reputable local production.

6. Industrial policy: the challenges and opportunity

Local pharmaceutical production in Tanzania is being rebuilt. It faces immense challenges but the industry can be further developed given a proper policy environment.

Training, technological learning and discovery

Some critics of African plans to regenerate pharmaceutical production argue that firms cannot become competitive because small market size restricts economies of scale (Kaplan and Laing, 2005; Rovira, 2006). Economies of scale are important in API production. However in formulations, they are limited³⁸, a finding supported by firms such as Shelys' demonstrated ability to compete with imports in the generic-generic market.

Much more challenging for industrial policy makers and investors are the problems of creating local technological competencies to produce drugs efficiently. What is required is policy-induced space for training, technological learning and upgrading, and discovery by both private and public actors of the scope for reaching international competitiveness in manufacture.

Tanzania has a National Drug Policy, which accords high priority to local production. The Policy, enacted in 1991 aims to make the country self reliant in formulations. It also speaks of long term policy 'to support the gradual development of self-sufficiency in the production of intermediary and raw materials on such chemical entities, where Tanzania has a comparative advantage in production.' It further states 'the promotion and development of the national pharmaceutical industries will become a multi-sectoral activity, both encouraging national and international investment and transfer of technology. It will provide the necessary protection, until the industries have matured to full competitiveness. (Ministry of Health, 1993: 12). If implemented effectively, these policies can go a long way in developing manufacturing capability.

Independent Tanzania began with a small industrial sector. Even British investments were meagre, favouring the neighbouring country of Kenya (Costello, 1994). Initially Tanzania followed a private sector-led import substituting industrial strategy. Later, a state-led industrialization programme up to the mid-1980s supported public industrial investment, but stunted the growth of a private entrepreneurial class. The weakness of local entrepreneurship became evident in the economic crisis and market reforms of the mid-1980s, while the market reforms in their turn dislocated and discarded some of the useful industrial capacities created during the socialist phase (Wangwe, 2003).

When Keko and TPI were privatized, the government retained 40 % equity. However it has stopped providing any funds to these companies, making their growth quite difficult³⁹. Three industrial R&D institutions were set up in the early 1980s, but the R&D output was underutilized due to poor links with the industrial firms, in contrast to India. Since the mid-1990s these institutions have been starved of funds, and the Science and Technology policy making body, COSTECH also suffers from underfunding (Diyamett and Wangwe, 2001, pp. 9-10).

Tanzania is furthermore in a less advantageous market situation than India, making an active government role essential. The government cannot afford to withdraw from the economy as it was doing under market reforms. The private sector in Tanzania has shown itself capable of development, but too small and weak to be left alone. Developing the pharmaceutical industry in Tanzania is actually much more difficult than it was in India. Tanzania lacks a higher education system like India's which supplied scientific personnel necessary for science-based industries such as pharmaceuticals. The pharmaceutical industry in Tanzania also lacked the opportunity of technological learning which resulted from the patent reforms in India. Tanzania today also faces intense competition from Indian generic companies – and as we have discussed above, not always fairly. When India started developing her industry in the 1970s, she did not face competition from other developing country generic producers. India's competitors were mainly the MNCs who were not keen on producing drugs in developing countries, preferring developed country locations despite high labour costs.

Despite such difficulties, several policy initiatives are available to further development of the pharmaceutical industry in Tanzania. The government in Tanzania could announce a “negative list” of drug products, for which imports are banned, as in Ghana and Nigeria. In Nigeria, the “import prohibition list” comprises 18 types of products including paracetamol tablets and syrups, metronidazole tablets and syrups, haematinic formulations, multivitamin tablets and capsules.⁴⁰ In Tanzania, the Ministry of Health & Social Welfare (2006) recommended the introduction of such a list, to include technologically simple products where substantial local capacities have been created but are not adequately utilized. Such a measure is unlikely to increase prices: rather,

international competition will be replaced by local competition. The competition among the local manufacturers in this low income market is intense enough to keep prices low.

There can be and must be close collaboration between the government and the private sector to create effective industrial policy: Rodrik (2004) emphasises the importance of learning by both government and business. If India's experience is any guide, a big "push" is required for the development of the industry. The entrepreneurial spirit of the Indian private sector was actively supported through public investments in R&D and manufacturing (Chaudhuri, 2005). Even if large investments by the government are not feasible under the current circumstances in Tanzania, the government can provide strategic coordination of drug production and procurement.

