www.repoa.or.tz

No 43 July 2014

Repoa Brief

Reversing Pharmaceutical Manufacturing Decline in Tanzania: Policy Options and Constraints.

By Samuel Wangwe, Paula Tibandebage, Edwin Mhede, Caroline Israel, Phares Mujinja, Maureen Mackintosh

Key messages

- Pharmaceutical production has been a Tanzanian industrial success, generating industrial skills and employment and sustaining access to essential medicines for the Tanzanian population, especially in rural areas.
- Tanzania now risks accelerated loss of this key industrial sector, under interacting pressures from external competition, requirements to upgrade technology, unsupportive procurement and tax frameworks, and problems of probity and management oversight.
- Loss of the local pharmaceutical industry threatens security and flexibility in supply of essential medicines, contributes to industrial decline, and adds to the trade deficit.
- Policies to reverse decline exist; they require "joined up" government action on tax and trade policies, procurement policies, and targeted business support, plus active government collaboration with manufacturers.

Overview:

Importance of the problem

Tanzania is rapidly losing its pharmaceutical production capability, and therefore its ability to supply one of its population's basic needs. The loss undermines Tanzania's medium-term security of supply of essential medicines. It threatens cumulative industrial and employment decline in one of Tanzania's few higher-skill sectors and in local suppliers, including plastics and packaging. It increases the trade deficit, and misses opportunities to exploit development synergies between health needs, health financing, and industrial growth.

This policy brief reports findings from a REPOA research project, with The Open University, UK, and ACTS, Nairobi, entitled *Industrial Productivity and Health Sector Performance.*

Findings:

Growth and industrial decline in pharmaceuticals

Industrial growth

Pharmaceutical production began in Tanzania in 1960–1980 with four firms. The 1980s economic crisis closed two. However, 1989–2009 saw renewed expansion: two government firms reopened partly privatised; Shelys created Tanzania's largest pharmaceutical firm; and four new firms emerged, including Zenufa Laboratories. New investment included Shelys' penicillins plant and Tanzanian Pharmaceutical Industries (TPI) anti-retroviral (ARVs) production. From 2003, the Tanzanian Food and

Drug Authority (TFDA) sharply improved regulation. By 2009, local production supplied around a third of medicines, and was particularly important for rural medicines access (Mujinja et al. 2014). Pharmaceuticals were a success story in Tanzania's challenging industrial environment.

Turnaround to industrial decline

Yet in 2014, the industry in Tanzania is in decline. Industry insiders estimate that local pharmaceutical producers' public and private market share fell from around 30% in 2006 to less than 20% in 2013. World Health Organisation (WHO) data support this trend (see Box below). Local producers' share of public-sector medicine procurement by the Medical Stores Department (MSD) has been falling. A non-profit wholesaler estimated buying locally "far less than half" than four years ago. A private wholesaler, who in 2010/11 had bought local medicines worth Tshs 1.5–2 bn, was now buying "almost nothing, a few syrups".

Box: Decline in medicines made in Tanzania

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

Source: *WHO/HAI survey data 2006, 2009, 2012, supplied by Mary Justin-Temu; 2006 sample of facilities and medicines only, for comparability.*

In 2007, eight firms were producing medicines. By 2014, this fell to five, with just one actively tendering for MSD contracts. The product range was narrowing, with basic antibiotics an important casualty: in 2006 and 2009 around 75% of amoxicillin tablets available were locally produced; in 2012, that number was 13%[1], but zero in REPOA's 2013 survey. A domestic medicine market worth around USD 250 mn is now supplied almost entirely from imports paid in dollars.

The drivers of decline

A series of interacting pressures, some external, some policy-influenced, have driven this turnaround to decline, creating cumulative uncertainty and falling profitability that has undermined investment and growth.

- *Rising barriers to market entry for local firms*
  Anti-malarial medicines were an important domestic market: in 2006 90% of the first-line treatment for uncomplicated malaria (SP) was sourced locally. From 2007, subsidised import of the new combination therapy (ALu) meant local firms could not compete: one firm lost a third of its cash flow.

- *Increasing import price competition*
  Local firms are moving out of production of basic affordable medicines because they are no longer profitable, reducing production scale and potentially undermining ability to invest. They confirmed that basic antibiotics are increasingly unprofitable: import prices had fallen below local production costs, or even below full materials costs, suggesting dumping of Asian production.

- *Worsening power and infrastructure constraints*
  Well-known problems of power and infrastructure are being exacerbated by power-price increases, and unpredictable power outages that damage machinery and create output losses.

- *Costs of continuous upgrading to meet competitive and regulatory pressures*
  All local firms are upgrading to meet Good Manufacturing Practice (GMP) guidelines and external competition. TFDA works actively with manufacturers to improve processes while ensuring safe current operation, inspecting local firms more frequently than overseas competitors. Continuous upgrading requires large investments in technology and staff training; support from government, joint venture partners, or donors, for finance and access to technology, is essential if upgrading is not to price firms out of local markets.

- *A tightening skills constraint*
  Continuous upgrading tightens the skills constraint in Tanzania. Pharmaceuticals are a higher-skill sector. Firms invest heavily in training staff with low basic education, who may struggle with the rigorous rule-following culture of GMP. Pharmacists and chemists must be trained on industrial equipment and techniques, and there are few pharmaceutical technicians. Firms face high turnover of skilled staff and complain of the difficulty and cost of obtaining work permits for essential expatriates.