The government could announce a list of products to be exclusively procured by MSD from local units. This could be larger than the negative list mentioned above. It might also signal additional drugs which are not currently produced or not adequately produced, but which could be produced by Tanzanian manufacturers competitively within a reasonable period of time. The target can be, not only development of new formulations, but also the development of the capacity and capability to produce APIs. In India, close collaboration between government laboratories and private industry contributed to development of efficient processes for manufacturing many drugs. The same model can be attempted in Tanzania. The government can assure a market through MSD procurement; public R&D institutions can develop laboratory-scale processes; and manufacturers can scale up these processes and manufacture the drugs. The government should coordinate these processes, led by consideration of the country's health needs. Tanzania can learn from technology policies adopted elsewhere to strengthen R&D and manufacturing capability (Mani, 2002)

Note that drugs to be produced and procured by MSD in this way can include patented drugs. Tanzania's current patent law permits "government use" of patents: the government can empower local manufacturers to produce the drugs (on payment of royalty to the patentees). The fact that these drugs would be procured by MSD for distribution through public health facilities will satisfy the condition that such

government use is for “public interest” or “health or the development of vital sectors of the public-economy.” (Section 61 of the Patents Act, 1987).⁴¹

Volume of production is more important for viability of API production than for formulations. Where economies of scale are considered to be particularly important, exports can be developed, initially at least to the regional market in East Africa. Certain restrictions on the export of drugs in the patent regime under TRIPS have been removed for regional markets.⁴² Coordination among the government procurement agencies of the countries in the East African Community, for example would make it possible for each country to develop capacities for different drugs.

Finally, the government can further develop assistance to local firms to improve drug quality. The technical resources built up by the TFDA and university laboratories are a major resource to support upgrading, and the TFDA includes such responsibilities in its remit. A key objective is approval of Tanzanian plants under the WHO prequalification project and the USFDA, greatly widening the market for local industry.

Patent reforms

Many developing countries, including India and Tanzania, as colonial countries basically duplicated the patent system of their imperial masters. However the inherited patent system can be changed, to form an important element of effective industrial policy, as India’s experience shows (Chaudhuri, 2005).

Before the WTO came into being in 1995, individual countries were free to have their own patent regime. Before the Patents Act, 1987 (which came into effect in 1994), Tanzania did not have an independent patent system. Under the Patent (Registration) Ordinance (chapter 217) of 1962 enacted soon after Tanzanian independence, patents granted in UK were automatically eligible for registration in the country with all the patent rights of the UK patent (Mwalimu, 2003). When Tanzania enacted a new law in 1987, she could have abolished pharmaceutical product patents, as India did in 1970 by replacing the British Act of 1911. But she chose not to do so. Under the Act of 1987, which is currently in force, both pharmaceutical products and processes can be patented in Tanzania.

The negative impacts of product patents in pharmaceuticals, in developing countries in particular, are now widely understood and discussed. African and other developing countries recognizing product patents paid exorbitant prices for HIV/AIDS medicines (MSF, 2008). The WTO Ministerial Conference at Doha adopted a special declaration on issues related to TRIPS and public health in November 2001. The Doha Declaration clarified and confirmed the rights, which member countries have in taking appropriate measures to protect public health. In a highly significant step, LDCs, were exempted from providing product patent protection in pharmaceuticals until 1 January 2016 (para 7). As an LDC, Tanzania thus can currently produce new patented drugs, and the older generic products, without violating international law, creating a window of opportunity for industrial development.

Yet international concerns about product patents have yet to have much impact in Tanzania, though it is among the worst sufferers. Tanzania retains the 1987 Act, which is much more stringent than the minimum standards required under TRIPS except perhaps in the term of patents. TRIPS requires a minimum term of 20 years, but in Tanzania the term is only 10 years, that can be extended for further periods of 5 years (Section 38(2)(a and b) of Patents Act, 1987). Even if Tanzania chose not to abolish product patents in pharmaceuticals, it could have amended the law to take advantage of flexibilities permitted under TRIPS and to minimize the effects of product patents (Losse *et al.* 2007; Chaudhuri, 2008).

Tanzania has initiated the process of amending the Patents Act, 1987, through a task force with membership of different stakeholders. However this forms part of an elaborate exercise to revise and consolidate the entire intellectual property system, including other laws such as the Trade and Service Marks Act, 1986.⁴³ This suggests a lack of urgency on the part of the Tanzanian government to use the window of opportunity provided by LDC flexibility under the WTO. Tanzania could have simply suspended pharmaceutical product patenting, in a separate move from other slower changes. The TRIPS transition period was extended to 2016 for pharmaceutical products alone (2013 for other products). Furthermore, for pharmaceuticals alone any existing laws and regulations can be amended or suspended.⁴⁴ Considering that only few years are available, the opportunity

should not be to overemphasized. However, together with other aspects of industrial and technological policies, some gains can still be realized if Tanzania acts fast.

Constraints on local production and the benefits of local competition

An additional constraint on increasing the share of local production in public and private markets is created by international regulatory changes. These have raised the quality hurdle for entry into major aspects of this market. Drug procurement for HIV/AIDS, malaria, tuberculosis has increased sharply under international initiatives such as Global Fund and the United States President's Emergency Plan for AIDS Relief (PEPFAR), and Tanzania is a beneficiary under both programmes. However, to be eligible to supply drugs, local manufacturing must meet United States Food and Drug Administration (USFDA) standards under PEPFAR, and WHO Prequalification project standards under the Global Fund. Tanzania manufacturers of anti-malarials and ARVs still lack Pre-qualification, so are unable to supply MSD under these programmes. The technological upgrading currently underway is key to accessing these tenders.

Increased local production can mitigate the inflexibility of supply created by high dependence on imports. Most MSD procurement is through one big annual tender. For unanticipated requirements, there are provisions for emergency purchases, which can be made rapidly from local producers. However, floating international tenders and arranging supplies from foreign manufacturers can take substantial time. Particularly in public health crises, this is a bottleneck to ensuring access to medicines. Shelys Pharmaceuticals managers consider manufacturing flexibility as an important advantage of the local industry: they can change their manufacturing schedule to respond to demand conditions.

Exporters in India are harder for the Tanzanians to regulate than local firms. While there may be political constraints in Africa on regulatory penalties for local firms⁴⁵, TFDA has shown itself able to enforce improvements in local manufacturers. For imports, TFDA checks at the border for registration, but does limited quality control. It tests samples only of tuberculosis, malaria and HIV/AIDS drugs, but not systematically of other products - only when there are suspicions. TFDA equipment has been upgraded but remains limited. Complaints against a locally manufactured product are investigated by

TFDA officials at the plant; for imported products, the complaint is merely communicated to the manufacturer. TFDA officials inspect plants abroad for new registrations, but cannot ensure that products are actually manufactured in the plants approved by TFDA.

If TFDA can attain a position of ‘embedded autonomy’ (Evans, 1995) from local business – involving mutual learning but retaining regulatory leverage – then local production can be effectively regulated. In 2006 clinicians’ complaints about Tanzanian medicines were mainly about poor packaging rather than poor technical quality⁴⁶, and a combination of TFDA scrutiny and MSD purchasing and quality testing should provide incentives to sustain quality and upgrade.

7. Conclusions

We have argued that Tanzania will face severe problems in improving access to essential medicines for its population if it continues to rely heavily on foreign exporting sources such as India. Local production already contributes importantly to access to essential medicines by the poorest part of the population. Its further development can reduce dependence on foreign exporters, make supplies more reliable, enhance local price competition, and make it easier for drug control administration to ensure quality. There are thus major developmental and health benefits to be gained from an effective industrial policy to promote development of the local pharmaceutical industry.

We have identified the scale of the challenge this involves – and we recognise the widespread scepticism among international health policy analysts about its desirability and possibility. We have argued however that there exists a feasible set of policy interventions available to promote market development, investment and technological upgrading. Indian experience provides some guide, although Tanzania faces immense disadvantages of context and timing. Furthermore, there are indicators in experience to date of Tanzanian government competence to pursue an industrial policy agenda in this sector. A major programme of industrial upgrading is required, led by government integration of health policy needs with industrial policy activism.