- *Duties and tariffs incentivize imports*
  Imported medicines are exempt from duties; this has created problematic tax rules for local manufacturers. The Tanzania Revenue Authority (TRA) does not aim to disadvantage local producers, but VAT on inputs (with slow reimbursement), combined with difficulties pharmaceutical manufacturers experience in obtaining exemption from duties for some imported inputs, undermines local competitiveness. Rules also appear unclear and unstable, discouraging investment.

- *Continuing registration delays*
  Firms still report 1.5–2-year delays by TFDA in testing and registering products, despite promises of fast-tracking for local firms. This seriously reduces profitability, as does a lack of consultation and forewarning when clinical guidelines change.

- *Local procurement relationships weakening*
  MSD gives local firms a valued 15% price preference. However, working relationships with local suppliers are problematic. Local firms complain of financial risk from rising payments delays, lack of clear delivery dates, and failure to complete contracted purchases, plus low probability of winning (expensive) tenders. MSD is perceived as giving preference to imports, by providing trade credit only to overseas suppliers and buying supplies 'bundled' by local importers. MSD itself faces serious financing delays (Prinz et al. 2013), and complains of quality and delivery problems from local suppliers. A build-up of mutual mistrust has undermined local tendering.

- *Lack of active public sector support in contrast to competing countries*
  "Government policy is totally unfriendly to pharmaceutical manufacturing [in Tanzania]." (Experienced Tanzanian manufacturer)
  Manufacturers argue that government policy currently undermines investment and innovation in their industry. A lack of 'joined up' support across the key Ministries of Health, Industry, and Finance (at worst, active hostility) contrasts with active support elsewhere. South Africa, Ghana, Sudan, Ethiopia, and Morocco all now actively protect and support local producers, as did India, resulting in investment and diversification of local production.

Recommendations:

Active industrial regeneration in pharmaceuticals
As successful African experiences show, the pharmaceutical industry *can* be sustained and grown with an active industrial policy. Turnaround to renewed growth demands, however, unprecedented collaboration between Health, Industry, and Finance to create a policy framework of active support and facilitation for pharmaceuticals. That in turn requires an effective champion within government, donor support, and active involvement of manufacturers. Manufacturing expertise within TFDA could be tapped, perhaps through secondments to Ministries.

1. *Restructure trade, tax, and credit policies to favour local producers over importers*

   "The key constraint in this market is demand" (local manufacturer). Local market access generates cash flow to support investment and expansion, so the low-price essential medicines market needs trade protection, e.g.:

   - Duties on imports of finished pharmaceuticals;
   - A list of 'negative products' imported only if local manufacturers cannot supply reliable quality at acceptable prices;
   - Improved identification, and exemption from duties, of inputs for pharmaceuticals;
   - Reducing or removing VAT on inputs to pharmaceuticals, or at least faster reimbursement;
   - Raising the local preference rate above 15% in public procurement.

   Also required:

   - TFDA fast-tracking of tests and registrations of local products;
   - Trade credit for local suppliers to public procurement;
   - Full Ministry of Finance funding for procurement by MSD of local supplies.

2. *Integrate improved local procurement with support for industrial upgrading*
   Firms experience public procurement as increasingly risky and unprofitable. MSD's proposed longer-term contracts for new suppliers (MSD 2013) could be extended to existing local

firms investing in machinery upgrading, training, and product enhancement, in association with focused industrial support, e.g.:

- Moderating utility cost increases;
- Streamlining slow, overlapping, expensive licensing;
- Funding technical assistance and staff retraining with donor support; facilitating temporary hiring of expatriate staff;
- Facilitating existing firms' joint ventures to bring technical expertise;
- Using government minority shareholdings actively or selling to new investors who bring technology and investment.

Turnaround to growth is possible, building on past success. Key policy changes such as a negative products list could re-establish confidence in Tanzania as a manufacturing location for pharmaceuticals, and generate new stability of supplies for the health sector.

References

Medical Supplies Department (MSD) (2013). *Medium Term Strategic Plan II 2014 – 2020*. Dar es Salaam, October.

Ministry of Health & Social Welfare MoHSW) (2006). *Strategies for promotion of local production of pharmaceuticals in Tanzania 2006–2016*. Dar es Salaam.

Mujinja, P.G.M., Mackintosh, M., Justin-Temu, M., Wuyts, M. (2014). Local production of pharmaceuticals in Africa and access to essential medicines. *Globalization & Health*, 10(12) 1–12.

Printz, N., Amenyah, J., Serumaga, B., Van Wyk, D. (2013). *Tanzania: Strategic Review of the National Supply Chain for Health Commodities*. MoHSW / USAID, Dar es Salaam.

REPOA
157 Mgombani Street, Regent Estate
P. O. Box 33223 | Dar es Salaam | Tanzania
Tel: + 255 22 2700083 | Cell: +255 75 409 1677 | Fax:+ 255 22 2705738
Website: www.repoa.or.tz | Email: repoa@repoa.or.tz

The findings, interpretations, conclusions and opinions expressed are those of the authors and do not necessarily reflect the views or polices of REPOA. Nor do they reflect the views of DFID or the UK ESRC, whose financial support is gratefully acknowledged.

Research jointly supported by the ESRC and DFID