Notes

1. This statement is supported by project interviews with NGOs and international donors..
2. UNIDO, Strengthening the Local Production of Essential Generic Drugs in Developing Countries (LDCs/DCs) <http://www.ics.trieste.it/Portal/ActivityDocument.aspx?id=6235> consulted 30.03.09
3. See the Resolution taken in the Assembly of the African Union, Fourth Ordinary Session, Abuja, 30-31, January, 2005, accessed from www.african-union.org See also Kitua (2007).
4. Interview with Action Medeor, Dusseldorf, Germany, 01.03.2007 confirmed their support for manufacturing development in Tanzania.
5. The interviews in India that particularly influenced the conclusions in this paper include: Intas Pharmaceuticals, 21 August, 2006, Ahmedabad; Torrent Pharmaceuticals, 21 August, 2006, Ahmedabad; Zydus Cadila, 22 August, 2006, Ahmedabad; USV, 6 May, 2008, Mumbai; Bluecross Laboratories, 7 May, 2008, Mumbai and personal communication, 23 May, 2008. Interviews were semi-structured and were not taped; detailed notes were taken.
6. In Tanzania, Shellys, TPI, Keko and Zenufa were interviewed in 2006 and 2008; wholesaler interviews included Generics & Specialities; Harsh Pharmaceuticals; Astra Pharma; Phillips Distributors; MMT, Pyramid, Diocare, MEMS, Action Medeor and MSD. These interviews were semi-structured, some were taped, all recorded in detailed notes.
7. More details of the study at http://www.open.ac.uk/ikd/projects_lowcostdrugs.shtml
8. *Epicom World Pharmaceutical Market Fact Book 2006* accessed at www.espicom.com June 2008
9. Data on chapter 30 pharmaceutical imports of countries have been obtained from the website of the International Trade Centre <http://www.intracen.org> accessed June 2008.
10. Directorate General of Commercial Intelligence and Statistics export data obtained from “India Trades” data base of the Centre for Monitoring Indian Economy, Mumbai.
11. Company Annual Reports and websites.
12. Mergers & Acquisitions database of the Centre for Monitoring Indian Economy, Mumbai, accessed 4 August, 2008
13. Information on the retail formulations market in India from ORG-IMS, ‘Stockist Secondary Audit’, December 2006.
14. Company-wise product registration data from the website of TFDA www.tfda.or.tz accessed 19 September 2007.
15. Guimer *et al.* (2004 annex 2) gives an illustrative list of pharmaceutical manufacturers in different sub-Saharan African countries.
16. Company Annual Reports and websites.
17. Import data were provided by the Tanzania Food & Drugs Authority (TFDA), which checks imports for registration status but does not process the import data for market analysis. This paragraph draws on Ministry of Health & Social Welfare (2006) which reports survey and estimated data for 2004-5. (The figures in Tanzanian shilling (TShs) have been converted to US \$ by using the average exchange rate of 0.00095 for the year July 2004 to June 2005 obtained from www.oanda.com).
18. Ministry of Health & Social Welfare (2006: 9, 12)

19. Industry sources. In 2004-05, MSD did not handle about \$ 6.6 million worth of donor-funded drugs imported. Now most donor-funded drugs are routed through MSD (interview with an official of the Ministry of Health and Social Welfare, 12 June, 2008, Dar-es-Salaam).
20. Interview with MSD officials, 8 September, 2006, Dar-es-Salaam.
21. Robust mean of percentage of each medicine sourced from Tanzanian manufacturers
22. TFDA website www.tfda.or.tz (accessed on 29 August 2008) mentioned 7 registered companies; Zenufa Laboratories had not yet been added.
23. Detail on pharmaceutical manufacturing drawn from Ministry of Health & Social Welfare, 2006, and project interviews.
24. Company website, www.zenufa.com accessed 11 June, 2008; interview with a company official, 11 June, 2008, Dar-es-Salaam.
25. Interview with Shelys Pharmaceuticals, 9 June, 2008, Dar-es-Salaam; Shelys Pharmaceuticals, 2008.
26. "Roche Engages in Four Additional AIDS Technology Transfers to Strengthen Local Manufacturing", January 9, 2008 www.reuters.com
27. Shelys Pharmaceuticals is a private limited company and information on its financial performance is not available publicly.
28. Calculated as the value of production of TSHs 5150 million as a percentage of value of production of TSHs 10500 million possible at full capacity.
29. Interview, Dar-es-Salaam, 9 June, 2008.
30. Interviews with TFDA officials 29 September, 2006 and 10 and 13, June, 2008.
31. A consensus among a wide range of interviewees and interests.
32. See, for example, Dailynewsonline, 8 June, 2008 <http://dailynews.habarileo.co.tz>
33. Interview with an official of the company, 22 August, 2006, Ahmedabad.
34. Interviews with NGO buyers in Tanzania and a WHO essential medicines expert.
35. Interviews with MSD officials October 2006.
36. Interview, 27 September, 2006, Dar-es-Salaam.
37. Interviews with rural retailers, four districts, October-December 2006
38. Simulations support this view (Guimer *et al.*, 2004)
39. One local industrialist characterized government, as an industrial partner, as 'inert'.
40. See the website of the National Agency for Food and Drug Administration and Control (NAFDAC) <http://www.nafdacnigeria.org> accessed 31 August, 2008.
41. A copy of the Patents Act, 1987 was obtained courtesy of Sandy Harnisch, then of UNCTAD, Geneva.
42. For the prospects of Tanzania in the East African Community see Losse *et al.*, 2007: 32-42
43. Interview at the Business Registrations and Licensing Agency (BRELA), Ministry of Industry, Trade and Marketing, 13 June, 2008, Dar-es-Salaam.
44. Draft UNCTAD document, Reference Guide to Intellectual Property and Pharmaceutical Production in Developing Countries, discussed in the informal peer review meeting, Geneva, 11 October, 2007; includes Tanzanian data.
45. A repeated comment in project interviews.
46. Interviews in NGO and private rural facilities 2006.

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Table 1 Indian companies with products registered in Tanzania

Company	No of products	Regulatory approvals in USA
Cipla	165	ANDA; DMF
Ranbaxy Laboratories	79	ANDA; DMF
IPCA Laboratories	59	ANDA; DMF
Aurochem Pharmaceuticals (India)	44	Neither
Panacea Biotec	41	Neither
Dr. Reddy's Laboratories	40	ANDA; DMF
Unichem Laboratories	40	ANDA; DMF
Aurobindo Pharma	37	ANDA; DMF
Intas Pharmaceuticals	37	Neither
Sun Pharmaceutical Industries	36	ANDA; DMF
Lincoln Pharmaceuticals	36	Neither
Cadila Pharmaceuticals	36	DMF
Glenmark Pharmaceuticals	36	ANDA; DMF
Wockhardt	34	ANDA; DMF
Medopharm	31	Neither
Alembic	28	DMF
Emcure Pharmaceuticals	24	DMF
Vital Healthcare	24	Neither
Unique Pharmaceutical Laboratories	21	ANDA; DMF
Cadila Healthcare	21	ANDA; DMF
Medreich Sterilab	20	Neither
Simrone Pharmaceutical Industries	20	Neither

Sources: (i) Col (2) - calculated from data on human drug products registered, obtained from the TFDA website (www.tfda.or.tz accessed 1 October 2007); (ii) Col (3) – obtained from the USFDA website, <http://www.fda.gov/cder/dmf/> (for DMF) and <http://www.fda.gov/cder/ob/> (for ANDA), accessed 8 August, 2008.

Note: Only those companies with 20 or more products registered in Tanzania are listed.

Table 2: Pharmaceutical Production and Exports, Tanzania, 2004-05

Company	Value of Production (\$ 000)	Value of Production (%)	Sales to MSD (\$ 000)	Sales to private retail market (\$ 000)	Exports (\$ 000)
Shelys Pharmaceuticals	16023	49.2	5689	7441	2893
Tanzania Pharmaceutical Ind	6650	20.4	3990	2470	190
Interchem Pharma	4893	15.0	151	4742	0
Keko Pharmaceuticals (1997)	3686	11.3	1045	2641	0
Mansoor Daya Chemicals	669	2.1	47	622	0
Tanzinsino United Pharm	513	1.6	162	351	0
A.A. Pharmaceuticals	137	0.4	0	137	0
Total	32570	100	11084	18403	3083

Source: Ministry of Health & Social Welfare (2006 pp. 9, 12). Figures in Tanzanian shillings (TShs) converted to US \$ using the average exchange rate of 0.00095 for the year July 2004 to June 2005 obtained from www.oanda.com.